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## LISTEN UP: An Ear Health Intervention for Rural Community Pharmacy

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## LISTEN UP: An Ear Health Intervention for Rural Community Pharmacy

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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:** 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.

For peer review only

## 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 health, 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

1  
2  
3 these expanded services, despite some reservation from the medical profession.(8-12) In response  
4 to this, a community pharmacy-based ear health service model was developed and trialled in two  
5 rural pharmacies in Australia.(13) The aim of this study is to determine the feasibility, accessibility  
6 and acceptability of the service model.(13)  
7

## 8 9 **METHODS**

10 The PRECEDE-PROCEED model was used to provide a framework to develop the research protocol  
11 for this study, LISTEN UP (Locally Integrated Screening and Testing Ear aNd aUral Program). LISTEN  
12 UP is a community pharmacy-based intervention to improve the management of ear health in rural  
13 community in Australia.(13, 14) The PRECEDE component included an assessment of the  
14 predisposing, reinforcing and enabling constructs to support practice change through a scoping  
15 review; stakeholder surveys and interviews; and consultation with professional authorities.(14) The  
16 PROCEED segment incorporated the evaluation of a six week service pilot and informed planned  
17 implementation, process, impact and outcome evaluation of the service.(14) The SQUIRE guidelines  
18 have provided a framework to report the new knowledge from this study.(15)  
19  
20  
21

### 22 **Study Design**

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

24  
25 Prior to the study commencing, the two participating pharmacies collected usual care data as a  
26 comparator for 8 weeks beginning November 2020. During this time twenty-three ear complaints  
27 were recorded as presenting to the pharmacy (child (8), adult (15)). These complaints were ear pain  
28 (35%) and ear wax (35%), swimmers ear (17%), hearing loss (4%) and other (discharge, fever,  
29 insomnia, blocked ear, vertigo) (4%).  
30  
31

32 The intervention was then piloted for six weeks at each pharmacy (14) before the six month study  
33 was conducted from February – July 2021.  
34  
35  
36

### 37 **Ethics approval**

38 This project has been approved by the Human Research Ethics Committee, James Cook University.  
39 (Reference number: H8187)  
40  
41

### 42 **Patient and Public Involvement**

43 This study was developed to address a gap in healthcare delivery for rural consumers. Patients  
44 (consumers) were recruited into the study as participants, however were not involved in the design  
45 or development of the study.  
46  
47  
48  
49  
50

### 51 **Setting and Recruitment**

52 Pharmacies who had participated in previous research on rural expanded pharmacy practice were  
53 invited to express an interest to participate in the LISTEN UP study.(8, 10, 12) Two community  
54 pharmacies (Modified Monash Model (MMM) category 6 – remote community, population 18,000  
55 and MMM category 4 – medium rural town, population 6000) expressed interest and were enrolled  
56 in the study. General practitioner (GP) practices at the intervention sites were invited to participate  
57 and one practice at each of the sites volunteered. An invitation to participate with an information  
58 sheet and informed consent form was provided to each pharmacist at the participating pharmacies  
59  
60



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 Benchmark 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.<sup>(17)</sup> This style of thematic analysis incorporated both the data-driven inductive approach and the deductive priori template of codes approach.<sup>(17)</sup> Diffusion of innovation theory and categories adapted from 'Qualitative data analysis for applied policy research' were combined to form a thematic map which provided a framework for the analysis (Figure 2).<sup>(18, 19)</sup> NVivo 12 software was used for all of the qualitative analysis.<sup>(20)</sup>

Transcriptions were read multiple times and an initial coding tree was created from the first four transcripts. Thematic analysis continued and codes which were conceptually similar were categorised into emerging themes, using an ethnographic technique of domain analysis.<sup>(21)</sup> Objectivity, assumed knowledge and bias were reduced by involvement of a second member of the research team who also analysed the first five interviews and any discrepancies were resolved. A member checking process was conducted with three participants to support validity of the data.

### 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>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.</i>  <i>Was really helpful in explaining what the issue was and what she was treating me with that day.</i>
Confidence	Trust, comfortability and confidence of the pharmacists' skills and knowledge to provide the service.	41	<i>They were trained very well...very knowledgeable.</i>  <i>What the doctor does is less, the pharmacist was more thorough.</i>
Availability of local GP appointments	Difficulty in being able to make a GP appointment in an appropriate timeframe.	32	<i>When I need to book to see a GP it takes two weeks.</i>  <i>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.</i>
Willingness to pay	Explanations of participants' willingness to pay or not pay for the service.	30	<i>I would pay because it was so quick, easy and inclusive.</i>  <i>I don't pay for the doctors so I wouldn't pay for the pharmacist.</i>  <i>You have to pay at the doctors so I don't see a difference.</i>

1 2 3 4 5 6 7 8	Reassurance	A feeling of reassurance about the ear complaint.	29	<i>I felt more comfortable about why I was having pain and treatment.</i>  <i>Put my mind at ease so I didn't need to go to the doctor.</i>
9 10 11 12 13 14 15	Pharmacy convenience and accessibility	Positive associations with pharmacy accessibility and immediate service provision.	29	<i>It was convenient, you didn't have to book an appointment.</i>  <i>Going to the pharmacy was easier because if I need something for my ears you have it there already.</i>
16 17 18 19 20 21 22 23 24 25 26 27	Expanded scope for pharmacists	Support for pharmacists to provide other expanded services or an extension of this service (e.g. prescribing and syringing)	9	<i>If the pharmacists can see it's infected, they should be able to give me the drops (antibiotics).</i>  <i>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.</i>

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)*

1  
2  
3 The pharmacists reported an **advantage** they expected of LISTEN UP was to increase rapport building  
4 with GPs through the direct referral process. GPs though, reported concerns about pharmacists taking  
5 work from junior doctors but recognised that in rural Australia the lack of health providers broadly  
6 means there is enough work for all.  
7

8  
9 *Providing services in rural communities across the board is very difficult, and anyone*  
10 *who can bring services where they aren't already should be encouraged. (GP6 – General*  
11 *Practitioner)*  
12

13 After the trial, GPs described the service and direct referral pathway as **compatible** with their current  
14 practice. They reported that all of the referrals they received were appropriate. GPs' perceived LISTEN  
15 UP to be an advantageous method of screening individuals who present to community pharmacy and  
16 setting them on a trajectory for GP care. They also expected young children to be more comfortable  
17 in the pharmacy setting.  
18

19  
20 *The foot traffic at a pharmacy is quite a lot on a daily basis. So the pharmacists are seeing*  
21 *people coming from different practices and bringing their prescriptions and whatever else*  
22 *they buy there. So having a good coverage of the community is an entry point for them to*  
23 *have that ear looked at. (GP2- General Practitioner)*  
24

25 The pharmacists felt the structured approach and protocol supported the delivery and  
26 professionalism of the service.  
27

28  
29 *We don't have existing ear care services, so this model has all the advantages because*  
30 *it's actually a model and actually a service. (P2 – Pharmacist)*  
31

32 GPs however, described a level of increased anxiety in consumers who had been referred and  
33 suspected this may be due to the language used by pharmacists when referring consumers.  
34

