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LISTEN UP: An Ear Health Intervention for Rural Community Pharmacy

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ABSTRACT

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. An ear health service model involving pharmacists in rural community pharmacy was trialed.

Objective: To evaluate the feasibility, accessibility and acceptability of a pharmacist-led intervention for ear disease in consumers presenting to community pharmacy.

Design: Prospective pre-post intervention.

Setting: Two rural community pharmacies across Queensland, Australia.

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

Intervention: Trained pharmacists conducted ear examinations using otoscopy and tympanometry on consumers following a protocol. They made recommendations including no treatment, pharmacy only products, or GP referral. Consumers were contacted seven days later for follow-up.

Results: Fifty-five 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. Ninety percent 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 trial other remunerated pharmacy tasks took priority over providing LISTEN UP.

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

What is already known about this subject?	What are the new findings?	How might it impact on clinical practice in the foreseeable future?
Ear disease is a major public health problem in rural and remote Australia, with disease burden having lifelong impacts.	Rural community pharmacists can follow a protocol to provide an acceptable and accessible ear health service.	Adequate funding to support rural community pharmacists to provide an ear health service will reduce costs and improve health outcomes.

Strengths and Limitations of the Study

- This study is the first in Australia to present a structured ear care intervention for rural community pharmacy.
- This study provides valuable data pertaining to expanded practice broadly and considerations for expanded services in the rural and remote context.
- The study, although included only two community pharmacies, does provide evidence of the success of an expanded scope of practice that could be applied to rural and remote settings both within Australia and internationally.

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.(1-3) Disadvantage resulting from hearing loss is well recognised with poorer employment opportunities and higher incarceration rates.(2) The impact of ear disease for young people is profound and includes poorer educational outcomes, social and behavioral outcomes and a disrupted connection land, culture and community.(2)

The World Health Organisation (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.(1) 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.(1) 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.(1) 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 heath, especially in rural and remote communities .(2)

In Australia, one in six people experience some form of hearing impairment with an expected increase as the population ages.(4) 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.(2) 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.(2)

Pharmacists play an essential healthcare role in both clinical and community settings.(5) 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.(5) In many cases, the pharmacist is the only permanent health professional in a rural community. (5) 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.(5) In rural and remote Australia, community pharmacists provide a highly skilled workforce with accessibility extended afterhours and weekends, with potential to provide services to address the ear disease in these vulnerable communities.(2, 5)

Despite rural community pharmacists' knowledge and embedded role in community, pharmacy ear care service provisions are limited without any structured service model. A scoping review of pharmacists' involvement in ear health care 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.(6) Pharmacists in Australia did not provide ear services, instead they reported audiometry services offering hearing screening through the pharmacy.(6)

Internationally, rural pharmacists are expanding their scope of practice and providing innovative services to meet the needs of communities for improved health outcomes.(7) 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.(7) 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.(8-12) In response to this, a community pharmacy-based ear health service model was developed and trialled in two rural pharmacies in Australia.(13) The aim of this study is to determine the feasibility, accessibility and acceptability of the service model.(13)

METHODS

The PRECEDE-PROCEED model was used to provide a framework to develop the research protocol for this study, LISTEN UP (**L**ocally **I**ntegrated **S**creening and **T**esting **E**ar a**N**d a**U**ral **P**rogram). LISTEN UP is a community pharmacy-based intervention to improve the management of ear health in rural community in Australia.(13, 14) 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; and consultation with professional authorities.(14) The PROCEED segment incorporated the evaluation of a six week service pilot and informed planned implementation, process, impact and outcome evaluation of the service.(14) The SQUIRE guidelines have provided a framework to report the new knowledge from this study.(15)

Study Design

The prospective pre- and post-design study is described in Figure 1.

Prior to the study commencing, the two participating pharmacies collected usual care data as a comparator for 8 weeks beginning November 2020. During this time twenty-three ear complaints were recorded as presenting to the pharmacy (child (8), adult (15)). These complaints were ear pain (35%) and ear wax (35%), swimmers ear (17%), hearing loss (4%) and other (discharge, fever, insomnia, blocked ear, vertigo) (4%).

The intervention was then piloted for six weeks at each pharmacy (14) before the six month study was conducted from February – July 2021.

Ethics approval

This project has been approved by the Human Research Ethics Committee, James Cook University. (Reference number: H8187)

Patient and Public Involvement

This study was developed to address a gap in healthcare delivery for rural consumers. Patients (consumers) were recruited into the study as participants, however were not involved in the design or development of the study.

Setting and Recruitment

Pharmacies who had participated in previous research on rural expanded pharmacy practice were invited to express an interest to participate in the LISTEN UP study.(8, 10, 12) 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. General practitioner (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 Modified Monash Model classification system categories 4-7.(13, 16)

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 Benchmarque Group.(15) 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 TYMPTY001 - 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 six months of age.

Data Collection

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

Table 1: Data collection sources and methods.

	Consumer	Pharmacist	General Practitioners
Pre-Intervention		Semi-structured Interview [FAS]	Semi-structured Interview [FAS]
During Intervention	Consumer Satisfaction Survey [AS]	Service Summary Document [F]	
Post-Intervention	Semi-structured Interview (7-day follow up) [FAS]	Semi-structured Interview [FAS]	Semi-structured Interview [FAS]

[Legend: F Feasibility data source; S Accessibility data source; A Acceptability data source]

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 (previously published –supplementary data (flow chart)) 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.(13)

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 COVID19 risk consumer (e.g. travelled in a COVID19 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' (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 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 seven days (Interview Guide - Appendix 2). 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 trial period. The MedRx video otoscope and Amplivox Otowave 102 tympanometer were used in this study.

Outcome and data analysis

Demographic information, clinical characteristics 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.(17) This style of thematic analysis incorporated both the data-driven inductive approach and the deductive priori template of codes approach.(17) 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).(18, 19) NVivo 12 software was used for all of the qualitative analysis.(20)

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.(21) 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.

RESULTS

Fifty-five consumers participated in the trial (mean age = 42 years). One in five participants were Aboriginal and 85% of participants were over 19 years of age (ethics approval for children younger than 13 was gained halfway through the trial). Duration of the ear complaint ranged from 1 – 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 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 (1), consumer unwilling to be examined (4), ruptured ear drum (1), ear canal too large (1), unknown (3).

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

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%)		

OTC (over the counter). Other clinical impressions: ruptured ear drum (3), poor compliance of tympanic membrane (1), sinus congestion (1). Some participants received more than one recommendation.

Pharmacists recommended over-the-counter (OTC) products to two-thirds of the participants. OTC products recommended included wax removal drops (19), analgesia (11), drying agent ear drops (1), decongestant nasal spray (3), oral decongestants and antihistamines (3). One quarter 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 (3) and watch and wait (4).

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

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

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"		

NOTE: Available survey answers range 5 point likert (strongly disagree – strongly agree)

Consumer Post-Intervention 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 (1), leaving town directly (1), or attending scheduled hospital appointment instead (1).

Data from these interviews were analysed using quantitative content analysis. Every participant described their experience at the pharmacy with a positive term (e.g. marvelous, 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 (e.g. throat) were the only two service improvements recommended. Most participants (87%) reported they would pay for this type of pharmacy service, with suggested amounts ranging from AUD$1-20 (33%), $21-50 (33%). The average value that participants were willing to pay was AUD$33 with values of AUD$100, $150 and $200 also suggested.

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 (e.g. 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.*

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 kilometers.

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 minutes with an average of 25 minutes.

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 trial was undertaken, consumer *acceptability* was expected by both participant groups.

Pharmacists described difficulty with accessing health professionals, wait lists in excess of two weeks for GP's and allied health professions as well as a lack of permanent health care 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 trial, 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 trial pharmacists continued to report a positive ***pharmacist behaviour shift*** towards expanded pharmacy broadly. Pharmacists described the trial 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 trial.

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 trial, 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 emergency department (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 trial 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 trial 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 trial 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 ten 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 trial 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 trial, workflow demands however were identified as a barrier to both the trial 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 trial. 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 trial 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 trial 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 trial. 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 trial and happy to be involved. After the trial 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 trial 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 trial 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 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 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.(1) 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.(2) This study has found that consumers having difficulty accessing GP appointments consequently present to emergency departments for ear complaints. In addition, pharmacists prior to the intervention reported regularly referring consumers to emergency departments, due to an inability to access timely GP appointments. In a study of GP-type presentations to emergency departments undertaken at one of the ear trial sites, it was found that half of all presentations over a six month period were GP-appropriate problems.(22)

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 emergency departments to appropriate settings.

Pharmacist Level

The provision of expanded services is an emerging area for Australian pharmacists.(23) To date no formal protocols have been developed to support pharmacists to provide expanded services, despite major developments for pharmacists' scope of practice internationally.(7) 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.(10, 12) 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 emergency departments. 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.(24) 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.(24)

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.(25) 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. 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.

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 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.(8)

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 health care delivery for rural and remote communities. A larger trial with multiple sites is needed to further consider this model of care, 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 emergency departments. 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 a framework for similar expanded services to be modeled 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.

Figure 1: Process diagram of LISTEN UP study.

Figure 2: Thematic map illustrating the themes and codes for qualitative analysis of GP and Pharmacist Interviews.

DECLARATIONS

Ethics approval and consent to participate

This project has been approved by the Human Research Ethics Committee, James Cook University. (Reference number: H8187) Informed consent obtained from study participants is in written form.

Availability of data and materials

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.

Competing interests

The authors declare that they have no competing interests.

Funding

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Authors' contributions

ST, AC, and BG contributed to the design of the study. ST conducted the data management with secondary assistance from BG. ST prepared the first draft of the manuscript, which was reviewed and edited by AC and BG. All authors read and approved the final manuscript.

