

# BMJ Open Feasibility, accessibility and acceptability a pharmacist-led ear health intervention at rural community pharmacies (LISTEN UP): a mixed-methods study in Queensland, Australia

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## ABSTRACT

**Objective** Ear disease in rural and remote communities is occurring at high rates, with limited access to health services and health providers contributing to the problem. Community pharmacists are well-placed to provide expanded services to improve ear health in rural communities. We aimed to evaluate the feasibility, accessibility and acceptability of a pharmacist-led intervention for ear disease in consumers presenting to community pharmacy.

**Design** Prospective preintervention and postintervention mixed-methods study. An ethnographic lens of rural culture was applied to the descriptive qualitative component of the study.

**Setting** Two rural community pharmacies in Queensland, Australia.

**Participants** People aged 6 months or older, who present with an ear complaint to a participating community pharmacy.

**Intervention** LISTEN UP (Locally Integrated Screening and Testing Ear aNd aUral Programme) is a community pharmacy-based intervention to improve the management of ear health. Trained pharmacists conducted ear examinations using otoscopy and tympanometry on consumers following a LISTEN UP protocol. They made recommendations including no treatment, pharmacy only products or general practitioner (GP) referral. Consumers were contacted 7 days later for follow-up.

**Results** 55 rural consumers participated in the study. The most commonly reported complaints were 'blocked ear' and 'ear pain'. Pharmacists recommended over-the-counter products to two-thirds of the participants and referred one quarter to a GP. 90% (50/55) of the consumers were highly satisfied with the service and would recommend the service. All consumers described the service positively with particular reference to convenience, improved confidence and appreciation of the knowledge gained about their ear complaint. Pharmacists were motivated to upskill and manage workflow to incorporate the service and expected both consumers and GPs to be more accepting of future expanded services as a result of LISTEN UP. However, without funding to provide the service, during the study other remunerated pharmacy tasks took priority over providing LISTEN UP.

## Strengths and limitations of this study

- The study included only two community pharmacies and the small sample size represents a quarter of the expected sample.
- However, despite these limitations, the reported data provide new knowledge about an area of unmet need in rural health and could help to inform future work.

**Conclusion** Rural community pharmacists can provide an acceptable and accessible ear health service; however, it is not feasible without a clear funding structure to provide resources including additional pharmacists, equipment and training.

**Trial registration number** ACTRN12620001297910.

## INTRODUCTION

The ear, when working well, is a complex organ with receptors that respond 100 000 times every second, which allows hearing, a sense through which humans communicate, express thoughts, gain an education and engage socially.<sup>1-3</sup> Disadvantage resulting from hearing loss is well recognised with poorer employment opportunities and higher incarceration rates.<sup>2</sup> The impact of ear disease for young people is profound and includes poorer educational outcomes, social and behavioural outcomes and a disrupted connection land, culture and community.<sup>2</sup>

The WHO has identified that globally 1.5 billion people experience some decline in their hearing throughout their life course, with many more at risk of hearing loss due to preventable causes.<sup>1</sup> WHO has proposed an integrated people-centred approach to ear and hearing care service provision to provide a coordinated service across the continuum of care.<sup>1</sup> The provision of a comprehensive, safe, effective, timely, efficient and acceptable

service by a motivated and skilled workforce operating in a supportive environment is expected to provide equal access to quality ear and hearing care.<sup>1</sup> This overarching approach is a gold standard to work towards, however, in current practice, limited trained health professionals in ear health, a lack of resources and barriers to accessing ear care services impacts ear health, especially in rural and remote communities.<sup>2</sup>

In Australia, one in six people experience some form of hearing impairment with an expected increase as the population ages.<sup>4</sup> Australia has a first world healthcare system, however, reports rates of chronic ear disease as high as 50% for remote Indigenous communities in Northern and Central Australia.<sup>2</sup> This enormous burden of ear disease is expected to worsen with an estimated 900 million people to be affected worldwide by 2050 if no change to care is made.<sup>2</sup>

The impact of ear disease in Indigenous populations is undoubtedly profound, however, the underlying contributing factors are less visible. Inequities in health arise from inequities in society and the 17-year gap in life expectancy between Indigenous and non-Indigenous Australians spotlights major social inequities.<sup>5</sup> Social disadvantage, poverty, high rates of chronic disease and tobacco use are prevalent for Indigenous people and known to contribute to poor health outcomes.<sup>6</sup> Ear disease, in particular otitis media rates, have been attributed to historical disconnection to land and culture, and most evidently housing related social determinants including overcrowding, poor housing conditions, malnutrition, exposure to tobacco smoke, poor hygiene and limited access to services.<sup>6</sup>

Pharmacists play an essential healthcare role in both clinical and community settings.<sup>7</sup> Beyond medication dispensing, stewardship, and safety, pharmacists are often the first point of contact, especially in rural communities, playing a critical role in triaging care and referring community members to other health professionals.<sup>7</sup> In many cases, the pharmacist is the only permanent health professional in a rural community.<sup>7</sup> Pharmacies often serve as the local hub for community healthcare services, particularly in meeting the needs of rural communities, where disadvantage, limited health literacy and poorer health outcomes persist.<sup>7</sup> In rural and remote Australia, community pharmacists provide a highly skilled workforce with accessibility extended after hours and weekends, with potential to provide services to address the ear disease in these vulnerable communities.<sup>2,7</sup>

Despite rural community pharmacists' knowledge and embedded role in the community, pharmacy ear care service provisions are limited without any structured service model. A scoping review of pharmacists' involvement in ear healthcare interventions found eleven articles worldwide, including pharmacies partnering with audiometry services for hearing screening, an otoscopy pilot study, a pharmacy-based ear clinic and targeted education for undergraduate pharmacy students.<sup>8</sup> Pharmacists in Australia did not provide ear services, instead they

reported audiometry services offering hearing screening through the pharmacy.<sup>8</sup>

Internationally, rural pharmacists are expanding their scope of practice and providing innovative services to meet the needs of communities for improved health outcomes.<sup>9</sup> Expanded services including immunisations, screening and management of chronic and infectious diseases have reported positive outcomes in rural practice, where access to health professionals are limited.<sup>9</sup> Recent research into the perspectives of consumers, pharmacists, health professionals and stakeholders regarding rural pharmacists providing expanded services has highlighted support for these expanded services, despite some reservation from the medical profession.<sup>10–14</sup> In response to this, a community pharmacy-based ear health service model was developed and trialled in two rural pharmacies in Australia.<sup>15</sup> The aim of this study is to determine the feasibility, accessibility and acceptability of the service model.<sup>15</sup>