35 Pharmacists identified enabling factors (*feasibility*) to the implementation of an ear health expanded  
36 practice model. These included the *willingness of pharmacists to develop **expanded practice models***  
37 *and their professional skills.*  
38

39  
40 *We're familiar with the upskilling required, and we're enthusiastic about doing more*  
41 *application of health services, rather than hiding behind the dispensary. I think that the*  
42 *pharmacists coming through now are craving that and wanting that. (P1 – Pharmacist)*  
43

44 There was an expectation that this expanded service may be a springboard for further service  
45 development and for both consumers and health professionals to be more accepting of an expanded  
46 scope for pharmacists.  
47

48  
49 *I am expecting advancement in our placement in the minds of the community that we*  
50 *service, of what we can actually achieve and what we can do as a pharmacist for them. (P1 –*  
51 *Pharmacist)*  
52

53  
54 *I hope it will bring about some results that will elicit a meaningful change in terms of*  
55 *broadening our scope of practice. (P5 –Pharmacist)*  
56

57 Pharmacists reported the recent growth in professional service areas such as vaccinations had  
58 pharmacists feeling well placed to provide other expanded services for their communities. This was  
59 also identified as an enabler as some of the challenges of role conflict with GP's has already been  
60 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*

1  
2  
3 *that it's a known kind of service, it's great, but at first, it was like we were taking from*  
4 *their role. (P8 – Pharmacist)*  
5

6 After the trial pharmacists continued to report a positive **pharmacist behaviour shift** towards  
7 expanded pharmacy broadly. Pharmacists described the trial solidifying and extending their interest  
8 in working to their full scope.  
9

10 *I really have enjoyed pushing that scope, learning something new, delving into a new*  
11 *domain. I think we need to keep doing it as pharmacists. We need to offer as much care*  
12 *as we can for people, and we need to push ourselves to do that, and not just rest on*  
13 *dispensing a script, especially if we want to be valued members of the healthcare system*  
14 *going forward. (P2 – Pharmacist)*  
15  
16

17 **Consumer behaviour shift** through increased confidence and knowledge of the potential for expanded  
18 pharmacy roles was a reported benefit of the trial.  
19

20 *People started to see us as actual health professionals that are available to the*  
21 *community, that you can actually touch and feel, that you have access to without an*  
22 *appointment (P4-Pharmacist)*  
23

24 Prior to the trial, pharmacists reported advice on ear complaints was commonly sought by  
25 consumers with up to two presentations each day. They reported an overall lack of confidence with  
26 managing ear complaints based on symptomatic description from consumers and reported referring  
27 most ear complaints to a GP or hospital emergency department (ED). Pharmacists expected an  
28 improvement in their skills and knowledge in the management of ear complaints and the ability to  
29 provide better ear care in community.  
30

31 *My conversation is always...I can't look in your ear. I can understand your symptoms,*  
32 *I'm hearing what you're saying, but it covers a lot of different things and I can't make*  
33 *that decision on what you're telling me, and I also don't have much to offer you. (P5-*  
34 *Pharmacist)*  
35  
36

37 After the trial pharmacists reported increased **observability** and increased confidence in managing  
38 ear complaints as a result of having more information (otoscopy and tympanometry results) for  
39 decision making. The imaging of the ear canal was one of the most valued aspects of the service,  
40 improving pharmacist and consumer confidence in the service. Pharmacists were able to provide  
41 reassurance to patients and explain the anatomy and pathophysiology to consumers in real time.  
42  
43

44 *It's really nice showing them what their eardrum looks like, and explaining to some why*  
45 *they don't need antibiotics. (P2 – Pharmacist)*  
46

47 *Anything that we can get more data to help us be more definitive and clear in our referral*  
48 *pathways is helpful. (P2-Pharmacist)*  
49

50 Pharmacists reported being comfortable with recommending wax dissolvent and drying agents, but  
51 identified a barrier of the service model was the restriction of not being able to prescribe antibiotics  
52 or medicines only available with a doctor's prescription. There was optimism that the trial would  
53 positively influence more products to be down-scheduled to become available for pharmacists to  
54 provide.  
55

56 *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*  
57 *more. (P4 – Pharmacist)*  
58  
59  
60

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2  
3 After the trial the pharmacists reported that the skills learnt during LISTEN UP, including the training  
4 improved their confidence in managing ear complaints from below average to 7+ out of 10.  
5

6 The training alone however was not deemed enough to improve confidence. Pharmacists discussed  
7 the **complexity** of the training provided and suggested that more face-to-face case studies were  
8 needed in addition to more content related to clearly identifying various pathology (**trialability**). Some  
9 pharmacists who had not conducted many consultations during LISTEN UP felt the training needed to  
10 include a greater volume of case examples to improve their confidence to provide the service.  
11  
12

13 *I don't have the confidence for a diagnosis at all and it's just purely from not doing enough*  
14 *and not getting feedback. (P3-Pharmacist)*  
15

16 Confidence however, improved with clinical experience and an enabler was the structured LISTEN UP  
17 protocol, supporting decision-making. Pharmacists reported needing to conduct at least ten  
18 consultations in the community pharmacy before feeling confident to provide the service  
19 independently.  
20

21 *I think I needed the first five to ten hours of practice, mainly just to get comfortable with*  
22 *actually how to talk to consumers and look inside the ear and all the techniques. But after*  
23 *that, I felt very comfortable. (P4-Pharmacist)*  
24  
25

26 The flexibility and capacity of the current pharmacy service model was seen as both an enabler and  
27 barrier to LISTEN UP. Pharmacists expected the trial to fit into the current no-appointment necessary  
28 workflow with strategies such as having additional pharmacists available to focus on professional  
29 services, advising consumers of longer wait times for prescriptions and asking consumers to come  
30 back to collect medicines.  
31

32 *I'm very confident that there's going to be no problem with that. You just need to*  
33 *change your operational flow to support more hands-on time with the clients. (P1 –*  
34 *Pharmacist)*  
35  
36

37 After the trial, workflow demands however were identified as a barrier to both the trial and  
38 expanded practice generally. It was highlighted that a number of consumers received a consultation  
39 by a pharmacist but the occasion was not documented for the trial. Time required for the  
40 documentation process and competing dispensary demands were reported as the reasons for this  
41 occurring. In addition, it was noted that as influenza vaccinations increased, the availability of the  
42 consultation room was limited and this inhibited the ability to offer LISTEN UP.  
43  
44

45 *I'd say there's double the number of people who we probably could have done, that we*  
46 *haven't done, because it wasn't the right time, we were too busy. (P8-Pharmacist)*  
47

48 The length of the consultations were also raised as a potential barrier, with concerns when only one  
49 pharmacist was on-duty and expectation that it would be difficult to be able to offer the service  
50 during those times.  
51

52 *Time is the biggest factor, we are often under the pump with the supply role so I think the*  
53 *clinical service can press you that little bit further. (P7 – Pharmacist)*  
54

55 All pharmacists reported a lack of funding as a major barrier to LISTEN UP. They were concerned  
56 about the amount of time the consultations would take, the lack of remuneration for the trial and no  
57 clear funding pathway for subsequent service provision.  
58  
59  
60