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ENDNOTE AUTOMATED REFERENCE (Please disregard)

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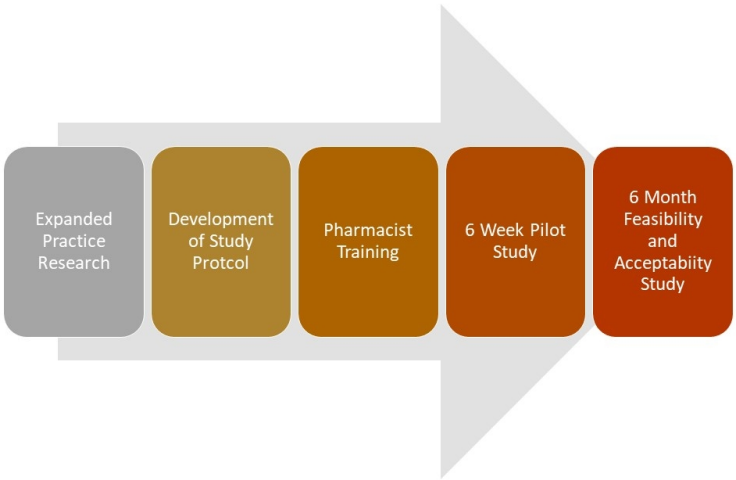

Figure 1: Process diagram of LISTEN UP study.

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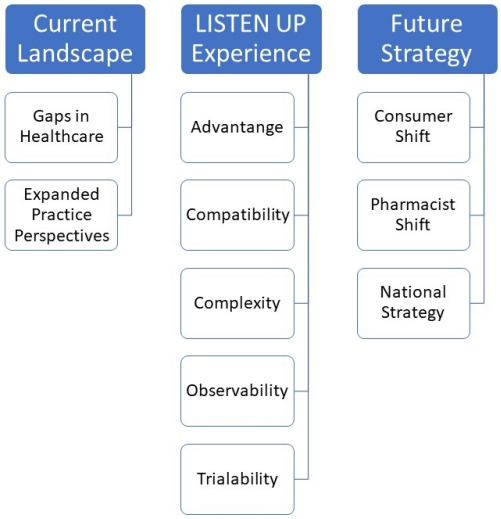

Figure 2: Thematic map illustrating the themes and codes for qualitative analysis of GP and Pharmacist Interviews.

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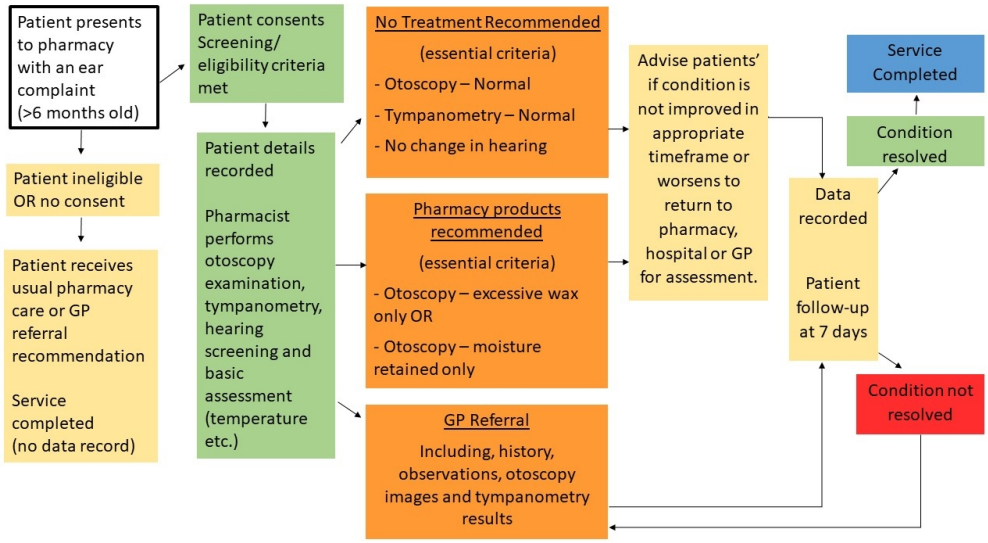

Supplementary Data Figure - LISTEN UP Study Protocol (adapted from reference 13)

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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	☐ Normal ☐ Abnormal	Tympanometry	☐Normal ☐ Abnormal
	Temperature:			
Brief Notes:				

Attach images and results

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

Time completed: _____

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.

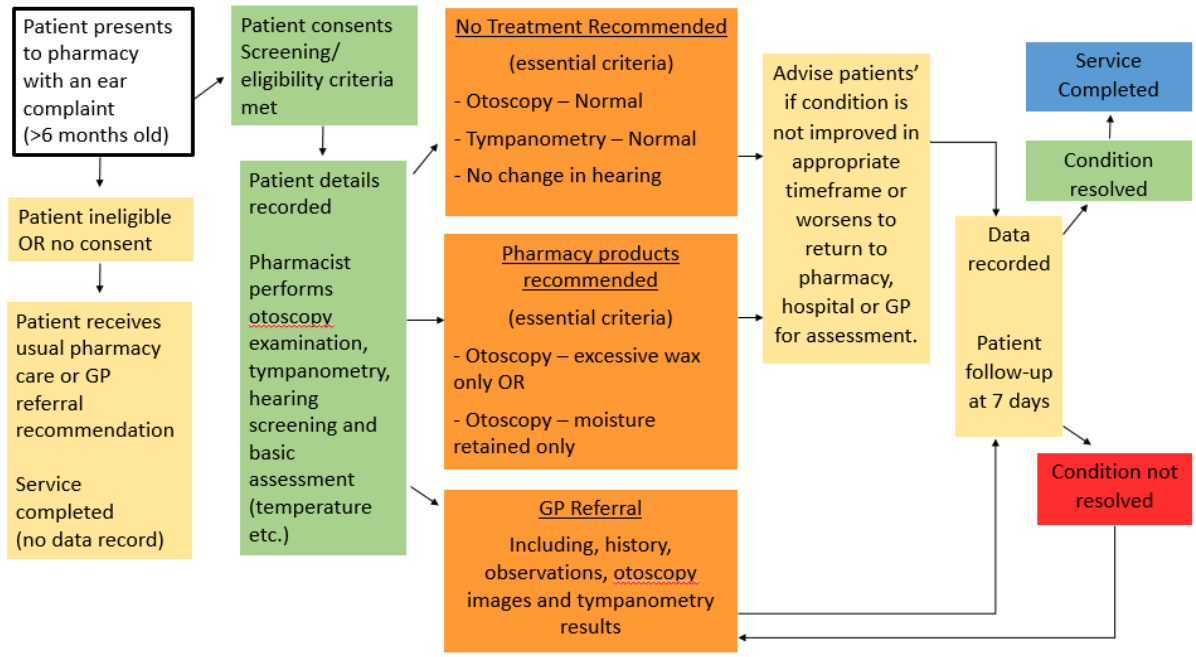
2. Demographics

1) What is your age in complete years? _____	2) What is your gender? ❑ Male ❑ Female ❑Other, please specify _____	3) What is your home postcode? _____	4) Ethnicity ❑ Caucasian ❑ ATSI ❑Other, please specify _____

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?

Clinical characteristics Table (N=55)

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

Taylor et al. Pilot and Feasibility Studies (2021) 7:124
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Pilot and Feasibility Studies

STUDY PROTOCOL Open Access

LISTEN UP (Locally Integrated Screening and Testing Ear aNd aUral Programme): a feasibility study protocol for a community pharmacy-based ear health intervention

Selina Maree Taylor[1*], Alice Cairns[2], Efi Mantzourani[3,4] and Beverley D. Glass[5]

Abstract

Background: Ear disease is a major cause of preventable hearing loss and is very common in rural communities, estimated to affect 1.3 million Australians. Rural community pharmacists are well placed to provide improved ear health care to people who are unable to easily access a general practitioner (GP). The purpose of this study is to apply an ear health intervention to the rural community-pharmacy setting in Queensland, Australia, to improve the management of ear disease. The aims are the following: (1) to evaluate the feasibility, potential effectiveness and acceptability of a community pharmacy-based intervention for ear health, (2) to evaluate the use of otoscopy and tympanometry by pharmacists in managing ear complaints in community pharmacy and (3) to evaluate the extended role of rural pharmacists in managing ear complaints, with the potential to expand nationally to improve minor ailment management in rural communities.

Methods/design: This is a longitudinal pre- and post-test study of a community-pharmacy-based intervention with a single cohort of up to 200 patients from two rural community pharmacies. Usual care practices pertaining to the management of ear complaints will be recorded prior to the intervention for 8 weeks. The intervention will then be piloted for 6 weeks, followed by a 12 month impact study. Patients aged > 13 years presenting to the pharmacies with an ear complaint will be invited to participate. Trained pharmacists will conduct an examination including a brief history, hearing screening, otoscopy and tympanometry assessments. Patients will be referred to a general practitioner (GP) if required, according to the study protocol. Patients will complete a satisfaction survey and receive a follow-up phone call at 7 days to explore outcomes including prescribed medications and referrals. Pharmacists and GPs will complete pre- and post- intervention interviews. Patient, pharmacist and GP data will be analysed using descriptive statistics and thematic analysis for the qualitative data.

Discussion: This study will demonstrate the implementation of a screening and referring ear health intervention in rural community pharmacy. Feasibility, potential effectiveness and acceptability of the intervention will be assessed.

Trial registration: Australian and New Zealand Clinical Trial Registry Number: ACTRN12620001297910.

Keywords: Community pharmacy, Rural and remote, Pharmacy practice, Scope of practice, Ear

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Background

Ear care is recognised as important for the health of the population [1]. Ear disease is increasing globally with the World Health Organisation (WHO) proposing that by 2050 we can expect 900 million people to have disabling hearing loss, twice that of 2019 [2]. In Australia, more than 1.3 million people are living with a hearing condition that could have been prevented [3]. In rural and remote communities, the prevalence rate of middle ear diseases is as high as 50% in children under 3 years of age, double the prevalence recognised by WHO as a 'massive public health problem' [1, 2]. As well as the health consequences, unmanaged ear disease correlates with poor educational, social and behavioural outcomes [1].

Access to trained health care providers and a lack of infrastructure and supplies have been recognised as major challenges to providing ear care internationally [1]. There is currently a shortage of health care workers in rural and remote communities able to provide ear health care, which is predicted to worsen in the future [4]. Despite these shortages, there have been a number of innovative models of care developed to utilise consistently accessible health care professionals such as pharmacists to improve ear care [5]. A scoping review of community pharmacist interventions in ear health identified eight studies, whereby pharmacists provided a targeted ear health service, including hearing screening (4 in Australia), an otoscopy pilot study (1 in England) and pharmacy-based ear clinics (1 in USA; 2 in England) [5].