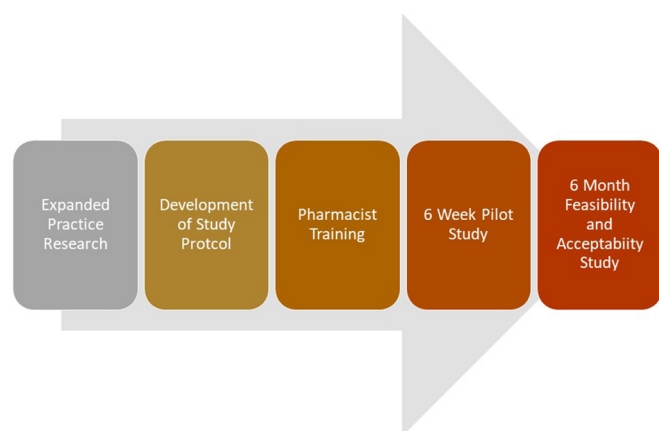
## METHODS

The PRECEDE (Predisposing, Reinforcing, and Enabling Constructs in Educational Diagnosis and Evaluation)–PROCEED (Policy, Regulatory, and Organisational Constructs in Educational and Environmental Development) model was used to provide a framework to develop the research protocol for this study, LISTEN UP (Locally Integrated Screening and Testing Ear and aUral Programme). LISTEN UP is a community pharmacy-based intervention to improve the management of ear health in rural community in Australia.<sup>15,16</sup> The PRECEDE component included an assessment of the predisposing, reinforcing and enabling constructs to support practice change through a scoping review; stakeholder surveys and interviews (piloted); and consultation with health professionals (including general practitioners (GPs) and ear nose and throat specialists) and relevant authorities.<sup>16</sup> The PROCEED segment incorporated the evaluation of a 6-week service pilot and informed planned implementation, process, impact and outcome evaluation of the service.<sup>16</sup> The Standards for Quality Improvement Reporting Excellence guidelines have provided a framework to report the new knowledge from this study.<sup>17</sup>

## Study design

The prospective preintervention and postintervention mixed-methods study is described in figure 1. The descriptive qualitative component of the study was undertaken through an ethnographic lens of rural culture. The researchers are all located in regional, rural and remote locations, with extensive experience in rural health both globally and locally from a clinical and academic perspective.

Prior to the study commencing, the two participating pharmacies collected usual care data as a comparator for 8 weeks beginning November 2020.



**Figure 1** Process diagram of Locally Integrated Screening and Testing Ear and aUral Programme study.

The intervention was then piloted for 6 weeks at each pharmacy<sup>16</sup> before the 6-month study was conducted from February to July 2021.

### Setting and recruitment

Pharmacies that had participated in previous research on rural expanded pharmacy practice were invited to express an interest to participate in the LISTEN UP study.<sup>10 12 14</sup> Two community pharmacies (Modified Monash Model (MMM) category 6—remote community, population 18 000 and MMM category 4—medium rural town, population 6000) expressed interest and were enrolled in the study. GP practices at the intervention sites were invited to participate and one practice at each of the sites volunteered. An invitation to participate with an information sheet and informed consent form was provided to each pharmacist at the participating pharmacies and each GP at the participating general practice. Participating pharmacies met eligibility criteria including being classified as rural or remote by the MMM classification system categories 4–7.<sup>15 18</sup>

Each participating pharmacist undertook nationally credentialed training in ear health including otoscopy and tympanometry. This training was delivered via mixed modes with online and face-to-face components over 55 hours including two full days of workshops provided by the Benchmark Group.<sup>15</sup> The training addressed the following units of competencies: EHHPEH002—promote, educate and manage ear health, EHHAEH001—assess ear health, EHHPEA004—paediatric ear health assessment and TYMPHY001—perform tympanometry.

Consumer participants were recruited into the study via convenience sampling through community pharmacy, when they presented with an ear complaint. Initially, ethics approval had been granted for persons 13 years or old, however, in June 2021, additional approval was granted for children from 6 months of age.

### Data collection

Data were collected from consumers, pharmacists and GPs (table 1). Data relating to the feasibility (the extent

**Table 1** Data collection sources and methods

	Consumer	Pharmacist	General practitioners
Preintervention		Semi-structured interview (FAS)	Semi-structured interview (FAS)
During intervention	Consumer satisfaction survey (AS)	Service summary document (F)	
Postintervention	Semi-structured interview (7-day follow-up) (FAS)	Semi-structured interview (FAS)	Semi-structured interview (FAS)

A, accessibility data source; F, feasibility data source; S, acceptability data source.

of the service to be provided viably), acceptability (the level of approval of the service) and accessibility (the extent of being easily able to receive/provide the service) of LISTEN UP were collected via multiple mixed methods (table 1).

All interviews were undertaken by ST, a rural pharmacy academic. Interviews were conducted with pharmacists and GPs face-to-face and online, and with consumers via phone. Interview recordings were transcribed verbatim and participants, people and places were de-identified in the transcription process. Field notes were recorded and revised.

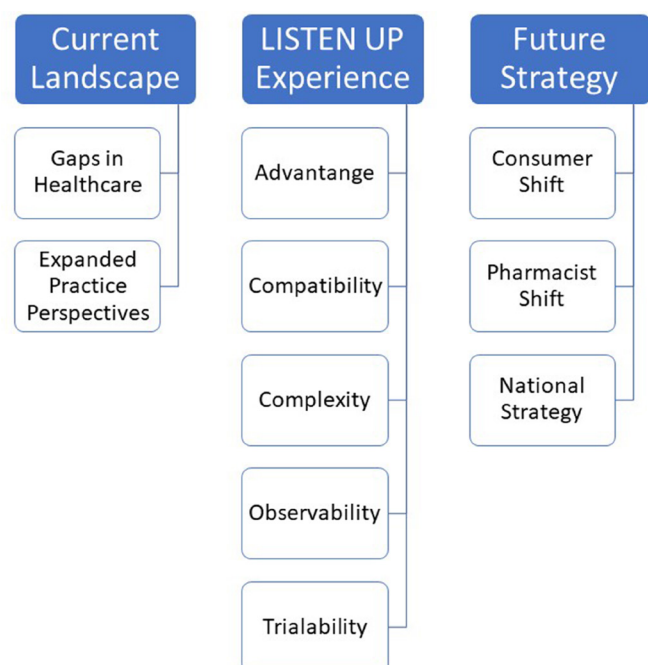
### Intervention

A study protocol (flow chart provided in online supplemental appendix 1) which pharmacists followed to provide the intervention involves trained pharmacists providing otoscopy and tympanometry assessments on consumers presenting to community pharmacy with ear complaints and includes an integrated direct referral pathway to local GP providers.<sup>15</sup>

Consumers who presented to the pharmacy with an ear complaint and met the eligibility criteria were invited to participate. To be eligible, participants were required to understand the English language at an appropriate level to provide informed consent, have no obvious major trauma to the ear and not be a high COVID-19 risk consumer (eg, travelled in a COVID-19 hotspot within 14 days). Participants were then provided a written information sheet and returned a signed informed consent sheet.

Pharmacists used the 'service summary document' (online supplemental appendix 1) to record consumer demographics, and details relating to the current episode of care including the presenting complaint, duration of the complaint and treatments tried. Pharmacist examination notes were recorded including temperature, otoscopy (normal/abnormal), tympanometry (normal/abnormal), brief notes and a clinical impression. Pharmacists completed a tick box list of usual recommendations and expanded practice recommendations. If consumers required a referral to a GP, the pharmacists





**Figure 2** Thematic map illustrating the themes and codes for qualitative analysis of general practitioner and pharmacist interviews. LISTEN UP, Locally Integrated Screening and Testing Ear aNd aUral Programme.

made the appointment with the consumer for the same day or next day. Consumers were offered a brief satisfaction survey directly after their LISTEN UP consultation. All consumers were then followed up with a phone call by a member of the research team at 7 days (Interview guide—online supplemental appendix 1). If their condition was unresolved, they were referred to the GP. Hearing screening via the *Sound Scouts* application with Sennheiser HD 300 headphones was also available, however, no hearing screens were conducted during the study period. The MedRx video otoscope and Amplivox Otowave 102 tympanometer were used in this study.