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2  
3 *Taking into consideration our hourly rate and if you don't actually sell anything...no*  
4 *remuneration would be a big barrier. (P6 – Pharmacist)*  
5

6 The **compatibility** of the service with rural practice was reliant on the number of pharmacists available  
7 at the pharmacies. Evidence of consumers being asked to come back at a time when more pharmacists  
8 were available was reported. This was compounded by the lack of remuneration associated with the  
9 trial and thus the priority being placed on services that were profitable such as vaccinations, or  
10 dispensary tasks.  
11

12  
13 *If there were just two [pharmacists], then we're stretching it a bit. And we just definitely*  
14 *wouldn't offer it if there was just the one pharmacist. If they came in on a weekend, we'd*  
15 *ask them to come back during the week. (P4 – Pharmacist)*  
16

17 Consumer and community support was highlighted as an enabler for the trial. The pharmacists  
18 expected that their local communities would be highly receptive of the service and they were  
19 pleased that the local GPs were also supportive of the trial and happy to be involved. After the trial  
20 pharmacists reported that they felt the service built trust, rapport and confidence from consumers.  
21

### 22 **Future directions**

23  
24 Integration of the documentation process into existing dispensary software was not achieved for this  
25 trial however would be a focus for future services.  
26

27  
28 *If we could have it incorporated into our workflow to make it easier, part of a*  
29 *platform we already use, that would be cool, because technology makes things easy*  
30 *for us, and integrated technology is even better. (P4 – Pharmacist)*  
31

32 The importance of the direct referral pathway with guaranteed appointment availability was also  
33 expected to be a major enabler for the trial however it is highly unlikely this could be a permanent  
34 feature of future service models given the burden this places on an already stretched GP workforce.  
35 However, maximising digital technologies could further enhance timely medical assessment. Images  
36 and results provided by the pharmacists would enable GPs to conduct a telehealth appointment for  
37 the consumer for an immediate diagnosis and treatment.  
38

39  
40 *You would have done all the work, because the only barrier to effectively diagnosing a*  
41 *consumer with an ear problem by telehealth is not having a look in the ear. But if we are*  
42 *presented with the photo ... then absolutely you will be able to make a diagnosis and treat*  
43 *the consumer effectively by telehealth using this model. (GP1 – General Practitioner)*  
44

45 When asked about whether LISTEN UP should be rolled-out as a **national strategy**, all pharmacists  
46 agreed that it is a service community pharmacists can and should be providing, taking into  
47 consideration discussed barriers that this service would address. There was focus placed on the  
48 greater need in rural and remote settings and an uncertainty about how the service would be  
49 received in metropolitan settings.  
50

51  
52 *I think every pharmacist should be able to have the skills and knowledge to be able*  
53 *to look in someone's ear and decrease doctor's visits and ED referrals if it's a simple*  
54 *wax impaction or something like that. (P3- Pharmacist)*  
55

### 56 **DISCUSSION**

57  
58 Exploring the feasibility, accessibility and acceptability of an ear health intervention from a health  
59 system, pharmacist and consumer level is integral to considering future expanded practice services  
60

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2  
3 for rural community pharmacy. This study has provided the first insight into the challenges and  
4 motivators for pharmacists to provide an ear care service and offers considerations for  
5 implementation of other expanded services going forward.  
6

### 7 ***Health System Level***

8  
9 WHO has recognised the major health burden ear disease presents for rural and remote  
10 communities and has called for change to be made to ensure all people have equal access to quality  
11 ear and hearing care across the life course.(1) Access to health providers trained in ear health has  
12 been identified as a major barrier to ear care previously, with difficulty increasing with distance from  
13 metropolitan areas.(2) This study has found that consumers having difficulty accessing GP  
14 appointments consequently present to emergency departments for ear complaints. In addition,  
15 pharmacists prior to the intervention reported regularly referring consumers to emergency  
16 departments, due to an inability to access timely GP appointments. In a study of GP-type  
17 presentations to emergency departments undertaken at one of the ear trial sites, it was found that  
18 half of all presentations over a six month period were GP-appropriate problems.(22)  
19

20  
21  
22 LISTEN UP has provided the improved access to ear care by upskilling permanent and highly  
23 accessible health professionals, local community pharmacists. Consumers also reported the  
24 immediate access and the integrated pathway of GP referral as a major benefit to the service. GPs  
25 reported the referrals they received were appropriate and most consumers were able to be  
26 managed by pharmacists with analgesia and reassurance. The provision of a screening and referral  
27 service within local community pharmacies is an effective model to redirect ear complaints from  
28 emergency departments to appropriate settings.  
29

### 30 ***Pharmacist Level***

31  
32  
33 The provision of expanded services is an emerging area for Australian pharmacists.(23) To date no  
34 formal protocols have been developed to support pharmacists to provide expanded services, despite  
35 major developments for pharmacists' scope of practice internationally.(7) Research has reported  
36 rural pharmacists are supportive and interested to provide expanded services with expectation that  
37 such services would improve health outcomes and could address current gaps in healthcare.(10, 12)  
38 LISTEN UP has confirmed that pharmacists were motivated to provide an expanded ear health  
39 service. They described a lack of options currently available to manage ear complaints in community  
40 pharmacy and the regularity of referring consumers to emergency departments. After completing  
41 the formal training for the service, pharmacists reported improved confidence in managing ear  
42 complaints, but uncertainty in identify pathology and making prescribing recommendations. They  
43 expected their confidence would improve with practice and thus suggested longer trialability of the  
44 service to further develop their skills. They also reported wanting a very detailed protocol to be  
45 provided to guide them to provide the service.  
46  
47  
48

49  
50 This lack of confidence in clinical abilities has been reported to be a major barrier to advancement of  
51 the pharmacy profession previously.(24) The culture of feeling inadequately prepared for unfamiliar  
52 tasks and fear of making definitive decisions has been linked to pharmacists' personality traits and  
53 thus the profession needs to make a transition from scientist to consumer-centred practitioner to  
54 successfully work in an expanded scope of practice.(24)  
55

56  
57 In addition concern has been raised that expanded practice may not be feasible for rural practice as  
58 those pharmacies are already short-staffed and under-resourced.(25) Findings from LISTEN UP align  
59 with this, with recognition that three pharmacists are required to be able to offer expanded services  
60 and many rural and remote community pharmacies are unable to recruit and maintain that number

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2  
3 of pharmacists. In addition, the time required to complete documentation was identified as a major  
4 barrier to the service implementation, mostly due to the pharmacists receiving no funding to provide  
5 the service with no cost to consumers. Without a dedicated professional practice pharmacist,  
6 consumers were unable to be offered the LISTEN UP service, thus limiting feasibility and defeating  
7 the purpose of expanded practice for rural community pharmacy.  
8  
9

### 10 **Consumer Level**

11 Findings from this study have highlighted a high level of acceptance from consumers with reports of  
12 trust and confidence from consumers for their local pharmacists. It has reported high levels of  
13 consumer satisfaction and a willingness to return for the service in future. Consumers have also  
14 reported a willingness to pay for the service due to the convenience and accessibility it provides.  
15 This willingness to pay for expanded services has been previously identified, however there is also  
16 recognition that those who are most vulnerable are likely not to be able to pay for the service and  
17 thus alternative funding models need to be considered.(8)  
18  
19