Pharmacists are trusted and accessible health professionals, who are motivated to meet local community needs [6]. Internationally, rural pharmacists are providing innovative models of care and working at expanded scopes of practice to better meet health needs [7]. Pharmacists, consumers and health professionals living in rural and remote locations in Australia are supportive of pharmacists expanding their service delivery to improve patient outcomes [8–10]. Rural pharmacists in Australia work in a unique setting with complex patients and limited access to health services and the potential for them to improve ear health care is unknown. A new pilot programme was developed to explore the impact of a pharmacist ear care intervention on patient-related outcomes.

Pilot and feasibility studies are an important step in the development of successful interventions for health [11]. There is emerging acknowledgement of the value of pilot studies to better understand the conduct and applicability of an intervention to allow the results to be better applied to patient care [11].

This paper describes the research protocol of the pilot, LISTEN UP (Locally Integrated Screening and Testing Ear aNd aUral Programme), a rural community pharmacy-based intervention to improve the management of ear health in the community in Australia.

Research aims

This study aims to: (1) explore the feasibility, potential effectiveness and acceptability of a community pharmacy-based intervention for ear health, (2) evaluate the use of otoscopy and tympanometry by pharmacists in managing ear complaints in community pharmacy and (3) evaluate the extended role of rural pharmacists in managing ear complaints, with potential to expand nationally to improve ear care minor ailment management in rural communities.

Methods and design

Study design and setting

This is a longitudinal pre- and post-design study of a community-pharmacy-based intervention piloted in two rural community pharmacies in Queensland, Australia. Co-design has been applied to this study with stakeholder, health professional, pharmacist and consumer perspectives from previous research utilised in conjunction with community consultation to inform the design of this study [8–10]. Prior to the intervention, participating pharmacies will collect usual care data for 8 weeks beginning November 2020. The intervention will then be piloted for 6 weeks at each pharmacy and then refinement and improvements will be made before the longitudinal impact study is conducted for 12 months.

Ethics approval

This project has been approved by the Human Research Ethics Committee, James Cook University (Reference number: H8187).

Pharmacies

Pharmacy eligibility criteria

Community pharmacies that meet the following criteria are eligible to participate as a study site:

- Participating pharmacists must hold unconditional registration with the Australian Health Practitioner Regulation Agency (AHPRA) [12].
- Maintain accreditation standards for quality assurance under the Quality Care Pharmacy Programme (QCPP) [13].
- Have a private counselling area within the pharmacy that is separated from the common pharmacy counter, where one-to-one consultations can be conducted.
- Have a high daily 'walk-in customer' number of more than 100 customers per day.
- Have suitable information technology including a computer with internet access, printer and scanner.

- Are classified as rural or remote by the Modified Monash Model classification system categories 4-7 [14].
- Are located in Queensland, Australia, due to COVID-19 interstate restrictions around travel for training.

Recruitment of pharmacies

Pharmacies who have participated in earlier research on rural expanded pharmacy practice will be invited to express an interest to participate in the LISTEN UP. Those pharmacies who are interested will be phoned by the principal investigator to provide further explanation of the study and obtain consent. Two pharmacies will be enrolled in the study. Each pharmacy will be linked with at least one participating general practitioner. An invitation to participate with an information sheet and informed consent form will be provided to each pharmacist at the participating pharmacies and each GP at the participating general practices.

Pharmacist training

Each participating pharmacist will undertake nationally credentialed training in ear health including otoscopy and tympanometry. This training will be mixed mode with online and face-to-face components. The training includes 55 h of online training and two full days of workshops and is provided by the Benchmarque Group [15]. The training will include the following units of competencies: EHHPEH002—promote, educate and manage ear health; EHHAEH001—assess ear health; EHHPEA004—paediatric and TYMPTY001—perform tympanometry.

Only pharmacists who have successfully completed the required training will be eligible to participate in the study. Completed certificates of training will be provided to the principal investigator.

All training, including training materials will be consistent with national standards and will be tailored to suit the needs of community pharmacists. In addition, pharmacists will be provided with a list of recommended supplemental readings and resources. A member of the research team who is a pharmacy academic will also provide face-to-face and virtual training to the pharmacists on documentation processes for the project.

General practitioners (GPs)

General practitioner eligibility criteria

GPs that meet the following criteria are eligible to participate in the study:

- Hold unconditional registration with the Australian Health Practitioner Regulation Agency (AHPRA).
- Have capacity to provide timely appointments (within 48 h) for participants referred to them for review.
- Have suitable information technology provisions including a computer with internet access, printer and scanner.
- Are classified as rural or remote by the Modified Monash Model classification system categories 4-7 [14].
- Are located in Queensland, Australia, due to COVID-19 interstate restrictions around travel for training.

Recruitment of GPs

At each pharmacy location, all GP practices within a 25-km radius will be invited to participate in the study.

Participants

Sample size

The sample size was calculated using the formula $n = Z^2P\ (1\text{-}P)/d^2$, where n=sample size, Z is the critical value of the normal distribution at α/2 for a confidence level of 95% where α is 0.05 and the critical value is 1.96, P = expected prevalence or proportion = 0.14 (14%) and d = precision = 0.05 (5%) [16]. To our knowledge, there is no published community pharmacy-based ear health interventions of similar nature, therefore no standard reference could be applied to accurately determine prevalence required to calculate the sample size. However, we have calculated a sample size based on data from the Australian Government Department of Health, which estimates 14% of Australians suffer from hearing loss [3]. Therefore, n = 185 + 10% for missing data = 203 participants.

Given the calculated sample size, it is expected that each of the two participating pharmacies would recruit 100 patients into the study during the impact study. The duration of the project will be extended for up to 12 months to ensure adequate patient participant numbers to power the study.

Recruitment of participants

Potential participants will be recruited from walk-in customers who present at participating pharmacies seeking advice or products for an ear complaint. Pharmacists will invite these patients to participate in the study, provide an information sheet (with verbal explanation), ensure patient meets eligibility criteria and completes an informed consent form. Informed consent obtained from study participants is in written form.

Participant eligibility criteria

To be eligible for participation in the study, patients must:

- Be aged 13 years or older (to be able to independently provide informed consent, those between 13-16 years can consent for self or parent/guardian may provide consent).
- Be able to understand the English language at a level appropriate to provide informed consent (pharmacists will use professional judgement to determine if participants are able to provide informed consent).
- Attend a participating pharmacy as a 'walk-in' customer seeking help for an ear complaint.

Patient will be excluded from the study if they:

- Are < 13 years old
- Have inadequate health literacy or English language skills to provide informed consent
- Have obvious major trauma to the ear
- Are a high COVID-19 risk patient (e.g. travelled in a COVID-19 hotspot within 14 days)
- Have not consented

Intervention participants

Participants' temperature will be measured in the waiting area, if > 37.5 Celsius COVID-19 precautions will be implemented and additional personal protection equipment (PPE) applied, including face mask, gloves and face shield. Pharmacists will conduct the consultation with eligible consenting participants in a private consultation space. Pharmacists will then document a brief history of the ear complaint including symptoms, duration and treatments tried by the patient on a template service summary document (Appendix 1) provided to them. Pharmacists will then examine the ears using otoscopy and tympanometry. If the complaint is hearing related, pharmacists will perform a hearing screening test using the *Sound Scouts* application [17]. *Sound Scouts* is an application based hearing check that can be used in persons over the age of 4 years to detect conductive hearing loss, sensorineural hearing loss and difficulties listening in noise [17].

Equipment

The otoscope used in this study is the MedRx video otoscope. The tympanometer is the Amplivox Otowave 102. Hearing screening will be conducted using the *Sound Scouts* application with Senheiser HD 300 headphones.

Patient data collection

Patient data collected includes full name, postcode, age, gender, allergies, medicines, medical conditions, pregnancy/breastfeeding status, temperature, brief history of the ear complaint including symptoms, duration and treatments tried by the patient, otoscopy, tympanometry and hearing screening findings/results. This information will be documented on the service summary record. This record will contain all the information collected by the pharmacists from the patient consultation. It was developed in consultation with an advisory group (consisting of stakeholder representatives from various organisations in the health sector), is formatted in Microsoft Office and is stored on a password protected hard drive.

Protocol

Pharmacists will follow a protocol to determine the pathway (Fig. 1) for the patient. If otoscopy and tympanometry assessments are normal and hearing is not affected, the pharmacist may recommend no treatment and advise patient to monitor and seek medical advice if condition does not improve or worsens. If otoscopy indicates excessive wax only or moisture retention from water activity only and no other symptoms are present, the pharmacist may recommend pharmacy products including ear drops containing drying agents or wax dissolvents. All other patients will be referred to a GP with an appointment made by the pharmacist before they leave the pharmacy. Pharmacists will be able to book appointments with the GPs via a public online booking platform or via telephoning the GP practice. If the pharmacist is unable to make a timely appointment with a GP, the patient will be recommended to attend the local emergency department. Participants will be asked to complete a patient satisfaction survey and consent to a follow-up phone call in 7 days.

GP referral

The GP to which the patient has been referred will be emailed a password encrypted file with all of the patient data including temperature, brief history of the ear complaint including symptoms, duration and treatments tried by the patient, otoscopy, tympanometry and hearing screening findings/results.

Pharmacist recommendations

Pharmacists will be asked to record their actual recommendations and recommendations they would have made if they had an expanded scope including if they would have recommended a prescription medicine or referral to other service providers including audiometrists, speech pathologists, or ear, nose and throat specialists. This information will be collected for research purposes only as current practice does not allow Australian pharmacists to recommend prescription medicines or refer patients to specialty services.