### Outcome and data analysis

Demographic information, clinical characteristics (online supplemental appendix 1) and survey data were analysed using descriptive statistics, with qualitative data from consumer interviews analysed using content analysis. Pharmacist and GP interview data were analysed using a hybrid approach of inductive and deductive coding and theme development exploring specifically for feasibility, accessibility and acceptability data.<sup>19</sup> This style of thematic analysis incorporated both the data-driven inductive approach and the deductive priori template of codes approach.<sup>19</sup> Diffusion of innovation theory and categories adapted from ‘Qualitative data analysis for applied policy research’ were combined to form a thematic map which provided a framework for the analysis (figure 2).<sup>20 21</sup> NVivo V.12 software was used for all of the qualitative analysis.<sup>22</sup>

Transcriptions were read multiple times and an initial coding tree was created from the first four transcripts.

Thematic analysis continued and codes which were conceptually similar were categorised into emerging themes, using an ethnographic technique of domain analysis.<sup>23</sup> Objectivity, assumed knowledge and bias were reduced by involvement of a second member of the research team who also analysed the first five interviews and any discrepancies were resolved. A member checking process was conducted with three participants to support validity of the data.

### Patient and public involvement

There was no patient or public involvement.

## RESULTS

To compare usual pharmacy ear presentations to those identified during the intervention, the pharmacists collected data pertaining to ear complaints for 8 weeks prior to the intervention period. During this time 23 ear complaints were recorded as presenting to the pharmacy (child,<sup>8</sup> adult<sup>15</sup>). These complaints were ear pain (35%) and ear wax (35%), swimmer’s ear (17%), hearing loss (4%) and other (discharge, fever, insomnia, blocked ear, vertigo; 4%). These complaints and frequencies were comparable to those reported during the intervention period.

Fifty-five consumers participated in the study (mean age=42 years). One in five participants were aboriginal (10/55) and 95% (52/55) of participants were over 19 years of age (ethics approval for children younger than 13 was gained halfway through the study). The planned sample size for this study was calculated to be 203 consumer participants.<sup>13</sup> The sample size was calculated using the formula  $n = Z^2 P (1-P) / d^2$ , where  $n$ =sample size,  $Z$  is the critical value of the normal distribution at  $\alpha/2$  for a confidence level of 95% where  $\alpha$  is 0.05 and the critical value is 1.96,  $p$ =expected prevalence or proportion=0.14 (14%) and  $d$ =precision=0.05 (5%).<sup>13</sup> The study was concluded at 6 months with 55 consumer participants due to the pharmacies being unable to focus pharmacist time on the intervention due to competing priorities of COVID-19 vaccinations being provided through community pharmacy. In addition, as the intervention was not remunerated, during periods of reduced staff levels, pharmacists were unable to provide the intervention as other competing funded services were prioritised. Although these issues reduced the sample size, an extensive quantity of rich qualitative data was able to be collected throughout the study to negate the influence of a small sample size from a quantitative perspective.

Duration of the ear complaint ranged from 1 to 30+ days (mean=39 days/median=3 days). Prior treatment included analgesia (paracetamol and anti-inflammatories) ( $n=11$ ), cleaning using cotton buds ( $n=6$ ), ear drops ( $n=9$ ) and other ( $n=11$ ). Other treatments tried included ear candles, hair dryer, antibiotics from home, nasal spray/rinse, oral decongestants, antihistamine, essential

**Table 2** Pharmacists clinical impressions and recommendations for presenting complaints

Clinical impression		Recommendation	
Normal ear	8 (15%)	No treatment	7
Wax impaction	21 (38%)	OTC products	36
Otitis externa	3 (5%)	Referral to GP	14
Otitis media	6 (11%)	Other	7
Other	4 (7%)		
Unsure	13 (24%)		

Other clinical impressions: ruptured ear drum,<sup>3</sup> poor compliance of tympanic membrane,<sup>1</sup> sinus congestion.<sup>1</sup> Some participants received more than one recommendation.  
GP, general practitioner; OTC, over-the-counter.

oils, complementary medicines, heat pack and vertigo treatments from home.

Otoscopy examination was performed for 52 (95%) participants (normal n=20 (40%), abnormal n=31 (60%)). Tympanometry was conducted for 45 (82%) participants (normal n=27 (60%), abnormal n=18 (40%)). Reasons for being unable to complete tympanometry included equipment failure,<sup>1</sup> consumer unwilling to be examined,<sup>4</sup> ruptured ear drum,<sup>1</sup> ear canal too large,<sup>1</sup> unknown.<sup>3</sup>

Table 2 represents the pharmacists reported clinical impressions based on their identification of presenting pathology and the recommendations they made following the protocol.

Pharmacists recommended over-the-counter (OTC) products to two-thirds (36/55) of the participants. OTC

products recommended included wax removal drops,<sup>19</sup> analgesia,<sup>11</sup> drying agent ear drops,<sup>1</sup> decongestant nasal spray,<sup>3</sup> oral decongestants and antihistamines.<sup>3</sup> One quarter (14/55) of participants were referred to a GP.

Seven participants were recommended no treatment at all. Pharmacists also recorded 'other' recommendations for seven participants and these included referral to emergency department (ED)<sup>3</sup> and watch and wait.<sup>4</sup>

Pharmacists were asked to indicate via tick-box if they would make any additional recommendations. One-third (18/55) of consultations recorded no expanded recommendations. Expanded recommendations that were made included prescribing a medication currently only available on doctors prescription,<sup>3</sup> referral to an ear, nose and throat specialist,<sup>11</sup> referral to speech therapy,<sup>4</sup> referral to audiometry<sup>24</sup> or other.<sup>9</sup>

Directly after the consultation at the pharmacy, participants were asked to complete a satisfaction survey. Data from this survey are presented in table 3.

### Consumer postintervention data (acceptability and accessibility of service)

Table 4 provides the qualitative data from the follow-up phone calls conducted by a member of the research team. At 7 days, three participants had not attended their scheduled GP appointment. Reasons for not attending GP appointment included being unable to wait for the appointment,<sup>1</sup> leaving town directly<sup>1</sup> or attending scheduled hospital appointment instead.<sup>1</sup>

Data from these interviews were analysed using quantitative content analysis. Every participant described their experience at the pharmacy with a positive term (eg,

**Table 3** Consumer satisfaction survey results

	Agree	Strongly agree
The pharmacist explained well the aims of the LISTEN UP service to me	5 (9%)	50 (91%)
I am satisfied with how the pharmacist checked my ears and decided if I needed treatment	3 (5%)	52 (95%)
I had the opportunity to raise questions or concerns related to the service	5 (9%)	50 (91%)
I now feel more confident about managing my ear problem	5 (9%)	50 (91%)
I am satisfied with the LISTEN UP service	5 (9%)	50 (91%)
I would recommend the LISTEN UP service to others	6 (11%)	49 (89%)
Questions with yes/no answer option	Yes	
Before coming to the pharmacy today, I tried to see a GP about my ear	15 (27%)	
If the service was not available today I would have gone to my GP	34 (62%)	
If the service was not available today I would have gone to the hospital	25 (45%)	
Next time I have an ear problem I will come to the pharmacy instead of a GP	54 (98%)	
Free text comments		
'Very good reassurance about my ears'		
'Service exceeded my expectation'		
'I am satisfied with how the pharmacist checked my ears. Great service'		
'Excellent support, information great, feel reassured. Thank you'		

Available survey answers range 5-point Likert (strongly disagree to strongly agree).