20  
21 This study provides first insight into the feasibility, accessibility and acceptability of expanded  
22 practice for rural community pharmacists and identifies challenges that need to be addressed for  
23 this expanded pharmacy practice to be a sustainable model of health care delivery for rural and  
24 remote communities. A larger trial with multiple sites is needed to further consider this model of  
25 care, however adequate funding is essential to ensure high quality training, sufficient pharmacist  
26 numbers and low cost provision for consumers.  
27  
28

### 29 **CONCLUSION**

30 Hearing is key to human function and its loss impacts the whole society. Ear care in rural community  
31 pharmacy is often fraught with uncertainty and referral to emergency departments. LISTEN UP  
32 provides a feasible protocol for trained pharmacists to provide immediate ear care with an  
33 accessible integrated pathway to general practice if needed. This model has been developed and  
34 accepted with extensive consultation and provides a framework for similar expanded services to be  
35 modeled on in the future. Rural community pharmacists remain motivated to provide expanded  
36 services, however sufficient funding and a paradigm shift for the pharmacy profession is essential for  
37 expanded services to be sustainable and thus contribute to improving healthcare in rural and remote  
38 communities.  
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46 Figure 1: Process diagram of LISTEN UP study.  
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49 Figure 2: Thematic map illustrating the themes and codes for qualitative analysis of GP and  
50 Pharmacist Interviews.  
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## 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

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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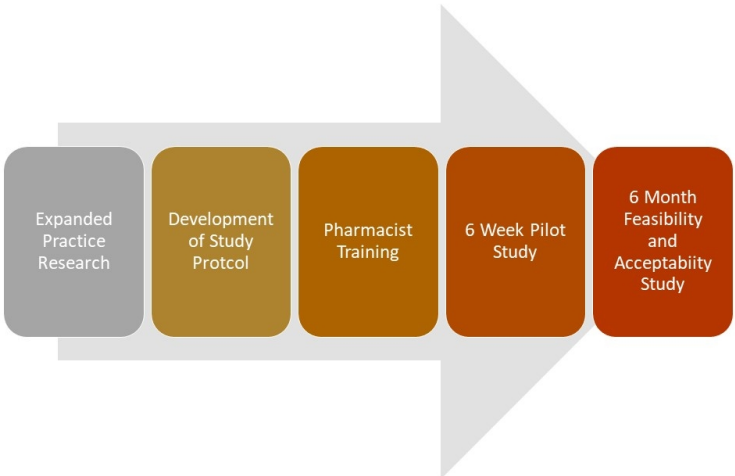


Figure 1: Process diagram of LISTEN UP study.

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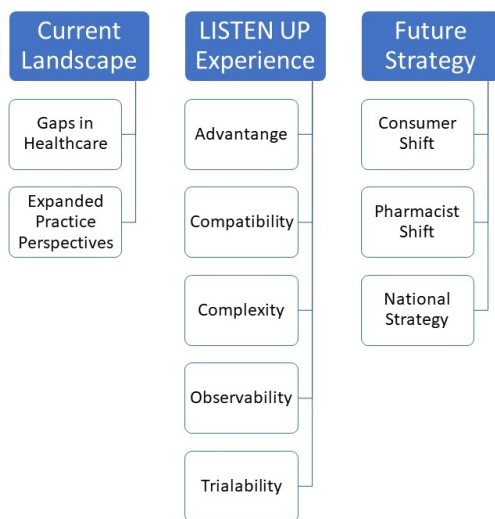
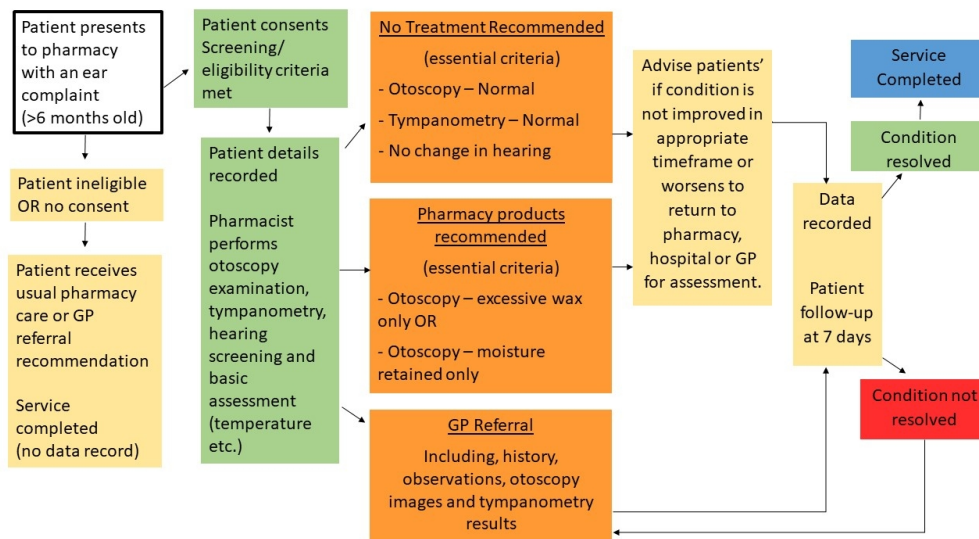


Figure 2: Thematic map illustrating the themes and codes for qualitative analysis of GP and Pharmacist Interviews.

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

338x190mm (96 x 96 DPI)