Follow-up

A member of the research team will phone all patient participants 7 days after their pharmacy consultation to

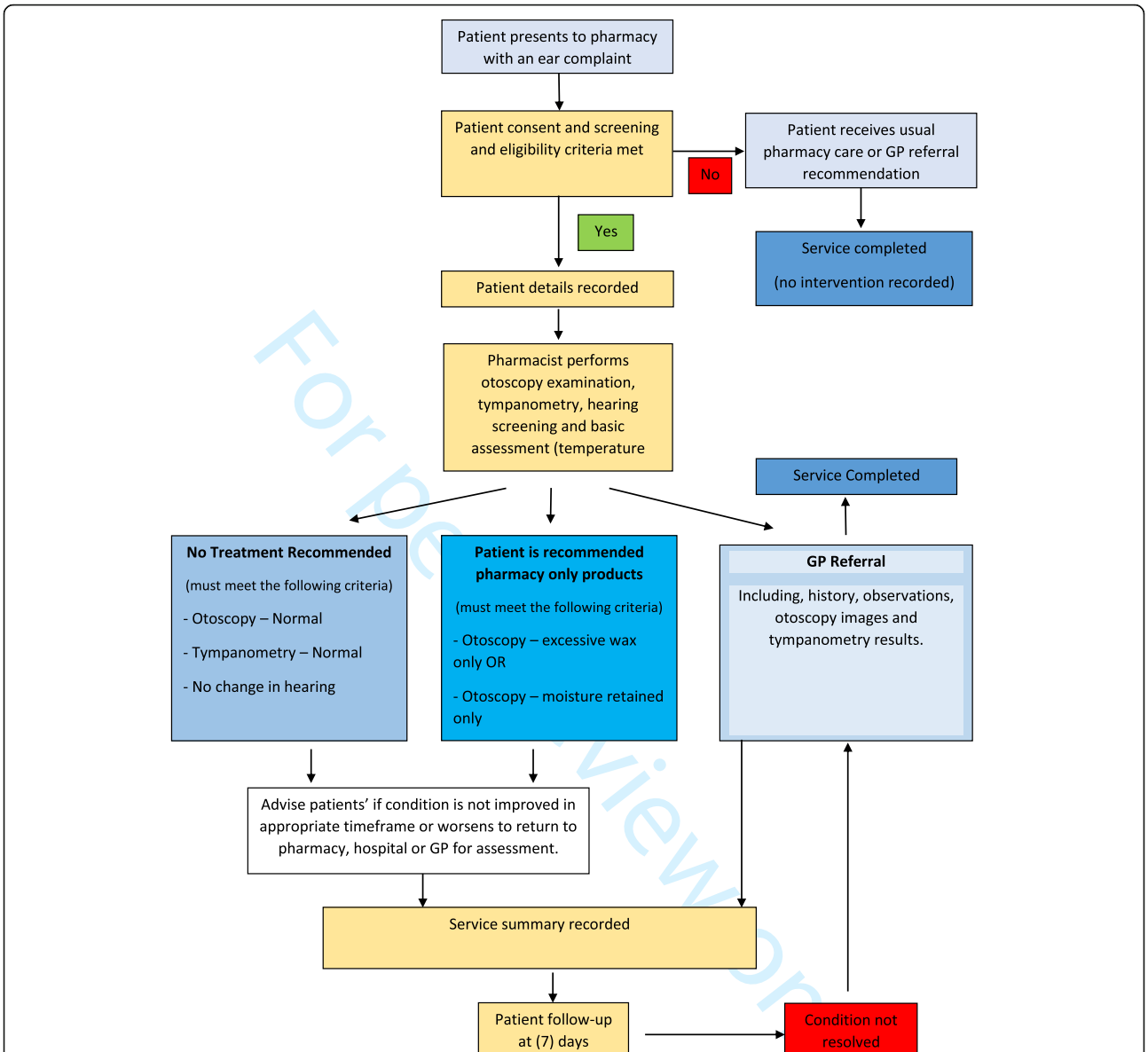

Fig. 1 LISTEN UP study protocol pathway

explore the patient outcomes from the intervention. Patients will be asked about the condition of their ear complaint (improvement/deterioration), their satisfaction with the pharmacy intervention (Likert scale), if they were referred to a GP, if they attended the GP appointment and what advice, prescription or referral they had received from the GP. If the patient indicates further deterioration of the condition, a lack of improvement or a concern about the complaint, the researcher will offer to refer the patient to the GP and/or advise the patient to seek further medical advice.

Data saturation

Total population sampling will be conducted in this study. We will attempt to interview all GPs and pharmacists by inviting them to participate in an interview three times. In addition, all participants will receive a follow-up phone call four times, including at least one out of

normal business hours, in an attempt to ensure as many as possible participants receive the follow-up phone call.

Study measurements and outcomes

Data pertaining to patient, pharmacist and GP experiences of the ear health intervention will be collected via semi-structured interviews pre- and post- intervention with pharmacists and GPs, service summary documentation, patient satisfaction surveys and 7-day follow-up interviews with patients. These data collection tools were developed in house to suit this innovative model. Pharmacist and GP interviews will include questions pertaining to perceptions of expanded pharmacy services, current local landscape of ear health (incidence, access to services) and expected/actual outcomes of the LISTEN UP project including pharmacist capacity, patient receptiveness and GP/pharmacist/patient interaction. Usual care data will be recorded for 8 weeks prior to the intervention. The usual care data will include a non-identifiable record of ear complaints presenting to the pharmacy, the description of the complaint and the pharmacists recommendations (Table 1).

Usual care data will record patient age groups, type of complaint (ear pain, ear wax, swimmers ear, ear itch, hearing loss or other), duration of the complaint, pharmacist recommendations (pharmacy products, verbal GP referral, verbal emergency department referral or other).

Initial study measurements are pharmacist and GP perspectives of ear health in the community, this described study protocol, expected outcomes, and anticipated enablers and barriers. This data will be collected prior to the study beginning via semi-structured interviews to explore the expected feasibility of the study. The interviews will be repeated post-study and the data collected from pre-intervention will be compared with data collected from these interviews to measure a change of opinion with pharmacists and GPs post-intervention.

Pharmacists will record the consultation data on a service summary document (Appendix 1). This document will also collect pharmacist recommendations for the patient, including they would have made if they had an expanded scope of practice such as prescription medicines and specialist referrals. This data will be compared with data provided by the patients at the 7-day follow-up phone call about the medicines they were prescribed and any referrals they may have received. In addition, qualitative data relating to the patient experience of the pharmacy service and patient perceived outcomes of the ear complaint will be collected during the patient interviews.

Study measurements

The study measurements collected in the intervention include pharmacist views, pharmacist recommendations, GP views and patient views. There measurements are aligned to the primary and secondary outcomes of the study (Table 2).

Study outcomes

The outcomes of this study will be assessed against the objective of implementing a rural community pharmacy-based 'model of care' to improve the management of ear complaints in the community.

Primary

(1) To evaluate the feasibility, acceptability and potential effectiveness of a community pharmacy-based intervention for ear health by exploring:
   a. Pharmacist views of:
      i. Pharmacist capacity and competence to provide the intervention (motivation, confidence, competence, experience of training, capacity (workflow/workload))
      ii. Patient acceptance
      iii. Pathway to GP service (timeliness of appointment, GP staff attitudes)
   b. Patient views of the service in terms of access, alternative health care options, satisfaction and willingness to pay (confidence/acceptance of pharmacist service, referral process, timeliness of pharmacists consult/GP consult).
   c. GP views on appropriateness of pharmacist referrals, collaborative care with pharmacists (use of telehealth).

(2) To evaluate the use of otoscopy and tympanometry by pharmacists to improve specificity of ear condition management in community pharmacy by comparing:
   a. Usual care data with intervention data pertaining to pharmacist recommendations.
   b. Pharmacist recommendations on the patient service summary record compared to GP

Table 1 Data collection methods for pre-, during and post-intervention phases

	Patients	Pharmacists	General practitioners
Pre-intervention	Record of usual care in pharmacy for 8 weeks	Semi-structured interview	Semi-structured interview
During intervention	Patient satisfaction survey	Service summary document	
Post-intervention	Semi-structured interview (7-day follow-up)	Semi-structured interview	Semi-structured interview

Table 2 Summary of study measurements aligned to study outcomes

Measurement	Instruments	Pre-study	During study	Post-study	Primary outcome	Secondary outcome
Pharmacist views	Semi-structured interview	X		X	1a	1, 2
Pharmacist recommendations	Service summary document		X			1, 2, 3
GP views	Semi-structured interview	X		X	1c	1, 2
Patient views	Satisfaction Survey			X	1b	1, 2
Patient views	Semi-structured interview			X	1b	1, 2, 3

prescriptions and referrals described by patients at the 7-day follow-up phone call.

c. Patient acceptance of pharmacists performing examinations with an otoscope and tympanometer.

Secondary

1) To evaluate the extended role of rural community pharmacists in managing ear complaints as a minor ailment in the community by evaluating, patient, GP and pharmacist perspectives of a community pharmacy-based ear health pre- and post-intervention.
2) To evaluate the potential for implementation of a national model of community pharmacy-based interventions to improve the management of minor ailments in rural communities.
3) To provide evidence to guide the scheduling of medicines to allow pharmacists to better manage minor ailments in community pharmacies.

Data analysis

Data collected via semi-structured interviews will be transcribed verbatim and thematically analysed both inductively and deductively, using the NVivo 12 software programme [18, 19]. Data collected from the patient surveys and patient service summary record will be analysed using descriptive statistics and frequencies using IBM SPSS Statistics 25 for Windows.

Discussion

The protocol and methods outlined will inform the development of an intervention framework for managing multiple minor ailments in the rural community pharmacy setting in Queensland, Australia. Positive outcomes from this study may demonstrate feasibility, potential effectiveness and acceptability of such an intervention. Internationally, expanded practice is becoming a common practice and is widely accepted in many countries; however, evidence to support expanded models of care in rural settings both internationally and in Australia are exceptionally limited and thus this protocol will add to the evidence base [7].

Preliminary discussions with professional pharmacy associations and professional indemnity insurers have been conducted and there is a high level of support for this programme.

Limitations of the study protocol

This is a small pilot study of a complex intervention, with no control group. If the pilot testing indicates feasibility and effectiveness of this intervention, it will be important to validate the study with larger numbers in varied locations with a control group to comprehensively determine effectiveness and scalability. In addition, it was deemed out of scope for the small scale pilot protocol to include an economic evaluation of the study and thus a larger study would be required to examine economic sustainability.