GP, general practitioner; LISTEN UP, Locally Integrated Screening and Testing Ear and aUral Programme.

**Table 4** Qualitative content analysis table of consumer interviews

Theme	Description	Count	Exemplars
Informative	Appreciation of the detailed information provided and the visual tour of the ear	48	I got to see the inside of my ear which I had never done before and have it explained to me which was really good. Was really helpful in explaining what the issue was and what she was treating me with that day.
Confidence	Trust, comfortability and confidence of the pharmacists' skills and knowledge to provide the service	41	They were trained very well ... very knowledgeable. What the doctor does is less, the pharmacist was more thorough.
Availability of local GP appointments	Difficulty in being able to make a GP appointment in an appropriate timeframe	32	When I need to book to see a GP it takes two weeks. You have no choice when your kid is sick here but to go to the hospital and wait for 7.5 hours because there is no GP appointments.
Willingness to pay	Explanations of participants' willingness to pay or not pay for the service	30	I would pay because it was so quick, easy and inclusive. I don't pay for the doctors so I wouldn't pay for the pharmacist. You have to pay at the doctors so I don't see a difference.
Reassurance	A feeling of reassurance about the ear complaint	29	I felt more comfortable about why I was having pain and treatment. Put my mind at ease so I didn't need to go to the doctor.
Pharmacy convenience and accessibility	Positive associations with pharmacy accessibility and immediate service provision	29	It was convenient, you didn't have to book an appointment. Going to the pharmacy was easier because if I need something for my ears you have it there already.
Expanded scope for pharmacists	Support for pharmacists to provide other expanded services or an extension of this service (eg, prescribing and syringing)	9	If the pharmacists can see it's infected, they should be able to give me the drops (antibiotics). Pharmacists are definitely trained to give you medications if you need them for something like a simple ear infection so giving them capabilities to be able to do that would be fantastic and it would relieve a lot of pressure off GPs.

GP, general practitioner.

marvellous, wonderful, better than a doctors surgery) and these affirmations were recorded 89 times. Participants reported being surprised that pharmacists were able to provide ear health services. More advertising and using the video-otoscope to examine other parts of the body (eg, throat) were the only two service improvements recommended. Most participants (87% (48/55)) reported they would pay for this type of pharmacy service, with suggested amounts ranging from \$A1 to \$A20 (33%), \$A21 to \$A50 (33%). The average value that participants were willing to pay was \$A33 with values of \$A100, \$A150 and \$A200 also suggested.

As well as information presented in [table 4](#), some consumers highlighted the opportunity to use telehealth GP services with the imaging provided from the service to overcome some of the barriers to accessing local GP

services, including cost of appointments/lack of bulk-billing and distances to access GPs of up to 600 km.

### Pharmacist and GP interview data (pre and post) feasibility and acceptability of service

Semi-structured interviews were conducted with participating pharmacists and GPs pre and post the intervention and analysed according to the thematic map ([figure 2](#)). The interview duration ranged from 13 to 73 min with an average of 25 min.

Prior to the service trial, pharmacist and GP's expectation of the acceptability and feasibility of the service was explored in the context of *the current rural health landscape*.

Due to *gap in accessible healthcare* in the rural communities where the study was undertaken, consumer *acceptability* was expected by both participant groups.

Pharmacists described difficulty with accessing health professionals, wait lists in excess of 2 weeks for GP's and allied health professions as well as a lack of permanent healthcare providers and rapid turn-over of staff as having a negative impact on consumer care.

Getting in to see a health professional is difficult, and then relationships as well, when they keep turning over, where our pharmacists seem to be pretty steady. A lot of remote areas that have visiting clinics, what happens when they're not visiting, who do they go and see? (P1—pharmacist)

There's a real scope for pharmacies to offer extra services, especially in rural areas ... Purely geographically a lack of access to services, and I don't think just because you live in a rural area your health should be hindered. (P5—pharmacist)

The pharmacists reported an *advantage* they expected of LISTEN UP was to increase rapport building with GPs through the direct referral process. GPs though, reported concerns about pharmacists taking work from junior doctors but recognised that in rural Australia the lack of health providers broadly means there is enough work for all.

Providing services in rural communities across the board is very difficult, and anyone who can bring services where they aren't already should be encouraged. (GP6—general practitioner)

After the study, GPs described the service and direct referral pathway as *compatible* with their current practice. They reported that all of the referrals they received were appropriate. GPs' perceived LISTEN UP to be an advantageous method of screening individuals who present to community pharmacy and setting them on a trajectory for GP care. They also expected young children to be more comfortable in the pharmacy setting.

The foot traffic at a pharmacy is quite a lot on a daily basis. So the pharmacists are seeing people coming from different practices and bringing their prescriptions and whatever else they buy there. So having a good coverage of the community is an entry point for them to have that ear looked at. (GP2—general practitioner)

The pharmacists felt the structured approach and protocol supported the delivery and professionalism of the service.

We don't have existing ear care services, so this model has all the advantages because it's actually a model and actually a service. (P2—pharmacist)

GPs however, described a level of increased anxiety in consumers who had been referred and suspected this may be due to the language used by pharmacists when referring consumers.

Pharmacists identified enabling factors (*feasibility*) to the implementation of an ear health expanded practice model. These included the *willingness of pharmacists to develop expanded practice models* and their professional skills.

We're familiar with the upskilling required, and we're enthusiastic about doing more application of health services, rather than hiding behind the dispensary. I think that the pharmacists coming through now are craving that and wanting that. (P1—pharmacist)

There was an expectation that this expanded service may be a springboard for further service development and for both consumers and health professionals to be more accepting of an expanded scope for pharmacists.

I am expecting advancement in our placement in the minds of the community that we service, of what we can actually achieve and what we can do as a pharmacist for them. (P1—pharmacist)

I hope it will bring about some results that will elicit a meaningful change in terms of broadening our scope of practice. (P5—pharmacist)

Pharmacists reported the recent growth in professional service areas such as vaccinations had pharmacists feeling well placed to provide other expanded services for their communities. This was also identified as an enabler as some of the challenges of role conflict with GP's has already been addressed and relationships between the professional groups had adjusted to new service models.

When we started the immunisation program, there was a lot of resistance there and now that it's a known kind of service, it's great, but at first, it was like we were taking from their role. (P8—pharmacist)

After the study pharmacists continued to report a positive *pharmacist behaviour shift* towards expanded pharmacy broadly. Pharmacists described the study solidifying and extending their interest in working to their full scope.

I really have enjoyed pushing that scope, learning something new, delving into a new domain. I think we need to keep doing it as pharmacists. We need to offer as much care as we can for people, and we need to push ourselves to do that, and not just rest on dispensing a script, especially if we want to be valued members of the healthcare system going forward. (P2—pharmacist)

*Consumer behaviour shift* through increased confidence and knowledge of the potential for expanded pharmacy roles was a reported benefit of the study.