## SERVICE SUMMARY DOCUMENT

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

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

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

Attach images and results

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

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

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

## 1. Introduction of self and purpose of the call.

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

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

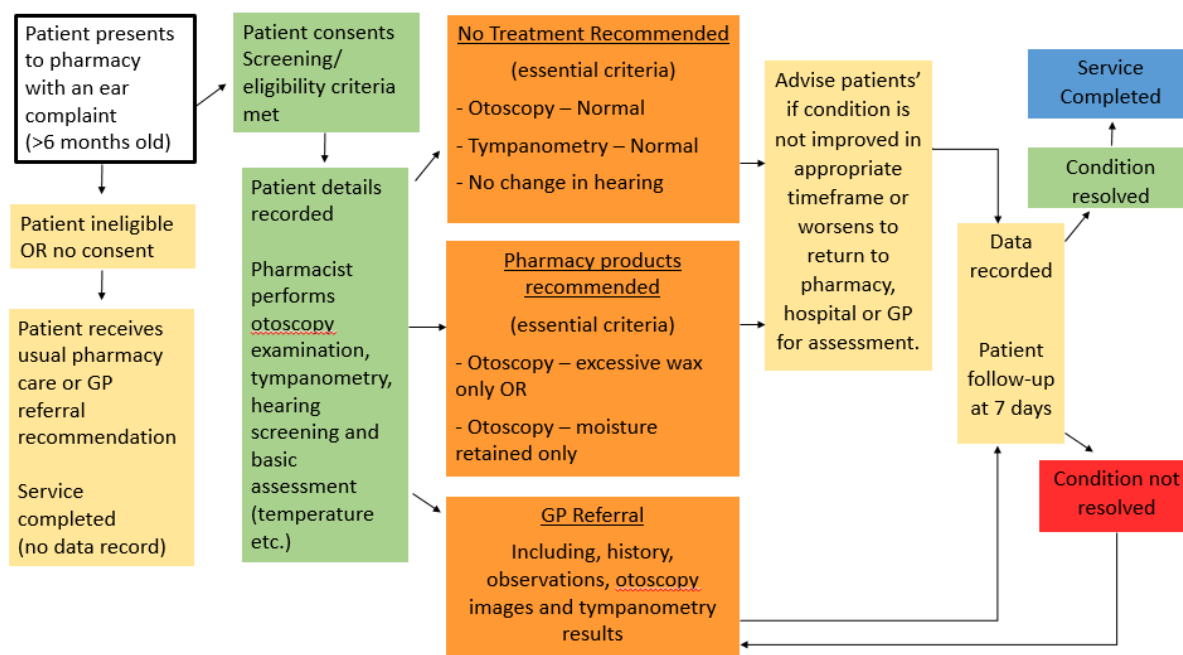
## 2. Demographics

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

Clinical characteristics Table (N=55)

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



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



## 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<sup>1\*</sup>, Alice Cairns<sup>2</sup>, Efi Mantzourani<sup>3,4</sup> and Beverley D. Glass<sup>5</sup>

## 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](https://www.anzctr.org.au/Trial/Registration/Trial.jsp?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 Benchmark 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  $n = Z^2 P (1-P)/d^2$ , where  $n$ =sample size,  $Z$  is the critical value of the normal distribution at  $\alpha/2$  for a confidence level of 95% where  $\alpha$  is 0.05 and the critical value is 1.96,  $P$  = expected prevalence or proportion = 0.14 (14%) and  $d$  = precision = 0.05 (5%) [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 solvents. 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

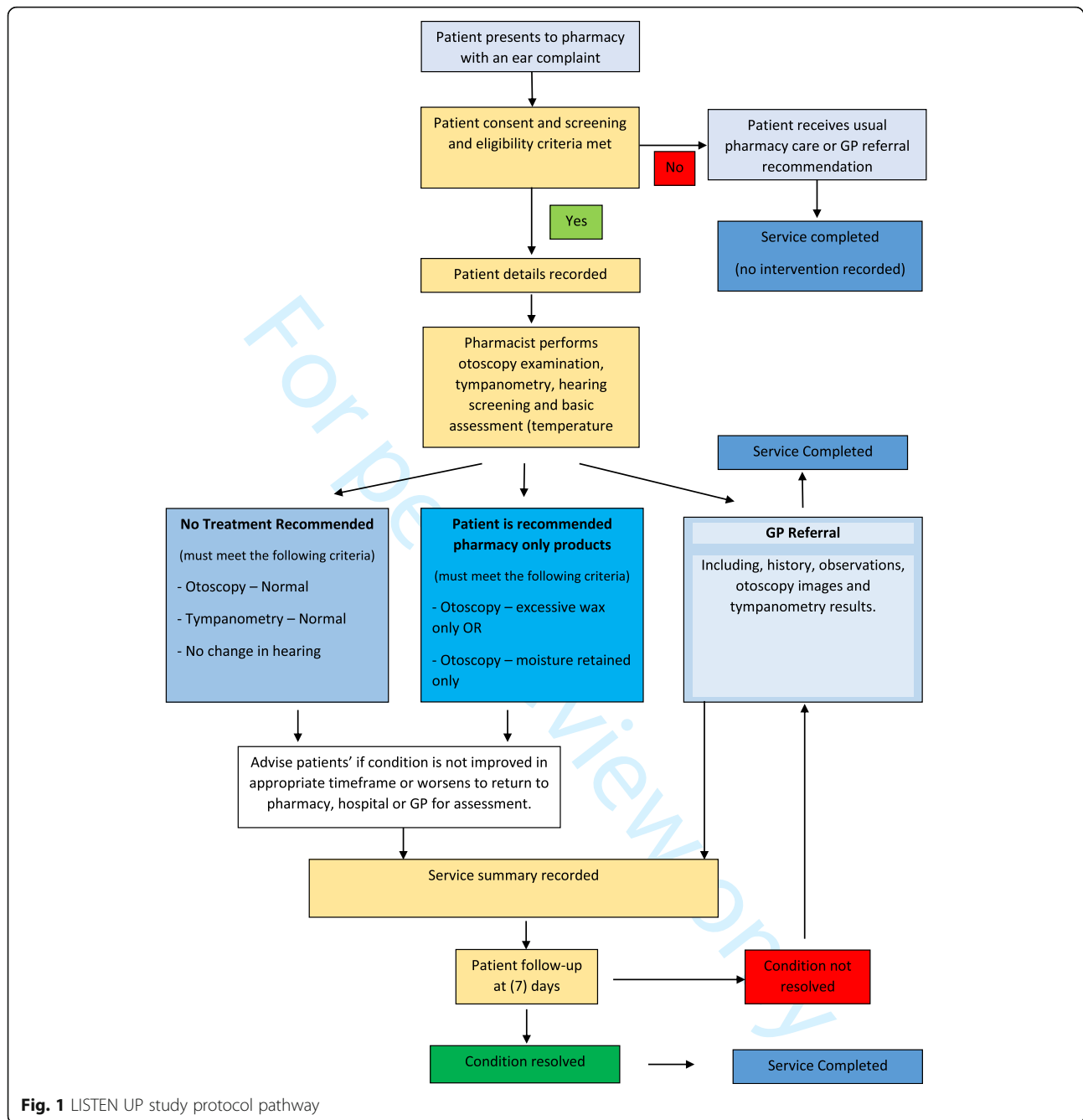
The GP to which the patient has been referred will be emailed a password encrypted file with all of the patient data including temperature, brief history of the ear complaint including symptoms, duration and treatments tried by the patient, otoscopy, tympanometry and hearing screening findings/results.

#### 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



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. These 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.

### Acknowledgements

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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.

### Funding

This study is funded by the Department of Health through the Centre for Rural and Remote Health. Additional information is provided as a separate document. 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.

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

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

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

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

**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**

1  
2  
3 Loss of the ability to perform other tasks or meet other responsibilities resulting from the diversion  
4 of resources needed to introduce, test, or sustain a particular [improvement](#) initiative  
5  
6

### 7 **Problem**

8 Meaningful disruption, failure, inadequacy, distress, confusion or other dysfunction in a healthcare  
9 service delivery [system](#) that adversely affects patients, staff, or the [system](#) as a whole, or that  
10 prevents care from reaching its full potential  
11

### 12 **Process**

13 The routines and other activities through which healthcare services are delivered  
14  
15

### 16 **Rationale**

17 Explanation of why particular [intervention\(s\)](#) were chosen and why it was expected to work, be  
18 sustainable, and be replicable elsewhere.  
19

### 20 **Systems**

21 The interrelated structures, people, [processes](#), and activities that together create healthcare services  
22 for and with individual patients and populations. For example, systems exist from the personal self-  
23 care system of a patient, to the individual provider-patient dyad system, to the microsystem, to the  
24 macrosystem, and all the way to the market/social/insurance system. These levels are nested within  
25 each other.  
26  
27

### 28 **Theory or theories**

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

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

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4 1 Mixed Methods Study of an Ear Health Intervention for Rural Community

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6 2 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.