Conclusions

Ear disease is recognised as a major public health concern for rural and remote communities, especially due to accessibility of health professionals, requiring innovative strategies for effective management. Patients with ear complaints regularly present to community pharmacies seeking help due to difficulty in accessing GPs outside of metropolitan locations. Currently, pharmacists provide recommendations based on symptomatic descriptions of ear complaints provided by patients. Pharmacists are in an appropriately positioned location to provide improved ear care and are well placed to ensure patients are able to access timely health care. To our knowledge, this is the first community pharmacy-based study providing a specific ear health intervention in rural pharmacy practice to enable a pharmacist to improve the management of ear complaints.

Abbreviations

GP: General practitioner; WHO: World Health Organisation; LISTEN UP: Locally Integrated Screening and Testing Ear aNd aUral Programme; AHPRA: Australian Health Practitioner Regulation Agency; QCCP: Quality Care Pharmacy Programme; PPE: Personal protective equipment

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s40814-021-00856-6.

Additional file 1. Service summary document.

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Authors' contributions
ST, AC, EM and BG contributed to the design of the study. ST prepared the first draft of the study protocol, which was reviewed and edited by AC, EM and BG. The authors read and approved the final manuscript.

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Availability of data and materials
The authors welcome any correspondence or requests for further details about this study protocol. The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
This project has been approved by the Human Research Ethics Committee, James Cook University (Reference number: H8187). Ethical approval documentation is included as supplementary material. Informed consent obtained from study participants is in written form.

Consent for publication
Not applicable

Competing interests
The authors declare that they have no competing interests.

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Publisher's Note

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

Text Section and Item Name	Section or Item Description
Notes to authors	• The SQUIRE guidelines provide a framework for reporting new knowledge about how to improve healthcare • The SQUIRE guidelines are intended for reports that describe system level work to improve the quality, safety, and value of healthcare, and used methods to establish that observed outcomes were due to the intervention(s). • A range of approaches exists for improving healthcare. SQUIRE may be adapted for reporting any of these. • Authors should consider every SQUIRE item, but it may be inappropriate or unnecessary to include every SQUIRE element in a particular manuscript. • The SQUIRE Glossary contains definitions of many of the key words in SQUIRE. • The Explanation and Elaboration document provides specific examples of well-written SQUIRE items, and an in-depth explanation of each item. • Please cite SQUIRE when it is used to write a manuscript.
Title and Abstract	
1. Title Page 2	Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patient-centeredness, timeliness, cost, efficiency, and equity of healthcare) P
2. Abstract Page 2	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 problem, methods, interventions, results, conclusions
Introduction	*Why did you start?*
3. Problem Description	Nature and significance of the local problem Page 4
4. Available knowledge	Summary of what is currently known about the problem, including relevant previous studies Page 4

5. Rationale	Informal or formal frameworks, models, concepts, and/or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s), and reasons why the intervention(s) was expected to work Page 4
6. Specific aims	Purpose of the project and of this report Page 5
Methods	*What did you do?*
7. Context	Contextual elements considered important at the outset of introducing the intervention(s) Page 5
8. Intervention(s)	a. Description of the intervention(s) in sufficient detail that others could reproduce it Page 6 and 7 b. Specifics of the team involved in the work
9. Study of the Intervention(s)	a. Approach chosen for assessing the impact of the intervention(s) b. Approach used to establish whether the observed outcomes were due to the intervention(s) Page 7
10. Measures	a. Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their operational definitions, and their validity and reliability Page 6 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. Analysis	a. Qualitative and quantitative methods used to draw inferences from the data b. Methods for understanding variation within the data, including the effects of time as a variable Page 7
12. Ethical Considerations	Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest Page 5
Results	*What did you find?*
13. Results	a. Initial steps of the intervention(s) and their evolution over time (*e.g.*, time-line diagram, flow chart, or table), including modifications made to the intervention during the project Page 7-14 b. Details of the process measures and outcome c. Contextual elements that interacted with the intervention(s) d. Observed associations between outcomes, interventions, and relevant contextual elements e. Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the intervention(s). f. Details about missing data
Discussion	*What does it mean?*
14. Summary	a. Key findings, including relevance to the rationale and specific aims b. Particular strengths of the project Page 2 and 16

15. Interpretation	a. Nature of the association between the intervention(s) and the outcomes b. Comparison of results with findings from other publications c. Impact of the project on people and systems d. Reasons for any differences between observed and anticipated outcomes, including the influence of context e. Costs and strategic trade-offs, including opportunity costs
16. Limitations	a. Limits to the generalizability of the work b. Factors that might have limited internal validity such as confounding, bias, or imprecision in the design, methods, measurement, or analysis c. Efforts made to minimize and adjust for limitations
17. Conclusions	a. Usefulness of the work b. Sustainability c. Potential for spread to other contexts d. Implications for practice and for further study in the field e. Suggested next steps
Other information	
18. Funding	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.

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Mixed Methods Study of an Ear Health Intervention for Rural Community Pharmacy: feasibility, accessibility and acceptability of LISTEN UP

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Mixed Methods Study of an Ear Health Intervention for Rural Community Pharmacy: feasibility, accessibility and acceptability of LISTEN UP

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LISTEN UP: An Ear Health Intervention for Rural Community Pharmacy

ABSTRACT

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. An ear health service model involving pharmacists in rural community pharmacy was trialed.

Objective: To evaluate the feasibility, accessibility and acceptability of a pharmacist-led intervention for ear disease in consumers presenting to community pharmacy.

Design: Mixed methods study of a prospective pre-post intervention.

Setting: Two rural community pharmacies across Queensland, Australia.

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

Intervention: Trained pharmacists conducted ear examinations using otoscopy and tympanometry on consumers following a protocol. They made recommendations including no treatment, pharmacy only products, or GP referral. Consumers were contacted seven days later for follow-up.

Results: Fifty-five 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. Ninety percent (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 trial other remunerated pharmacy tasks took priority over providing LISTEN UP.

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

Strengths and Limitations of the Study

- This study is the first in Australia to present a structured ear care intervention for rural community pharmacy.
- This study provides valuable data pertaining to expanded practice broadly and considerations for expanded services in the rural and remote context.
- The study, although included only two community pharmacies, does provide evidence of the success of an expanded scope of practice that could be applied to rural and remote settings both within Australia and internationally. The small sample size represents a quarter of the expected sample and is considered a limitation of this study. However the reported data provides new knowledge to an area of unmet need in rural health.

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.(1-3) Disadvantage resulting from hearing loss is well recognised with poorer employment opportunities and higher incarceration rates.(2) The impact of ear disease for young people is profound and includes poorer educational outcomes, social and behavioral outcomes and a disrupted connection land, culture and community.(2)

The World Health Organisation (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.(1) 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.(1) 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.(1) 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 heath, especially in rural and remote communities .(2)

In Australia, one in six people experience some form of hearing impairment with an expected increase as the population ages.(4) 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.(2) 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.(2)

Pharmacists play an essential healthcare role in both clinical and community settings.(5) 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.(5) In many cases, the pharmacist is the only permanent health professional in a rural community. (5) 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.(5) In rural and remote Australia, community pharmacists provide a highly skilled workforce with accessibility extended afterhours and weekends, with potential to provide services to address the ear disease in these vulnerable communities.(2, 5)

Despite rural community pharmacists' knowledge and embedded role in community, pharmacy ear care service provisions are limited without any structured service model. A scoping review of pharmacists' involvement in ear health care 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.(6) Pharmacists in Australia did not provide ear services, instead they reported audiometry services offering hearing screening through the pharmacy.(6)

Internationally, rural pharmacists are expanding their scope of practice and providing innovative services to meet the needs of communities for improved health outcomes.(7) 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.(7) 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.(8-12) In response to this, a community pharmacy-based ear health service model was developed and trialled in two rural pharmacies in Australia.(13) The aim of this study is to determine the feasibility, accessibility and acceptability of the service model.(13)

METHODS

The PRECEDE-PROCEED model was used to provide a framework to develop the research protocol for this study, LISTEN UP (**L**ocally **I**ntegrated **S**creening and **T**esting **E**ar a**N**d a**U**ral **P**rogram). LISTEN UP is a community pharmacy-based intervention to improve the management of ear health in rural community in Australia.(13, 14) 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 practioners (GPs) and ear nose and throat (ENT) specialists) and relevant authorities.(14) The PROCEED segment incorporated the evaluation of a six week service pilot and informed planned implementation, process, impact and outcome evaluation of the service.(14) The SQUIRE guidelines have provided a framework to report the new knowledge from this study.(15)

Study Design

The prospective pre- and post-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.

The intervention was then piloted for six weeks at each pharmacy (14) before the six month study was conducted from February – July 2021.

Ethics approval

This project has been approved by the Human Research Ethics Committee, James Cook University. (Reference number: H8187)

Setting and Recruitment

Pharmacies who had participated in previous research on rural expanded pharmacy practice were invited to express an interest to participate in the LISTEN UP study.(8, 10, 12) 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. General practitioner (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 Modified Monash Model classification system categories 4-7.(13, 16)

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 Benchmarque Group.(15) 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 TYMPTY001 - 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 six months of age.

Data Collection

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

Table 1: Data collection sources and methods.

	Consumer	Pharmacist	General Practitioners
Pre-Intervention		Semi-structured Interview [FAS]	Semi-structured Interview [FAS]
During Intervention	Consumer Satisfaction Survey [AS]	Service Summary Document [F]	
Post-Intervention	Semi-structured Interview (7-day follow up) [FAS]	Semi-structured Interview [FAS]	Semi-structured Interview [FAS]

[Legend: F Feasibility data source; S Accessibility data source; A Acceptability data source]

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 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.(13)

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 COVID19 risk consumer (e.g. travelled in a COVID19 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' (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 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 seven days (Interview Guide - 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 trial period. The MedRx video otoscope and Amplivox Otowave 102 tympanometer were used in this study.