People started to see us as actual health professionals that are available to the community, that you can actually touch and feel, that you have access to without an appointment. (P4—pharmacist)



Prior to the study, pharmacists reported advice on ear complaints was commonly sought by consumers with up to two presentations each day. They reported an overall lack of confidence with managing ear complaints based on symptomatic description from consumers and reported referring most ear complaints to a GP or hospital ED. Pharmacists expected an improvement in their skills and knowledge in the management of ear complaints and the ability to provide better ear care in community.

My conversation is always ... I can't look in your ear. I can understand your symptoms, I'm hearing what you're saying, but it covers a lot of different things and I can't make that decision on what you're telling me, and I also don't have much to offer you. (P5—pharmacist)

After the study pharmacists reported increased **observability** and increased confidence in managing ear complaints as a result of having more information (otoscopy and tympanometry results) for decision making. The imaging of the ear canal was one of the most valued aspects of the service, improving pharmacist and consumer confidence in the service. Pharmacists were able to provide reassurance to patients and explain the anatomy and pathophysiology to consumers in real time.

It's really nice showing them what their eardrum looks like, and explaining to some why they don't need antibiotics. (P2—pharmacist)

Anything that we can get more data to help us be more definitive and clear in our referral pathways is helpful. (P2—pharmacist)

Pharmacists reported being comfortable with recommending wax dissolvent and drying agents, but identified a barrier of the service model was the restriction of not being able to prescribe antibiotics or medicines only available with a doctor's prescription. There was optimism that the study would positively influence more products to be down-scheduled to become available for pharmacists to provide.

My hope is that I don't have to say that I'm sorry that I can't help you today, I wish I could do more. (P4—pharmacist)

After the study the pharmacists reported that the skills learnt during LISTEN UP, including the training improved their confidence in managing ear complaints from below average to 7+ out of 10.

The training alone however was not deemed enough to improve confidence. Pharmacists discussed the **complexity** of the training provided and suggested that more face-to-face case studies were needed in addition to more content related to clearly identifying various pathology (**trialability**). Some pharmacists who had not conducted many consultations during LISTEN UP felt the training needed to include a greater volume of case examples to improve their confidence to provide the service.

I don't have the confidence for a diagnosis at all and it's just purely from not doing enough and not getting feedback. (P3—pharmacist)

Confidence, however, improved with clinical experience and an enabler was the structured LISTEN UP protocol, supporting decision-making. Pharmacists reported needing to conduct at least 10 consultations in the community pharmacy before feeling confident to provide the service independently.

I think I needed the first five to ten hours of practice, mainly just to get comfortable with actually how to talk to consumers and look inside the ear and all the techniques. But after that, I felt very comfortable. (P4—pharmacist)

The flexibility and capacity of the current pharmacy service model was seen as both an enabler and barrier to LISTEN UP. Pharmacists expected the study to fit into the current no-appointment necessary workflow with strategies such as having additional pharmacists available to focus on professional services, advising consumers of longer wait times for prescriptions and asking consumers to come back to collect medicines.

I'm very confident that there's going to be no problem with that. You just need to change your operational flow to support more hands-on time with the clients. (P1—pharmacist)

After the study, workflow demands however were identified as a barrier to both the study and expanded practice generally. It was highlighted that a number of consumers received a consultation by a pharmacist but the occasion was not documented for the study. Time required for the documentation process and competing dispensary demands were reported as the reasons for this occurring. In addition, it was noted that as influenza vaccinations increased, the availability of the consultation room was limited and this inhibited the ability to offer LISTEN UP.

I'd say there's double the number of people who we probably could have done, that we haven't done, because it wasn't the right time, we were too busy. (P8—pharmacist)

The length of the consultations were also raised as a potential barrier, with concerns when only one pharmacist was on-duty and expectation that it would be difficult to be able to offer the service during those times.

Time is the biggest factor, we are often under the pump with the supply role so I think the clinical service can press you that little bit further. (P7—pharmacist)

All pharmacists reported a lack of funding as a major barrier to LISTEN UP. They were concerned about the amount of time the consultations would take, the lack of remuneration for the study and no clear funding pathway for subsequent service provision.



Taking into consideration our hourly rate and if you don't actually sell anything ... no remuneration would be a big barrier. (P6—pharmacist)

The *compatibility* of the service with rural practice was reliant on the number of pharmacists available at the pharmacies. Evidence of consumers being asked to come back at a time when more pharmacists were available was reported. This was compounded by the lack of remuneration associated with the study and thus the priority being placed on services that were profitable such as vaccinations, or dispensary tasks.

If there were just two [pharmacists], then we're stretching it a bit. And we just definitely wouldn't offer it if there was just the one pharmacist. If they came in on a weekend, we'd ask them to come back during the week. (P4—pharmacist)

Consumer and community support was highlighted as an enabler for the study. The pharmacists expected that their local communities would be highly receptive of the service and they were pleased that the local GPs were also supportive of the study and happy to be involved. After the study pharmacists reported that they felt the service built trust, rapport and confidence from consumers.

### Future directions

Integration of the documentation process into existing dispensary software was not achieved for this study however would be a focus for future services.

If we could have it incorporated into our workflow to make it easier, part of a platform we already use, that would be cool, because technology makes things easy for us, and integrated technology is even better. (P4—pharmacist)

The importance of the direct referral pathway with guaranteed appointment availability was also expected to be a major enabler for the study however it is highly unlikely this could be a permanent feature of future service models given the burden this places on an already stretched GP workforce. However, maximising digital technologies could further enhance timely medical assessment. Images and results provided by the pharmacists would enable GPs to conduct a telehealth appointment for the consumer for an immediate diagnosis and treatment.

You would have done all the work, because the only barrier to effectively diagnosing a consumer with an ear problem by telehealth is not having a look in the ear. But if we are presented with the photo ... then absolutely you will be able to make a diagnosis and treat the consumer effectively by telehealth using this model. (GP1—general practitioner)

When asked about whether LISTEN UP should be rolled out as a *national strategy*, all pharmacists agreed that it is a service community pharmacists can and should

be providing, taking into consideration discussed barriers that this service would address. There was a focus placed on the greater need in rural and remote settings and an uncertainty about how the service would be received in metropolitan settings.

I think every pharmacist should be able to have the skills and knowledge to be able to look in someone's ear and decrease doctor's visits and ED referrals if it's a simple wax impaction or something like that. (P3—pharmacist)

## DISCUSSION

Exploring the feasibility, accessibility and acceptability of an ear health intervention from a health system, pharmacist and consumer level is integral to considering future expanded practice services for rural community pharmacy. This study has provided the first insight into the challenges and motivators for pharmacists to provide an ear care service and offers considerations for implementation of this and other expanded services going forward.

### Health system level

WHO has recognised the major health burden ear disease presents for rural and remote communities and has called for change to be made to ensure all people have equal access to quality ear and hearing care across the life course.<sup>1</sup> Access to health providers trained in ear health has been identified as a major barrier to ear care previously, with difficulty increasing with distance from metropolitan areas.<sup>2</sup> This study has found that consumers having difficulty accessing GP appointments consequently present to EDs for ear complaints. In addition, pharmacists prior to the intervention reported regularly referring consumers to EDs, due to an inability to access timely GP appointments. In a study of GP-type presentations to EDs undertaken at one of the ear study sites, it was found that half of all presentations over a 6-month period were GP-appropriate problems.<sup>24</sup>

LISTEN UP has provided the improved access to ear care by upskilling permanent and highly accessible health professionals, local community pharmacists. Consumers also reported the immediate access and the integrated pathway of GP referral as a major benefit to the service. GPs reported the referrals they received were appropriate and most consumers were able to be managed by pharmacists with analgesia and reassurance. The provision of a screening and referral service within local community pharmacies is an effective model to redirect ear complaints from EDs to appropriate settings.