## 70 INTRODUCTION

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

77 The World Health Organisation (WHO) has identified that globally 1.5 billion people experience some  
78 decline in their hearing throughout their life course, with many more at risk of hearing loss due to  
79 preventable causes.(1) WHO has proposed an integrated people-centred approach to ear and  
80 hearing care service provision to provide a coordinated service across the continuum of care.(1) The  
81 provision of a comprehensive, safe, effective, timely, efficient and acceptable service by a motivated  
82 and skilled workforce operating in a supportive environment is expected to provide equal access to  
83 quality ear and hearing care.(1) This overarching approach is a gold standard to work towards,  
84 however in current practice, limited trained health professionals in ear health, a lack of resources  
85 and barriers to accessing ear care services impacts ear health, especially in rural and remote  
86 communities .(2)

87 In Australia, one in six people experience some form of hearing impairment with an expected  
88 increase as the population ages.(4) Australia has a first world healthcare system, however reports  
89 rates of chronic ear disease as high as 50% for remote Indigenous communities in Northern and  
90 Central Australia.(2) This enormous burden of ear disease is expected to worsen with an estimated  
91 900 million people to be affected worldwide by 2050 if no change to care is made.(2)

92  
93 Pharmacists play an essential healthcare role in both clinical and community settings.(5) Beyond  
94 medication dispensing, stewardship, and safety, pharmacists are often the first point of contact,  
95 especially in rural communities, playing a critical role in triaging care and referring community  
96 members to other health professionals.(5) In many cases, the pharmacist is the only permanent  
97 health professional in a rural community. (5) Pharmacies often serve as the local hub for community  
98 healthcare services, particularly in meeting the needs of rural communities, where disadvantage,  
99 limited health literacy, and poorer health outcomes persist.(5) In rural and remote Australia,  
100 community pharmacists provide a highly skilled workforce with accessibility extended afterhours  
101 and weekends, with potential to provide services to address the ear disease in these vulnerable  
102 communities.(2, 5)

103  
104 Despite rural community pharmacists' knowledge and embedded role in community, pharmacy ear  
105 care service provisions are limited without any structured service model. A scoping review of  
106 pharmacists' involvement in ear health care interventions found eleven articles worldwide, including  
107 pharmacies partnering with audiometry services for hearing screening, an otoscopy pilot study, a  
108 pharmacy-based ear clinic and targeted education for undergraduate pharmacy students.(6)  
109 Pharmacists in Australia did not provide ear services, instead they reported audiometry services  
110 offering hearing screening through the pharmacy.(6)

111  
112 Internationally, rural pharmacists are expanding their scope of practice and providing innovative  
113 services to meet the needs of communities for improved health outcomes.(7) Expanded services  
114 including immunisations, screening and management of chronic and infectious diseases have  
115 reported positive outcomes in rural practice, where access to health professionals are limited.(7)  
116 Recent research into the perspectives of consumers, pharmacists, health professionals and  
117 stakeholders regarding rural pharmacists providing expanded services has highlighted support for

1  
2  
3 118 these expanded services, despite some reservation from the medical profession.(8-12) In response  
4 119 to this, a community pharmacy-based ear health service model was developed and trialled in two  
5 120 rural pharmacies in Australia.(13) The aim of this study is to determine the feasibility, accessibility  
6 121 and acceptability of the service model.(13)  
7 122

## 9 123 **METHODS**

10 124 The PRECEDE-PROCEED model was used to provide a framework to develop the research protocol  
11 125 for this study, LISTEN UP (**L**ocally **I**ntegrated **S**creening and **T**esting **E**ar **a**nd **a**Ural **P**rogram). LISTEN  
12 126 UP is a community pharmacy-based intervention to improve the management of ear health in rural  
13 127 community in Australia.(13, 14) The PRECEDE component included an assessment of the  
14 128 predisposing, reinforcing and enabling constructs to support practice change through a scoping  
15 129 review; stakeholder surveys and interviews (piloted); and consultation with health professionals  
16 130 (including general practitioners (GPs) and ear nose and throat (ENT) specialists) and relevant  
17 131 authorities.(14) The PROCEED segment incorporated the evaluation of a six week service pilot and  
18 132 informed planned implementation, process, impact and outcome evaluation of the service.(14) The  
19 133 SQUIRE guidelines have provided a framework to report the new knowledge from this study.(15)  
20  
21  
22

### 23 134 **Study Design**

24  
25 135 The prospective pre- and post-mixed methods study is described in Figure 1. The descriptive  
26 136 qualitative component of the study was undertaken through an ethnographic lens of rural culture.  
27 137 The researchers are all located in regional, rural and remote locations, with extensive experience in  
28 138 rural health both globally and locally from a clinical and academic perspective.

29  
30  
31 139 Prior to the study commencing, the two participating pharmacies collected usual care data as a  
32 140 comparator for 8 weeks beginning November 2020.

33  
34 141 The intervention was then piloted for six weeks at each pharmacy (14) before the six month study  
35 142 was conducted from February – July 2021.

### 36 37 143 **Ethics approval**

38  
39 144 This project has been approved by the Human Research Ethics Committee, James Cook University.  
40 145 (Reference number: H8187)

### 41 42 146 **Setting and Recruitment**

43  
44 147 Pharmacies who had participated in previous research on rural expanded pharmacy practice were  
45 148 invited to express an interest to participate in the LISTEN UP study.(8, 10, 12) Two community  
46 149 pharmacies (Modified Monash Model (MMM) category 6 – remote community, population 18,000  
47 150 and MMM category 4 – medium rural town, population 6000) expressed interest and were enrolled  
48 151 in the study. General practitioner (GP) practices at the intervention sites were invited to participate  
49 152 and one practice at each of the sites volunteered. An invitation to participate with an information  
50 153 sheet and informed consent form was provided to each pharmacist at the participating pharmacies  
51 154 and each GP at the participating general practice. Participating pharmacies met eligibility criteria  
52 155 including being classified as rural or remote by the Modified Monash Model classification system  
53 156 categories 4-7.(13, 16)

54  
55  
56 157 Each participating pharmacist undertook nationally credentialed training in ear health including  
57 158 otoscopy and tympanometry. This training was delivered via mixed modes with online and face-to-  
58 159 face components over 55 hours including two full days of workshops provided by the Benchmark  
59 160 Group.(15) The training addressed the following units of competencies: EHHPEH002 - Promote,

161 educate and manage ear health, EHHAEH001 - Assess ear health, EHHPEA004 – Paediatric ear health  
162 assessment and TYMPY001 - Perform Tympanometry.

163  
164 Consumer participants were recruited into the study via convenience sampling through community  
165 pharmacy, when they presented with an ear complaint. Initially ethics approval had been granted for  
166 persons 13 years or old, however in June 2021, additional approval was granted for children from six  
167 months of age.