Outcome and data analysis

Demographic information, clinical characteristics (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.(17) This style of thematic analysis incorporated both the data-driven inductive approach and the deductive priori template of codes approach.(17) 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).(18, 19) NVivo 12 software was used for all of the qualitative analysis.(20)

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.(21) 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 eight weeks prior to the intervention period. During this time twenty-three ear complaints were recorded as presenting to the pharmacy (child (8), adult (15)). These complaints were ear pain (35%) and ear wax (35%), swimmers 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 trial (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 trial). The planned sample size for this study was calculated to be 203 consumer participants.(13) The sample size was calculated using the formula $n = Z^2P\ (1\text{-}P)/d^2$, where n=sample size, Z is the critical value of the normal distribution at $\alpha/2$ for a confidence level of 95% where α is 0.05 and the critical value is 1.96, P = expected prevalence or proportion = 0.14 (14%) and d = precision = 0.05 (5%). (13) The trial was concluded at six 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 negative the influence of a small sample size from a quantitative perspective.

Duration of the ear complaint ranged from 1 – 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 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 (1), consumer unwilling to be examined (4), ruptured ear drum (1), ear canal too large (1), unknown (3).

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

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%)		

OTC (over the counter). Other clinical impressions: ruptured ear drum (3), poor compliance of tympanic membrane (1), sinus congestion (1). Some participants received more than one recommendation.

Pharmacists recommended over-the-counter (OTC) products to two-thirds (36/55) of the participants. OTC products recommended included wax removal drops (19), analgesia (11), drying agent ear drops (1), decongestant nasal spray (3), oral decongestants and antihistamines (3). 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 (3) and watch and wait (4).

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 (3), referral to an ear, nose and throat specialist (11), referral to speech therapy (4), referral to audiometry (24) or other (9).

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

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"		

NOTE: Available survey answers range 5 point likert (strongly disagree – strongly agree)

Consumer Post-Intervention 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 (1), leaving town directly (1), or attending scheduled hospital appointment instead (1).

Data from these interviews were analysed using quantitative content analysis. Every participant described their experience at the pharmacy with a positive term (e.g. marvelous, 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 (e.g. 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 AUD$1-20 (33%), $21-50 (33%). The average value that participants were willing to pay was AUD$33 with values of AUD$100, $150 and $200 also suggested.

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 (e.g. 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.*

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 kilometers.

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 minutes with an average of 25 minutes.

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 trial was undertaken, consumer *acceptability* was expected by both participant groups.

Pharmacists described difficulty with accessing health professionals, wait lists in excess of two weeks for GP's and allied health professions as well as a lack of permanent health care 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 trial, 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 trial pharmacists continued to report a positive ***pharmacist behaviour shift*** towards expanded pharmacy broadly. Pharmacists described the trial 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 trial.

> *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 trial, 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 emergency department (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 trial 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 trial 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 trial 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 ten 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 trial 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 trial, workflow demands however were identified as a barrier to both the trial 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 trial. 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 trial 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 trial 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 trial. 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 trial and happy to be involved. After the trial 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 trial 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 trial 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 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.(1) 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.(2) This study has found that consumers having difficulty accessing GP appointments consequently present to emergency departments for ear complaints. In addition, pharmacists prior to the intervention reported regularly referring consumers to emergency departments, due to an inability to access timely GP appointments. In a study of GP-type presentations to emergency departments undertaken at one of the ear trial sites, it was found that half of all presentations over a six month period were GP-appropriate problems.(22)

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 emergency departments to appropriate settings.

Pharmacist Level

The provision of expanded services is an emerging area for Australian pharmacists.(23) To date no formal protocols have been developed to support pharmacists to provide expanded services, despite major developments for pharmacists' scope of practice internationally.(7) 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.(10, 12) 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 emergency departments. 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.(24) 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.(24)

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.(25) 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 trial. This smaller sample size also reduces the transferability and generalisability of the findings of this trial and reinforces the importance of a larger remunerated trial 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.(26)

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 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.(8)

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 health care 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 trial with multiple sites is needed to further consider this model of care, including sustainabilility, 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 emergency departments. 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 modeled 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.

Figure 1: Process diagram of LISTEN UP study.

Figure 2: Thematic map illustrating the themes and codes for qualitative analysis of GP and Pharmacist Interviews.

DECLARATIONS

Ethics approval and consent to participate

This project has been approved by the Human Research Ethics Committee, James Cook University. (Reference number: H8187) Informed consent obtained from study participants is in written form.

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.

Competing interests

The authors declare that they have no competing interests.

Funding

This study is funded by the Department of Health through the Centre for Rural and Remote Health. The study has been reviewed by the Centre for Rural and Remote Health and an advisory panel consisting of key stakeholder organisations including Pharmaceutical Society of Australia, Pharmacy Guild of Australia, Gidgee Healing (Aboriginal Medical Service), and Australian Primary Health Network.

Authors' contributions

ST, AC, and BG contributed to the design of the study. ST conducted the data management with secondary assistance from BG. ST prepared the first draft of the manuscript, which was reviewed and edited by AC and BG. All authors read and approved the final manuscript.

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ENDNOTE AUTOMATED REFERENCE (Please disregard)

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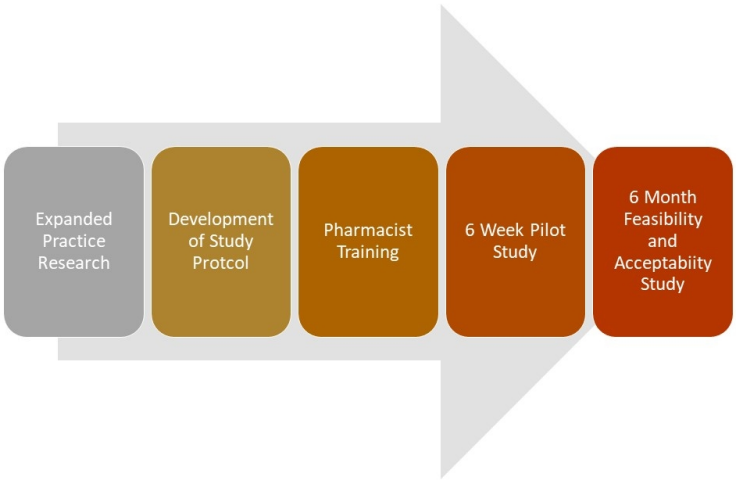


Figure 1: Process diagram of LISTEN UP study.

338x190mm (96 x 96 DPI)

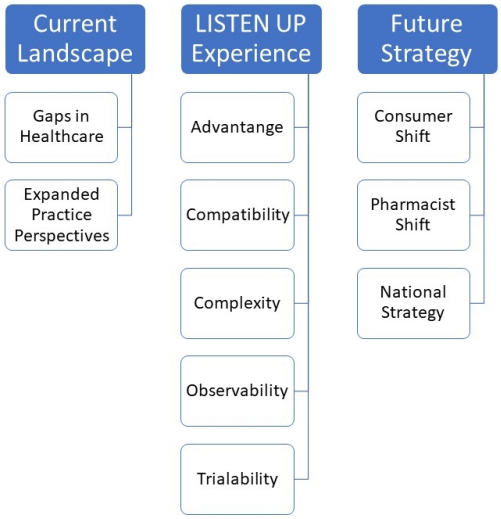
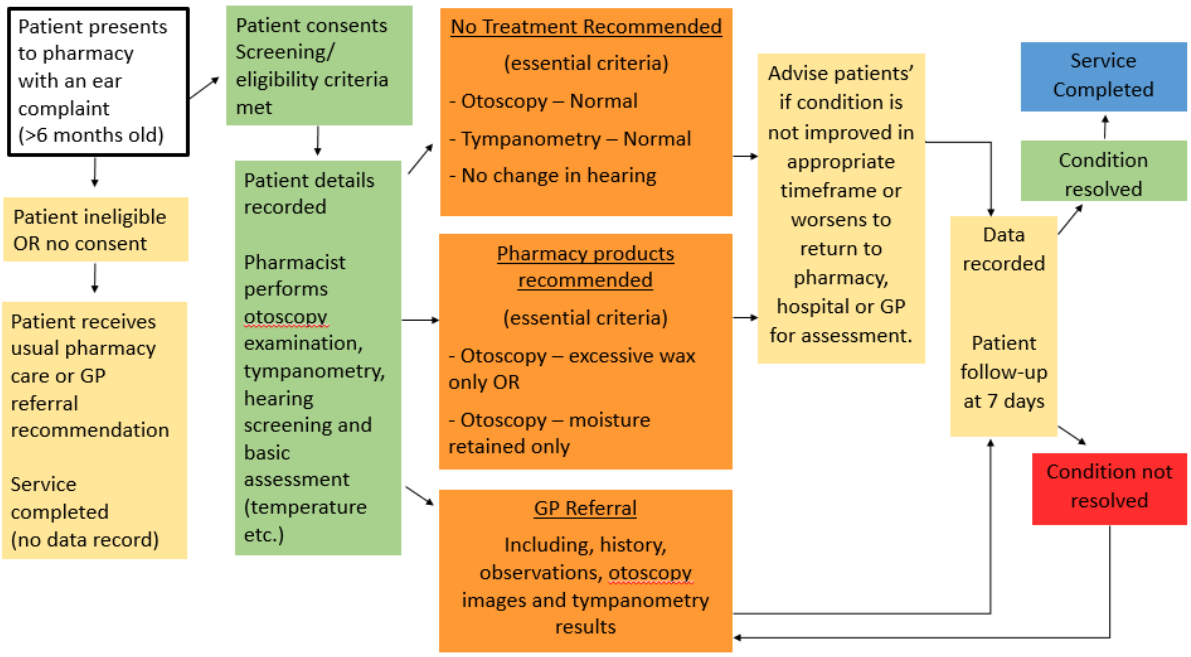


Figure 2: Thematic map illustrating the themes and codes for qualitative analysis of GP and Pharmacist Interviews.

338x190mm (96 x 96 DPI)



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))

Clinical characteristics Table (N=55)

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

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	☐ Normal ☐ Abnormal	Tympanometry	☐Normal ☐ Abnormal
	Temperature:			
Brief Notes:				

Attach images and results

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

Time completed: _____

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? ❑ Male ❑ Female ❑Other, please specify _____	3) What is your home postcode? _____	4) Ethnicity ❑ Caucasian ❑ ATSI ❑Other, please specify _____

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?