### Pharmacist level

The provision of expanded services is an emerging area for Australian pharmacists.<sup>25</sup> To date no formal protocols have been developed to support pharmacists to provide expanded services, despite major developments for pharmacists' scope of practice internationally.<sup>9</sup> Research has

reported rural pharmacists are supportive and interested to provide expanded services with expectation that such services would improve health outcomes and could address current gaps in healthcare.<sup>12 14</sup> LISTEN UP has confirmed that pharmacists were motivated to provide an expanded ear health service. They described a lack of options currently available to manage ear complaints in community pharmacy and the regularity of referring consumers to EDs. After completing the formal training for the service, pharmacists reported improved confidence in managing ear complaints, but uncertainty in identify pathology and making prescribing recommendations. They expected their confidence would improve with practice and thus suggested longer trialability of the service to further develop their skills. They also reported wanting a very detailed protocol to be provided to guide them to provide the service.

This lack of confidence in clinical abilities has been reported to be a major barrier to advancement of the pharmacy profession previously.<sup>26</sup> The culture of feeling inadequately prepared for unfamiliar tasks and fear of making definitive decisions has been linked to pharmacists' personality traits and thus the profession needs to make a transition from scientist to consumer-centred practitioner to successfully work in an expanded scope of practice.<sup>26</sup>

In addition, concern has been raised that expanded practice may not be feasible for rural practice as those pharmacies are already short-staffed and under-resourced.<sup>27</sup> Findings from LISTEN UP align with this, with recognition that three pharmacists are required to be able to offer expanded services and many rural and remote community pharmacies are unable to recruit and maintain that number of pharmacists. In addition, the time required to complete documentation was identified as a major barrier to the service implementation, mostly due to the pharmacists receiving no funding to provide the service with no cost to consumers. These challenges were reflected in the smaller than expected sample size and consequently the shorter duration of the study. This smaller sample size also reduces the transferability and generalisability of the findings of this study and reinforces the importance of a larger remunerated study with more participating pharmacies in future studies. Without a dedicated professional practice pharmacist, consumers were unable to be offered the LISTEN UP service, thus limiting feasibility and defeating the purpose of expanded practice for rural community pharmacy.

The value of a collaborative model of care for expanded practice must be considered for rural practice. Community pharmacists historically have worked independently of other professions, however, literature indicates that collaboration between health professional and community pharmacists is expected to improve health outcomes, particularly in chronic disease management.<sup>28</sup>

## Consumer level

Findings from this study have highlighted a high level of acceptance from consumers with reports of trust and confidence from consumers for their local pharmacists. It has reported high levels of consumer satisfaction and a willingness to return for the service in the future. Consumers have also reported a willingness to pay for the service due to the convenience and accessibility it provides. This willingness to pay for expanded services has been previously identified, however, there is also recognition that those who are most vulnerable are likely not to be able to pay for the service and thus alternative funding models need to be considered.<sup>10</sup>

This study provides first insight into the feasibility, accessibility and acceptability of expanded practice for rural community pharmacists and identifies challenges that need to be addressed for this expanded pharmacy practice to be a sustainable model of healthcare delivery for rural and remote communities. It provides new knowledge to an area of unmet need in rural community and highlights challenges to ear care from consumer, health professional and pharmacist perspectives. A larger study with multiple sites is needed to further consider this model of care, including sustainability, patient outcomes and collaborative integration in rural and remote communities. However adequate funding is essential to ensure high quality training, sufficient pharmacist numbers and low-cost provision for consumers.

## CONCLUSION

Hearing is key to human function and its loss impacts the whole society. Ear care in rural community pharmacy is often fraught with uncertainty and referral to EDs. LISTEN UP provides a feasible protocol for trained pharmacists to provide immediate ear care with an accessible integrated pathway to general practice if needed. This model has been developed and accepted with extensive consultation and provides an initial framework for similar expanded services to be modelled on in the future. Rural community pharmacists remain motivated to provide expanded services, however sufficient funding and a paradigm shift for the pharmacy profession is essential for expanded services to be sustainable and thus contribute to improving healthcare in rural and remote communities.

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**Competing interests** None declared.

**Patient and public involvement** Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

**Patient consent for publication** Not applicable.

**Ethics approval** This study involves human participants and this project has been approved by the Human Research Ethics Committee, James Cook University (reference number: H8187). Participants gave informed consent to participate in the study before taking part.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data availability statement** The authors welcome any correspondence or requests for further details about this study. The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request. NA.

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## Standards for Reporting Qualitative Research (SRQR)\*

<http://www.equator-network.org/reporting-guidelines/srqr/>

Page/line no(s).

### Title and abstract

<b>Title</b> - Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended	1 and 2
<b>Abstract</b> - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions	32-57

### Introduction

<b>Problem formulation</b> - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement	76-126
<b>Purpose or research question</b> - Purpose of the study and specific objectives or questions	36

### Methods

<b>Qualitative approach and research paradigm</b> - Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale**	140-141
<b>Researcher characteristics and reflexivity</b> - Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability	142-143
<b>Context</b> - Setting/site and salient contextual factors; rationale**	156-165
<b>Sampling strategy</b> - How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale**	156-176
<b>Ethical issues pertaining to human subjects</b> - Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	148-150
<b>Data collection methods</b> - Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale**	177-187



<b>Data collection instruments and technologies</b> - Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	181-190
<b>Units of study</b> - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	245-254
<b>Data processing</b> - Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/de-identification of excerpts	218-232
<b>Data analysis</b> - Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale**	218-232
<b>Techniques to enhance trustworthiness</b> - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	227-232

**Results/findings**

<b>Synthesis and interpretation</b> - Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	485-489
<b>Links to empirical data</b> - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	286-483

**Discussion**

<b>Integration with prior work, implications, transferability, and contribution(s) to the field</b> - Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	484-554
<b>Limitations</b> - Trustworthiness and limitations of findings	61-71

**Other**

<b>Conflicts of interest</b> - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	584-585
<b>Funding</b> - Sources of funding and other support; role of funders in data collection, interpretation, and reporting	586-591

\*The authors created the SRQR by searching the literature to identify guidelines, reporting standards, and critical appraisal criteria for qualitative research; reviewing the reference lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research.

**\*\*The rationale should briefly discuss the justification for choosing that theory, approach, method, or technique rather than other options available, the assumptions and limitations implicit in those choices, and how those choices influence study conclusions and transferability. As appropriate, the rationale for several items might be discussed together.**

**Reference:**

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. **Standards for reporting qualitative research: a synthesis of recommendations.** *Academic Medicine*, Vol. 89, No. 9 / Sept 2014  
DOI: 10.1097/ACM.0000000000000388

# Interview Questions for Semi-Structured Interview with Consumers (7 Day Follow-Up)

1. Introduction of self and purpose of the call.
- Please feel free to speak freely. There is no right or wrong answer to the questions, it is your views and opinions that we are interested in. I would like to assure you that all of the transcribed material resulting from this discussion will be anonymised in the final report.