## 168 Data Collection

169 Data were collected from consumers, pharmacists and GPs (Table 1). Data relating to the feasibility  
170 (the extent of the service to be provided viably), acceptability (the level of approval of the service)  
171 and accessibility (the extent of being easily able to receive/provide the service) of LISTEN UP were  
172 collected via multiple mixed methods (Table 1).

173 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]

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

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

## 179 Intervention

180 A study protocol (flow chart provided in Appendix 1) which pharmacists followed to provide the  
181 intervention involves trained pharmacists providing otoscopy and tympanometry assessments on  
182 consumers presenting to community pharmacy with ear complaints and includes an integrated  
183 direct referral pathway to local GP providers.(13)

184 Consumers who presented to the pharmacy with an ear complaint and met the eligibility criteria  
185 were invited to participate. To be eligible, participants were required to understand the English  
186 language at an appropriate level to provide informed consent, have no obvious major trauma to the  
187 ear and not be a high COVID19 risk consumer (e.g. travelled in a COVID19 hotspot within 14 days).  
188 Participants were then provided a written information sheet and returned a signed informed  
189 consent sheet.

190 Pharmacists used the 'service summary document' (Appendix 1) to record consumer demographics,  
191 and details relating to the current episode of care including the presenting complaint, duration of  
192 the complaint and treatments tried. Pharmacist examination notes were recorded including  
193 temperature, otoscopy (normal/abnormal), tympanometry (normal/abnormal), brief notes and a  
194 clinical impression. Pharmacists completed a tick box list of usual recommendations and expanded  
195 practice recommendations. If consumers required a referral to a GP, the pharmacists made the  
196 appointment with the consumer for the same-day or next-day. Consumers were offered a brief  
197 satisfaction survey directly after their LISTEN UP consultation. All consumers were then followed-up

1  
2  
3 198 with a phone call by a member of the research team at seven days (Interview Guide - Appendix 1). If  
4 199 their condition was unresolved, they were referred to the GP. Hearing screening via the *Sound*  
5 200 *Scouts* application with Sennheiser HD 300 headphones was also available, however no hearing  
6 201 screens were conducted during the trial period. The MedRx video otoscope and Amplivox Otowave  
7 202 102 tympanometer were used in this study.

### 203 **Outcome and data analysis**

204 Demographic information, clinical characteristics (Appendix 1) and survey data were analysed using  
205 descriptive statistics, with qualitative data from consumer interviews analysed using content  
206 analysis. Pharmacist and GP interview data were analysed using a hybrid approach of inductive and  
207 deductive coding and theme development exploring specifically for feasibility, accessibility and  
208 acceptability data.(17) This style of thematic analysis incorporated both the data-driven inductive  
209 approach and the deductive priori template of codes approach.(17) Diffusion of innovation theory  
210 and categories adapted from 'Qualitative data analysis for applied policy research' were combined  
211 to form a thematic map which provided a framework for the analysis (Figure 2).(18, 19) NVivo 12  
212 software was used for all of the qualitative analysis.(20)

213 Transcriptions were read multiple times and an initial coding tree was created from the first four  
214 transcripts. Thematic analysis continued and codes which were conceptually similar were  
215 categorised into emerging themes, using an ethnographic technique of domain analysis.(21)  
216 Objectivity, assumed knowledge and bias were reduced by involvement of a second member of the  
217 research team who also analysed the first five interviews and any discrepancies were resolved. A  
218 member checking process was conducted with three participants to support validity of the data.

### 219 **Patient and Public Involvement**

220 There was no patient or public involvement.

## 222 **RESULTS**

223 To compare usual pharmacy ear presentations to those identified during the intervention, the  
224 pharmacists collected data pertaining to ear complaints for eight weeks prior to the intervention  
225 period. During this time twenty-three ear complaints were recorded as presenting to the pharmacy  
226 (child (8), adult (15)). These complaints were ear pain (35%) and ear wax (35%), swimmers ear (17%),  
227 hearing loss (4%) and other (discharge, fever, insomnia, blocked ear, vertigo) (4%).These complaints  
228 and frequencies were comparable to those reported during the intervention period.

229 Fifty-five consumers participated in the trial (mean age = 42 years). One in five participants were  
230 Aboriginal (10/55) and 95% (52/55) of participants were over 19 years of age (ethics approval for  
231 children younger than 13 was gained halfway through the trial). The planned sample size for this  
232 study was calculated to be 203 consumer participants.(13) The sample size was calculated using the  
233 formula  $n = Z^2P(1-P)/d^2$ , where  $n$ =sample size,  $Z$  is the critical value of the normal distribution at  $\alpha/2$   
234 for a confidence level of 95% where  $\alpha$  is 0.05 and the critical value is 1.96,  $P$  = expected prevalence  
235 or proportion = 0.14 (14%) and  $d$  = precision = 0.05 (5%). (13) The trial was concluded at six months  
236 with 55 consumer participants due to the pharmacies being unable to focus pharmacist time on the  
237 intervention due to competing priorities of COVID-19 vaccinations being provided through  
238 community pharmacy. In addition, as the intervention was not remunerated, during periods of  
239 reduced staff levels, pharmacists were unable to provide the intervention as other competing  
240 funded services were prioritised. Although these issues reduced the sample size, an extensive

241 quantity of rich qualitative data was able to be collected throughout the study to negative the  
 242 influence of a small sample size from a quantitative perspective.

243 Duration of the ear complaint ranged from 1 – 30+ days (mean = 39 days/median = 3 days). Prior  
 244 treatment included analgesia (paracetamol and anti-inflammatories) (n=11), cleaning using cotton  
 245 buds (n = 6), ear drops (n=9) and other (n=11). Other treatments tried included ear candles, hair  
 246 dryer, antibiotics from home, nasal spray/rinse, oral decongestants, antihistamine, essential oils,  
 247 complementary medicines, heat pack and vertigo treatments from home.

248 Otoscopy examination was performed for 52 (95%) participants (normal n=20 (40%), abnormal n=31  
 249 (60%)). Tympanometry was conducted for 45 (82%) participants (normal n = 27 (60%), abnormal  
 250 n=18 (40%)). Reasons for being unable to complete tympanometry included equipment failure (1),  
 251 consumer unwilling to be examined (4), ruptured ear drum (1), ear canal too large (1), unknown (3).

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

254 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%)		

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

258 Pharmacists recommended over-the-counter (OTC) products to two-thirds (36/55) of the  
 259 participants. OTC products recommended included wax removal drops (19), analgesia (11), drying  
 260 agent ear drops (1), decongestant nasal spray (3), oral decongestants and antihistamines (3). One  
 261 quarter (14/55) of participants were referred to a GP.

262 Seven participants were recommended no treatment at all. Pharmacists also recorded ‘other’  
 263 recommendations for seven participants and these included referral to emergency department (3)  
 264 and watch and wait (4).