Standards for Reporting Qualitative Research (SRQR)*

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

	Page/line no(s).
Title and abstract	
Title - 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
Abstract - 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	
Problem formulation - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement	76-126
Purpose or research question - Purpose of the study and specific objectives or questions	36
Methods	
Qualitative approach and research paradigm - 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
Researcher characteristics and reflexivity - 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
Context - Setting/site and salient contextual factors; rationale**	156-165
Sampling strategy - 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
Ethical issues pertaining to human subjects - 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
Data collection methods - 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

Data collection instruments and technologies - 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
Units of study - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	245-254
Data processing - 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
Data analysis - 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
Techniques to enhance trustworthiness - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	227-232

Results/findings

Synthesis and interpretation - 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
Links to empirical data - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	286-483

Discussion

Integration with prior work, implications, transferability, and contribution(s) to the field - 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
Limitations - Trustworthiness and limitations of findings	61-71

Other

Conflicts of interest - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	584-585
Funding - 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

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

Text Section and Item Name	Section or Item Description
Notes to authors	• The SQUIRE guidelines provide a framework for reporting new knowledge about how to improve healthcare • The SQUIRE guidelines are intended for reports that describe system level work to improve the quality, safety, and value of healthcare, and used methods to establish that observed outcomes were due to the intervention(s). • A range of approaches exists for improving healthcare. SQUIRE may be adapted for reporting any of these. • Authors should consider every SQUIRE item, but it may be inappropriate or unnecessary to include every SQUIRE element in a particular manuscript. • The SQUIRE Glossary contains definitions of many of the key words in SQUIRE. • The Explanation and Elaboration document provides specific examples of well-written SQUIRE items, and an in-depth explanation of each item. • Please cite SQUIRE when it is used to write a manuscript.
Title and Abstract	
1. Title Page 2	Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patient-centeredness, timeliness, cost, efficiency, and equity of healthcare) P
2. Abstract Page 2	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 problem, methods, interventions, results, conclusions
Introduction	*Why did you start?*
3. Problem Description	Nature and significance of the local problem Page 4
4. Available knowledge	Summary of what is currently known about the problem, including relevant previous studies Page 4

5. Rationale	Informal or formal frameworks, models, concepts, and/or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s), and reasons why the intervention(s) was expected to work Page 4
6. Specific aims	Purpose of the project and of this report Page 5
Methods	*What did you do?*
7. Context	Contextual elements considered important at the outset of introducing the intervention(s) Page 5
8. Intervention(s)	a. Description of the intervention(s) in sufficient detail that others could reproduce it Page 6 and 7 b. Specifics of the team involved in the work
9. Study of the Intervention(s)	a. Approach chosen for assessing the impact of the intervention(s) b. Approach used to establish whether the observed outcomes were due to the intervention(s) Page 7
10. Measures	a. Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their operational definitions, and their validity and reliability Page 6 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. Analysis	a. Qualitative and quantitative methods used to draw inferences from the data b. Methods for understanding variation within the data, including the effects of time as a variable Page 7
12. Ethical Considerations	Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest Page 5
Results	*What did you find?*
13. Results	a. Initial steps of the intervention(s) and their evolution over time (*e.g.*, time-line diagram, flow chart, or table), including modifications made to the intervention during the project Page 7-14 b. Details of the process measures and outcome c. Contextual elements that interacted with the intervention(s) d. Observed associations between outcomes, interventions, and relevant contextual elements e. Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the intervention(s). f. Details about missing data
Discussion	*What does it mean?*
14. Summary	a. Key findings, including relevance to the rationale and specific aims b. Particular strengths of the project Page 2 and 16

15. Interpretation	a. Nature of the association between the intervention(s) and the outcomes b. Comparison of results with findings from other publications c. Impact of the project on people and systems d. Reasons for any differences between observed and anticipated outcomes, including the influence of context e. Costs and strategic trade-offs, including opportunity costs
16. Limitations	a. Limits to the generalizability of the work b. Factors that might have limited internal validity such as confounding, bias, or imprecision in the design, methods, measurement, or analysis c. Efforts made to minimize and adjust for limitations
17. Conclusions	a. Usefulness of the work b. Sustainability c. Potential for spread to other contexts d. Implications for practice and for further study in the field e. Suggested next steps
Other information	
18. Funding	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.

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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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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 pre- and post-intervention 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 six months or older, who present with an ear complaint to a participating community pharmacy.

Intervention: LISTEN UP (**L**ocally **I**ntegrated **S**creening and **T**esting **E**ar a**N**d a**U**ral **P**rogram) 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 GP referral. Consumers were contacted seven 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.

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.

Study registration: ACTRN12620001297910.

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.

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.(1-3) Disadvantage resulting from hearing loss is well recognised

with poorer employment opportunities and higher incarceration rates.(2) The impact of ear disease for young people is profound and includes poorer educational outcomes, social and behavioral outcomes and a disrupted connection land, culture and community.(2)

The World Health Organization (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.(1) 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.(1) 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.(1) 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 heath, especially in rural and remote communities .(2)

In Australia, one in six people experience some form of hearing impairment with an expected increase as the population ages.(4) 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.(2) 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.(2)

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.(5) Social disadvantage, poverty, high rates of chronic disease and tobacco use are prevalent for Indigenous people and known to contribute to poor health outcomes.(6) 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.(6)

Pharmacists play an essential healthcare role in both clinical and community settings.(7) 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.(7) In many cases, the pharmacist is the only permanent health professional in a rural community. (7) 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.(7) In rural and remote Australia, community pharmacists provide a highly skilled workforce with accessibility extended afterhours and weekends, with potential to provide services to address the ear disease in these vulnerable communities.(2, 7)

Despite rural community pharmacists' knowledge and embedded role in community, pharmacy ear care service provisions are limited without any structured service model. A scoping review of pharmacists' involvement in ear health care 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.(8) Pharmacists in Australia did not provide ear services, instead they reported audiometry services offering hearing screening through the pharmacy.(8)

Internationally, rural pharmacists are expanding their scope of practice and providing innovative services to meet the needs of communities for improved health outcomes.(9) 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.(9) 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.(10-14) In response to this, a community pharmacy-based ear health service model was developed and trialled in two rural pharmacies in Australia.(15) The aim of this study is to determine the feasibility, accessibility and acceptability of the service model.(15)

METHODS

The PRECEDE-PROCEED model was used to provide a framework to develop the research protocol for this study, LISTEN UP (**L**ocally **I**ntegrated **S**creening and **T**esting **E**ar a**N**d a**U**ral **P**rogram). LISTEN UP is a community pharmacy-based intervention to improve the management of ear health in rural community in Australia.(15, 16) 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 practioners (GPs) and ear nose and throat (ENT) specialists) and relevant authorities.(16) The PROCEED segment incorporated the evaluation of a six week service pilot and informed planned implementation, process, impact and outcome evaluation of the service.(16) The SQUIRE guidelines have provided a framework to report the new knowledge from this study.(17)

Study design

The prospective pre- and post-intervention 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.

The intervention was then piloted for six weeks at each pharmacy (16) before the six month study was conducted from February – July 2021.

Ethics approval

This project has been approved by the Human Research Ethics Committee, James Cook University (reference number: H8187).

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.(10, 12, 14) 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. General practitioner (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 Modified Monash Model classification system categories 4-7.(15, 18)

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 Benchmarque Group.(15) 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 TYMPTY001 - 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 six months of age.

Data collection

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

Table 1: Data collection sources and methods.

	Consumer	Pharmacist	General Practitioners
Pre-Intervention		Semi-structured Interview [FAS]	Semi-structured Interview [FAS]
During Intervention	Consumer Satisfaction Survey [AS]	Service Summary Document [F]	
Post-Intervention	Semi-structured Interview (7-day follow up) [FAS]	Semi-structured Interview [FAS]	Semi-structured Interview [FAS]

[Legend: F Feasibility data source; S Accessibility data source; A Acceptability data source]

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 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.(15)

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 COVID19 risk consumer (e.g. travelled in a COVID19 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' (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 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 seven days (Interview Guide - 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 (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.(19) This style of thematic analysis incorporated both the data-driven inductive approach and the deductive priori template of codes approach.(19) 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).(20, 21) NVivo 12 software was used for all of the qualitative analysis.(22)

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.(23) 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 eight weeks prior to the intervention period. During this time 23 ear complaints were recorded as presenting to the pharmacy (child (8), adult (15)). 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.

55 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.(13) The sample size was calculated using the formula $n = Z^2P(1-P)/d^2$, where n=sample size, Z is the critical value of the normal distribution at $\alpha/2$ for a confidence level of 95% where α is 0.05 and the critical value is 1.96, P = expected prevalence or proportion = 0.14 (14%) and d = precision = 0.05 (5%). (13) The study was concluded at six 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 – 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 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 (1), consumer unwilling to be examined (4), ruptured ear drum (1), ear canal too large (1), unknown (3).

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

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%)		

OTC (over the counter). Other clinical impressions: ruptured ear drum (3), poor compliance of tympanic membrane (1), sinus congestion (1). Some participants received more than one recommendation.

Pharmacists recommended over-the-counter (OTC) products to two-thirds (36/55) of the participants. OTC products recommended included wax removal drops (19), analgesia (11), drying agent ear drops (1), decongestant nasal spray (3), oral decongestants and antihistamines (3). 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 (3) and watch and wait (4).

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 (3), referral to an ear, nose and throat specialist (11), referral to speech therapy (4), referral to audiometry (24) or other (9).

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

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"		

NOTE: Available survey answers range 5 point likert (strongly disagree – strongly agree)

Consumer Post-Intervention 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 (1), leaving town directly (1), or attending scheduled hospital appointment instead (1).

Data from these interviews were analysed using quantitative content analysis. Every participant described their experience at the pharmacy with a positive term (e.g. marvelous, 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 (e.g. 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 AUD$1-20 (33%), $21-50 (33%). The average value that participants were willing to pay was AUD$33 with values of AUD$100, $150 and $200 also suggested.

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 (e.g. 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.*

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 kilometers.

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 minutes with an average of 25 minutes.