Before we start, can I check that you have read the information sheet and you have signed the consent form? Whenever you are ready, please can you confirm that you are happy for me to start the recording? If you have any questions throughout the interview, please let me know.

2. Demographics

1) What is your age in complete years?  _____	2) What is your gender? <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Other, please specify  _____	3) What is your home postcode?  _____	4) Ethnicity <input type="checkbox"/> Caucasian <input type="checkbox"/> ATSI <input type="checkbox"/> Other, please specify  _____
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3. Please could you tell me about your initial feelings towards seeing a pharmacist for your ear complaint?
4. Please can you describe to me your experience at the pharmacy? (who explained what, how was examination conducted, need for referral/treatment etc)
5. How confident did you feel at the end of the consultation about the result?
6. After having your ears examined at the pharmacy, were you referred to a GP?
7. If yes, did you attend? What treatment or referrals did you receive?
8. If no, can you please explain why?
9. How are you feeling today? Has your ear complaint been resolved? (?Need to re-refer)
10. Overall, tell me about your satisfaction with the LISTEN UP service – [Question: 1 am satisfied with the LISTEN UP service – 0 – worst – 10 best.
11. Is there anything you would like changed about the service.
12. Would you pay for this service and what value in the future? \$10, \$20, \$30, \$40, \$50
13. Is there any other comments about the LISTEN UP service you would like to make before we finish?

## SERVICE SUMMARY DOCUMENT

- ☐ Patient has received and reviewed information about the trial and research evaluation.
- ☐ Patient has signed an informed consent form to participate in the trial and research evaluation.
- ☐ Patient meets eligibility criteria to participate in the trial.

Date: \_\_/\_\_/\_\_ Time: \_\_\_\_\_

Patient Contact Details					
First Name:			Last Name:		
Address:					
DOB:			Gender:	Male/Female/Other	
Allergies:			Medical Conditions:		
Pregnant?			Breastfeeding		
Medications:					
Episode of Care					
Presenting Complaint:					
Duration of Complaint:			Treatments tried:		
Pharmacist Examinations:	Otoscopy	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	Tympanometry	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	
	Temperature:				
Brief Notes:					

Attach images and results



Pharmacists clinical impression: Eg. Otitis externa, wax impaction	
Recommendations Made	
Pharmacist Recommendations	<input type="checkbox"/> No treatment <input type="checkbox"/> Pharmacy-based treatment (please specify: _____) <input type="checkbox"/> Referral with appointment made to GP <input type="checkbox"/> Other (please specify: _____)
Expanded Practice Recommendations [RESEARCH PURPOSES ONLY]	
<input type="checkbox"/> Prescription-only medicine (please specify exact drug/strength/dose: _____) <input type="checkbox"/> Immediate emergency department referral <input type="checkbox"/> Specialist ENT Referral <input type="checkbox"/> Speech Therapy Referral <input type="checkbox"/> Audiometry Hearing Test Referral <input type="checkbox"/> Other (please specify: _____)	

Time completed: \_\_\_\_\_

**Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0)**  
**September 15, 2015**

Text Section and Item Name	Section or Item Description
<b>Notes to authors</b>	<ul style="list-style-type: none"> <li>• The SQUIRE guidelines provide a framework for reporting new knowledge about how to improve healthcare</li> <li>• The SQUIRE guidelines are intended for reports that describe <a href="#">system</a> level work to improve the quality, safety, and value of healthcare, and used methods to establish that observed outcomes were due to the <a href="#">intervention(s)</a>.</li> <li>• A range of approaches exists for improving healthcare. SQUIRE may be adapted for reporting any of these.</li> <li>• Authors should consider every SQUIRE item, but it may be inappropriate or unnecessary to include every SQUIRE element in a particular manuscript.</li> <li>• The SQUIRE Glossary contains definitions of many of the key words in SQUIRE.</li> <li>• The Explanation and Elaboration document provides specific examples of well-written SQUIRE items, and an in-depth explanation of each item.</li> <li>• Please cite SQUIRE when it is used to write a manuscript.</li> </ul>
<b>Title and Abstract</b>	
<b>1. Title</b>	Indicate that the manuscript concerns an <a href="#">initiative</a> to improve healthcare (broadly defined to include the quality, safety, effectiveness, patient-centeredness, timeliness, cost, efficiency, and equity of healthcare)
<b>2. Abstract</b>	a. Provide adequate information to aid in searching and indexing b. Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local <a href="#">problem</a> , methods, interventions, results, conclusions
<b>Introduction</b>	<i>Why did you start?</i>
<b>3. <a href="#">Problem Description</a></b>	Nature and significance of the local <a href="#">problem</a>
<b>4. Available knowledge</b>	Summary of what is currently known about the <a href="#">problem</a> , including relevant previous studies

5. <a href="#">Rationale</a>	Informal or formal frameworks, models, concepts, and/or <a href="#">theories</a> used to explain the <a href="#">problem</a> , any reasons or <a href="#">assumptions</a> that were used to develop the <a href="#">intervention(s)</a> , and reasons why the <a href="#">intervention(s)</a> was expected to work
6. <b>Specific aims</b>	Purpose of the project and of this report
<b>Methods</b>	<i>What did you do?</i>
7. <a href="#">Context</a>	Contextual elements considered important at the outset of introducing the <a href="#">intervention(s)</a>
8. <a href="#">Intervention(s)</a>	a. Description of the <a href="#">intervention(s)</a> in sufficient detail that others could reproduce it b. Specifics of the team involved in the work
9. <b>Study of the Intervention(s)</b>	a. Approach chosen for assessing the impact of the <a href="#">intervention(s)</a> b. Approach used to establish whether the observed outcomes were due to the <a href="#">intervention(s)</a>
10. <b>Measures</b>	a. Measures chosen for studying <a href="#">processes</a> and outcomes of the <a href="#">intervention(s)</a> , including rationale for choosing them, their operational definitions, and their validity and reliability b. Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency, and cost c. Methods employed for assessing completeness and accuracy of data
11. <b>Analysis</b>	a. Qualitative and quantitative methods used to draw <a href="#">inferences</a> from the data b. Methods for understanding variation within the data, including the effects of time as a variable
12. <b>Ethical Considerations</b>	<a href="#">Ethical aspects</a> of implementing and studying the <a href="#">intervention(s)</a> and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest
<b>Results</b>	<i>What did you find?</i>
13. <b>Results</b>	a. Initial steps of the <a href="#">intervention(s)</a> and their evolution over time ( <i>e.g.</i> , time-line diagram, flow chart, or table), including modifications made to the intervention during the project b. Details of the <a href="#">process</a> measures and outcome c. Contextual elements that interacted with the <a href="#">intervention(s)</a> d. Observed associations between outcomes, interventions, and relevant contextual elements e. Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the <a href="#">intervention(s)</a> . f. Details about missing data
<b>Discussion</b>	<i>What does it mean?</i>
14. <b>Summary</b>	a. Key findings, including relevance to the <a href="#">rationale</a> and specific aims b. Particular strengths of the project

<b>15. Interpretation</b>	<ul style="list-style-type: none"> <li>a. Nature of the association between the <a href="#">intervention(s)</a> and the outcomes</li> <li>b. Comparison of results with findings from other publications</li> <li>c. Impact of the project on people and <a href="#">systems</a></li> <li>d. Reasons for any differences between observed and anticipated outcomes, including the influence of <a href="#">context</a></li> <li>e. Costs and strategic trade-offs, including <a href="#">opportunity costs</a></li> </ul>
<b>16. Limitations</b>	<ul style="list-style-type: none"> <li>a. Limits to the <a href="#">generalizability</a> of the work</li> <li>b. Factors that might have limited <a href="#">internal validity</a> such as confounding, bias, or imprecision in the design, methods, measurement, or analysis</li> <li>c. Efforts made to minimize and adjust for limitations</li> </ul>
<b>17. Conclusions</b>	<ul style="list-style-type: none"> <li>a. Usefulness of the work</li> <li>b. Sustainability</li> <li>c. Potential for spread to other <a href="#">contexts</a></li> <li>d. Implications for practice and for further study in the field</li> <li>e. Suggested next steps</li> </ul>
<b>Other information</b>	
<b>18. Funding</b>	Sources of funding that supported this work. Role, if any, of the funding organization in the design, implementation, interpretation, and reporting



**Table 2. Glossary of key terms used in SQUIRE 2.0. This Glossary provides the intended meaning of selected words and phrases as they are used in the SQUIRE 2.0 Guidelines. They may, and often do, have different meanings in other disciplines, situations, and settings.**

### **Assumptions**

Reasons for choosing the activities and tools used to bring about changes in healthcare services at the [system](#) level.

### **Context**

Physical and sociocultural makeup of the local environment (for example, external environmental factors, organizational dynamics, collaboration, resources, leadership, and the like), and the interpretation of these factors (“sense-making”) by the healthcare delivery professionals, patients, and caregivers that can affect the effectiveness and [generalizability](#) of [intervention\(s\)](#).

### **Ethical aspects**

The value of [system](#)-level [initiatives](#) relative to their potential for harm, burden, and cost to the stakeholders. Potential harms particularly associated with efforts to improve the quality, safety, and value of healthcare services include [opportunity costs](#), invasion of privacy, and staff distress resulting from disclosure of poor performance.

### **Generalizability**

The likelihood that the [intervention\(s\)](#) in a particular report would produce similar results in other settings, situations, or environments (also referred to as external validity).

### **Healthcare improvement**

Any systematic effort intended to raise the quality, safety, and value of healthcare services, usually done at the [system](#) level. We encourage the use of this phrase rather than “quality improvement,” which often refers to more narrowly defined approaches.

### **Inferences**

The meaning of findings or data, as interpreted by the stakeholders in healthcare services – improvers, healthcare delivery professionals, and/or patients and families

### **Initiative**

A broad term that can refer to organization-wide programs, narrowly focused projects, or the details of specific interventions (for example, planning, execution, and assessment)

### **Internal validity**

Demonstrable, credible evidence for efficacy (meaningful impact or change) resulting from introduction of a specific intervention into a particular healthcare [system](#).

### **Intervention(s)**

The specific activities and tools introduced into a healthcare [system](#) with the aim of changing its performance for the better. Complete description of an intervention includes its inputs, internal activities, and outputs (in the form of a logic model, for example), and the mechanism(s) by which these components are expected to produce changes in a [system's](#) performance.

### **Opportunity costs**

Loss of the ability to perform other tasks or meet other responsibilities resulting from the diversion of resources needed to introduce, test, or sustain a particular [improvement](#) initiative

**Problem**

Meaningful disruption, failure, inadequacy, distress, confusion or other dysfunction in a healthcare service delivery [system](#) that adversely affects patients, staff, or the [system](#) as a whole, or that prevents care from reaching its full potential

**Process**

The routines and other activities through which healthcare services are delivered

**Rationale**

Explanation of why particular [intervention\(s\)](#) were chosen and why it was expected to work, be sustainable, and be replicable elsewhere.

**Systems**

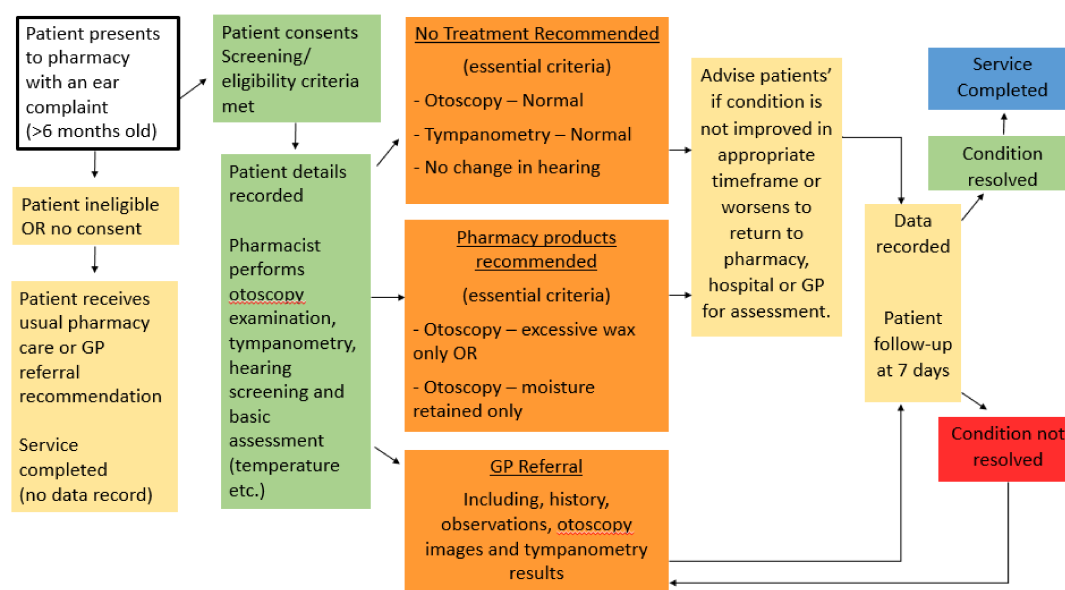
The interrelated structures, people, [processes](#), and activities that together create healthcare services for and with individual patients and populations. For example, systems exist from the personal self-care system of a patient, to the individual provider-patient dyad system, to the microsystem, to the macrosystem, and all the way to the market/social/insurance system. These levels are nested within each other.

**Theory or theories**

Any “reason-giving” account that asserts causal relationships between variables (causal theory) or that makes sense of an otherwise obscure [process](#) or situation (explanatory theory). Theories come in many forms, and serve different purposes in the phases of [improvement](#) work. It is important to be explicit and well-founded about any informal and formal theory (or theories) that are used.

Clinical characteristics Table (N=55)

Age (years)	0-6	3 (5%)
	7-18	0 (0%)
	19-34	14 (25%)
	35-54	19 (35%)
	55+	19 (35%)
Gender	Female	29 (53%)
	Male	26 (47%)
Ethnicity	Aboriginal	10 (18%)
	Caucasian	39 (71%)
	Other	6 (11%)
Complaint (more than 1 per N)	Blocked	28
	Pain	25
	Hearing	7
	Dizziness	3
	Itch	5



Supplementary data figure : Study protocol flow chart (adapted from LISTEN UP (Locally Integrated Screening and Testing Ear aNd aUral Programme): a feasibility study protocol for a community pharmacy-based ear health intervention (13))