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 two weeks for GP's and allied health professions as well as a lack of permanent health care 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 emergency department (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 ten 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 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.(1) 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.(2) This study has found that consumers having difficulty accessing GP appointments consequently present to emergency departments for ear complaints. In addition, pharmacists prior to the intervention reported regularly referring consumers to emergency departments, due to an inability to access timely GP appointments. In a study of GP-type presentations to emergency departments undertaken at one of the ear study sites, it was found that half of all presentations over a six month period were GP-appropriate problems.(24)

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 emergency departments to appropriate settings.

Pharmacist level

The provision of expanded services is an emerging area for Australian pharmacists.(25) To date no formal protocols have been developed to support pharmacists to provide expanded services, despite major developments for pharmacists' scope of practice internationally.(9) 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.(12, 14) 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 emergency departments. 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.(26) 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.(26)

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.(27) 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.(26)

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 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.(10)

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 health care 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 sustainabilility, 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 emergency departments. 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 modeled 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.

DECLARATIONS

Ethics approval and consent to participate

This project has been approved by the Human Research Ethics Committee, James Cook University (reference number: H8187). Written informed consent was obtained from the study participants.

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.

Competing interests

The authors declare that they have no competing interests.

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Contributors

ST, AC, and BG were involved in the conceptulisation and development of the study. ST and BG conducted the analysis. ST drafted the initial manuscript. AC and BG supervised the research, edited and reviewed the final manuscript.

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Figure 1: Process diagram of LISTEN UP study

Figure 2: Thematic map illustrating the themes and codes for qualitative analysis of GP and pharmacist Interviews

ENDNOTE AUTOMATED REFERENCE (Please disregard)

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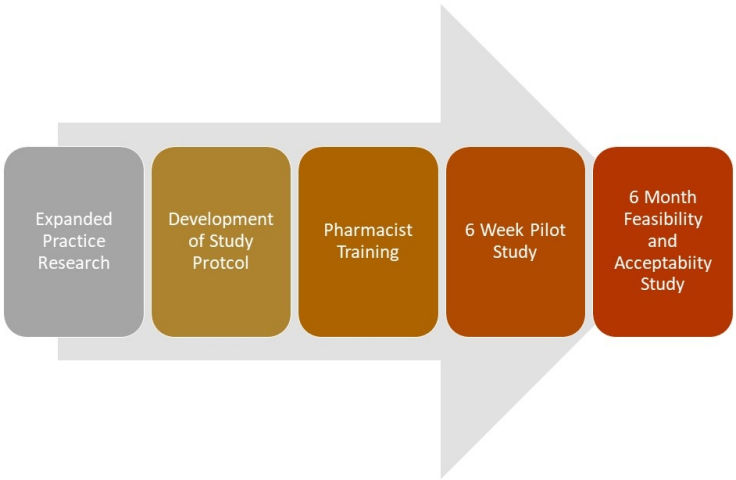


Figure 1: Process diagram of LISTEN UP study.

338x190mm (96 x 96 DPI)

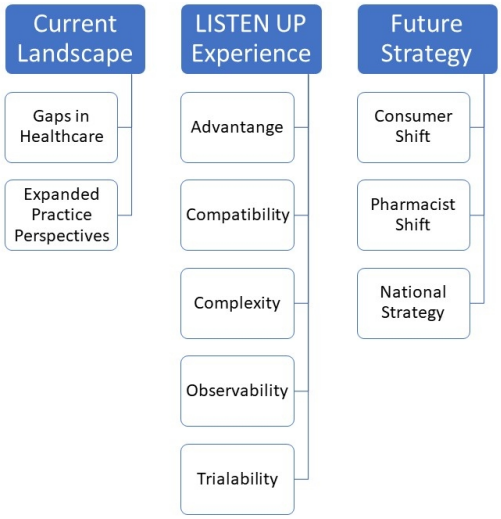


Figure 2: Thematic map illustrating the themes and codes for qualitative analysis of GP and Pharmacist Interviews.

338x190mm (96 x 96 DPI)

Standards for Reporting Qualitative Research (SRQR)*

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

	Page/line no(s).
Title and abstract	
Title - 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
Abstract - 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	
Problem formulation - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement	76-126
Purpose or research question - Purpose of the study and specific objectives or questions	36
Methods	
Qualitative approach and research paradigm - 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
Researcher characteristics and reflexivity - 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
Context - Setting/site and salient contextual factors; rationale**	156-165
Sampling strategy - 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
Ethical issues pertaining to human subjects - 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
Data collection methods - 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

Data collection instruments and technologies - 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
Units of study - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	245-254
Data processing - 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
Data analysis - 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
Techniques to enhance trustworthiness - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	227-232

Results/findings

Synthesis and interpretation - 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
Links to empirical data - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	286-483

Discussion

Integration with prior work, implications, transferability, and contribution(s) to the field - 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
Limitations - Trustworthiness and limitations of findings	61-71

Other

Conflicts of interest - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	584-585
Funding - 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? ❑ Male ❑ Female ❑Other, please specify _____	3) What is your home postcode? _____	4) Ethnicity ❑ Caucasian ❑ ATSI ❑Other, please specify _____

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	☐ Normal ☐ Abnormal	Tympanometry	☐Normal ☐ Abnormal
	Temperature:			
Brief Notes:				

Attach images and results

Pharmacists clinical impression: Eg. Otitis externa, wax impaction	
Recommendations Made	
Pharmacist Recommendations	☐ No treatment ☐ Pharmacy-based treatment (please specify:_____) ☐ Referral with appointment made to GP ☐ Other (please specify:_____)
Expanded Practice Recommendations [RESEARCH PURPOSES ONLY]	
☐ Prescription-only medicine (please specify exact drug/strength/dose: _____) ☐ Immediate emergency department referral ☐ Specialist ENT Referral ☐ Speech Therapy Referral ☐ Audiometry Hearing Test Referral ☐ 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
Notes to authors	• The SQUIRE guidelines provide a framework for reporting new knowledge about how to improve healthcare • The SQUIRE guidelines are intended for reports that describe system level work to improve the quality, safety, and value of healthcare, and used methods to establish that observed outcomes were due to the intervention(s). • A range of approaches exists for improving healthcare. SQUIRE may be adapted for reporting any of these. • Authors should consider every SQUIRE item, but it may be inappropriate or unnecessary to include every SQUIRE element in a particular manuscript. • The SQUIRE Glossary contains definitions of many of the key words in SQUIRE. • The Explanation and Elaboration document provides specific examples of well-written SQUIRE items, and an in-depth explanation of each item. • Please cite SQUIRE when it is used to write a manuscript.
Title and Abstract	
1. Title	Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patient-centeredness, timeliness, cost, efficiency, and equity of healthcare)
2. Abstract	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 problem, methods, interventions, results, conclusions
Introduction	*Why did you start?*
3. Problem Description	Nature and significance of the local problem
4. Available knowledge	Summary of what is currently known about the problem, including relevant previous studies

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

15. Interpretation	a. Nature of the association between the intervention(s) and the outcomes b. Comparison of results with findings from other publications c. Impact of the project on people and systems d. Reasons for any differences between observed and anticipated outcomes, including the influence of context e. Costs and strategic trade-offs, including opportunity costs
16. Limitations	a. Limits to the generalizability of the work b. Factors that might have limited internal validity such as confounding, bias, or imprecision in the design, methods, measurement, or analysis c. Efforts made to minimize and adjust for limitations
17. Conclusions	a. Usefulness of the work b. Sustainability c. Potential for spread to other contexts d. Implications for practice and for further study in the field e. Suggested next steps
Other information	
18. Funding	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

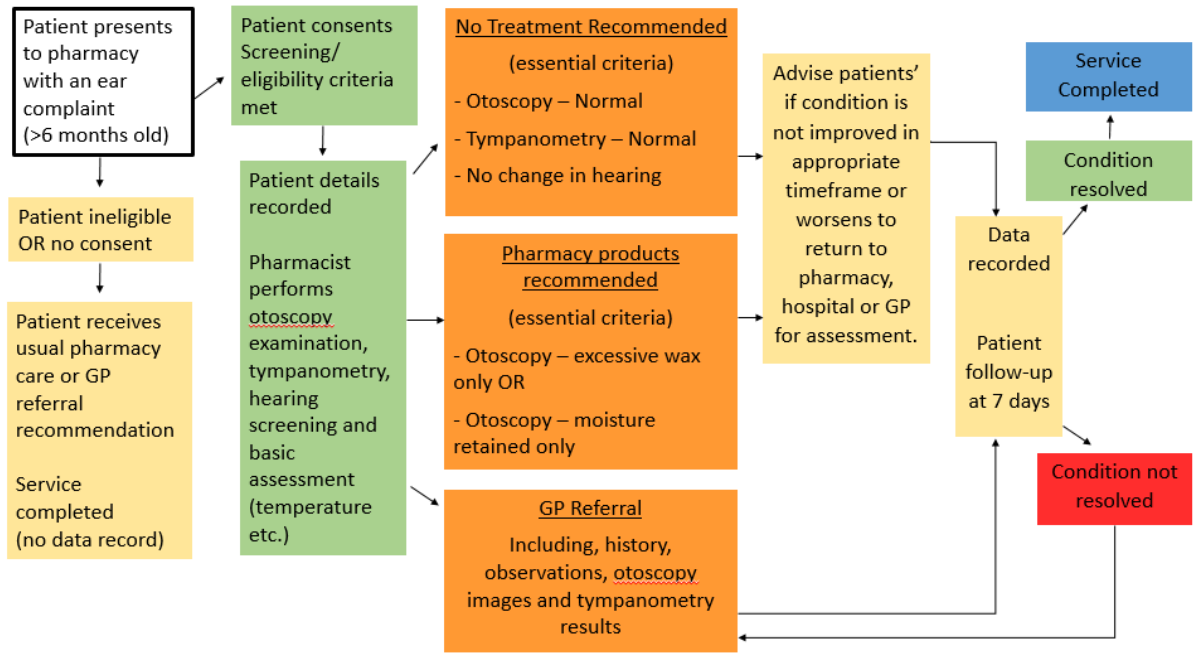
Rationale
Explanation of why particular intervention(s) were chosen and why it was expected to work, be sustainable, and be replicable elsewhere.

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