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

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

272 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%)
<b>Questions with Yes/No answer option</b>		<b>Yes</b>
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%)	
<b>Free Text Comments</b>		
<p>“Very good reassurance about my ears”</p> <p>“Service exceeded my expectation”</p> <p>“I am satisfied with how the pharmacist checked my ears. Great service.”</p> <p>“Excellent support, information great, feel reassured. Thank you”</p>		

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	<p><i>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.</i></p> <p><i>Was really helpful in explaining what the issue was and what she was treating me with that day.</i></p>
Confidence	Trust, comfortability and confidence of the pharmacists' skills and knowledge to provide the service.	41	<p><i>They were trained very well...very knowledgeable.</i></p> <p><i>What the doctor does is less, the pharmacist was more thorough.</i></p>

Availability of local GP appointments	Difficulty in being able to make a GP appointment in an appropriate timeframe.	32	<p><i>When I need to book to see a GP it takes two weeks.</i></p> <p><i>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.</i></p>
Willingness to pay	Explanations of participants' willingness to pay or not pay for the service.	30	<p><i>I would pay because it was so quick, easy and inclusive.</i></p> <p><i>I don't pay for the doctors so I wouldn't pay for the pharmacist.</i></p> <p><i>You have to pay at the doctors so I don't see a difference.</i></p>
Reassurance	A feeling of reassurance about the ear complaint.	29	<p><i>I felt more comfortable about why I was having pain and treatment.</i></p> <p><i>Put my mind at ease so I didn't need to go to the doctor.</i></p>
Pharmacy convenience and accessibility	Positive associations with pharmacy accessibility and immediate service provision.	29	<p><i>It was convenient, you didn't have to book an appointment.</i></p> <p><i>Going to the pharmacy was easier because if I need something for my ears you have it there already.</i></p>
Expanded scope for pharmacists	Support for pharmacists to provide other expanded services or an extension of this service (e.g. prescribing and syringing)	9	<p><i>If the pharmacists can see it's infected, they should be able to give me the drops (antibiotics).</i></p> <p><i>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.</i></p>

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291 As well as information presented in table 4, some consumers highlighted the opportunity to use  
 292 telehealth GP services with the imaging provided from the service to overcome some of the barriers  
 293 to accessing local GP services, including cost of appointments/lack of bulk-billing and distances to  
 294 access GPs of up to 600 kilometers.

#### 295 *Pharmacist and GP Interview Data (Pre- and Post-) Feasibility and acceptability of service*

296 Semi-structured interviews were conducted with participating pharmacists and GPs pre- and post-  
 297 the intervention and analysed according to the thematic map, Figure 2. The interview duration  
 298 ranged from 13 to 73 minutes with an average of 25 minutes.

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



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

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

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

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

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

317 *Providing services in rural communities across the board is very difficult, and anyone*  
318 *who can bring services where they aren't already should be encouraged. (GP6 – General*  
319 *Practitioner)*

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

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

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

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

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

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

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

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3 341 There was an expectation that this expanded service may be a springboard for further service  
4 342 development and for both consumers and health professionals to be more accepting of an expanded  
5 343 scope for pharmacists.

7 344 *I am expecting advancement in our placement in the minds of the community that we*  
8 345 *service, of what we can actually achieve and what we can do as a pharmacist for them. (P1 –*  
9 346 *Pharmacist)*

11 347 *I hope it will bring about some results that will elicit a meaningful change in terms of*  
12 348 *broadening our scope of practice. (P5 –Pharmacist)*

15 349 Pharmacists reported the recent growth in professional service areas such as vaccinations had  
16 350 pharmacists feeling well placed to provide other expanded services for their communities. This was  
17 351 also identified as an enabler as some of the challenges of role conflict with GP's has already been  
18 352 addressed and relationships between the professional groups had adjusted to new service models.

21 353 *When we started the immunisation program, there was a lot of resistance there and now*  
22 354 *that it's a known kind of service, it's great, but at first, it was like we were taking from*  
23 355 *their role. (P8 – Pharmacist)*

25 356 After the trial pharmacists continued to report a positive **pharmacist behaviour shift** towards  
26 357 expanded pharmacy broadly. Pharmacists described the trial solidifying and extending their interest  
27 358 in working to their full scope.

29 359 *I really have enjoyed pushing that scope, learning something new, delving into a new*  
30 360 *domain. I think we need to keep doing it as pharmacists. We need to offer as much care*  
31 361 *as we can for people, and we need to push ourselves to do that, and not just rest on*  
32 362 *dispensing a script, especially if we want to be valued members of the healthcare system*  
33 363 *going forward. (P2 – Pharmacist)*

35 364 **Consumer behaviour shift** through increased confidence and knowledge of the potential for expanded  
36 365 pharmacy roles was a reported benefit of the trial.

38 366 *People started to see us as actual health professionals that are available to the*  
39 367 *community, that you can actually touch and feel, that you have access to without an*  
40 368 *appointment. (P4-Pharmacist)*

42 369 Prior to the trial, pharmacists reported advice on ear complaints was commonly sought by  
43 370 consumers with up to two presentations each day. They reported an overall lack of confidence with  
44 371 managing ear complaints based on symptomatic description from consumers and reported referring  
45 372 most ear complaints to a GP or hospital emergency department (ED). Pharmacists expected an  
46 373 improvement in their skills and knowledge in the management of ear complaints and the ability to  
47 374 provide better ear care in community.

50 375 *My conversation is always...I can't look in your ear. I can understand your symptoms,*  
51 376 *I'm hearing what you're saying, but it covers a lot of different things and I can't make*  
52 377 *that decision on what you're telling me, and I also don't have much to offer you. (P5-*  
53 378 *Pharmacist)*

55 379 After the trial pharmacists reported increased **observability** and increased confidence in managing  
56 380 ear complaints as a result of having more information (otoscopy and tympanometry results) for  
57 381 decision making. The imaging of the ear canal was one of the most valued aspects of the service,

382 improving pharmacist and consumer confidence in the service. Pharmacists were able to provide  
383 reassurance to patients and explain the anatomy and pathophysiology to consumers in real time.

384 *It's really nice showing them what their eardrum looks like, and explaining to some why*  
385 *they don't need antibiotics. (P2 – Pharmacist)*

386 *Anything that we can get more data to help us be more definitive and clear in our referral*  
387 *pathways is helpful. (P2-Pharmacist)*

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

393 *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*  
394 *more. (P4 – Pharmacist)*

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

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

402 *I don't have the confidence for a diagnosis at all and it's just purely from not doing enough*  
403 *and not getting feedback. (P3-Pharmacist)*

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

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

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

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

419 After the trial, workflow demands however were identified as a barrier to both the trial and  
420 expanded practice generally. It was highlighted that a number of consumers received a consultation  
421 by a pharmacist but the occasion was not documented for the trial. Time required for the  
422 documentation process and competing dispensary demands were reported as the reasons for this

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3 423 occurring. In addition, it was noted that as influenza vaccinations increased, the availability of the  
4 424 consultation room was limited and this inhibited the ability to offer LISTEN UP.

6 425 *I'd say there's double the number of people who we probably could have done, that we*  
7 426 *haven't done, because it wasn't the right time, we were too busy. (P8-Pharmacist)*

9 427 The length of the consultations were also raised as a potential barrier, with concerns when only one  
10 428 pharmacist was on-duty and expectation that it would be difficult to be able to offer the service  
11 429 during those times.

13 430 *Time is the biggest factor, we are often under the pump with the supply role so I think the*  
14 431 *clinical service can press you that little bit further. (P7 – Pharmacist)*

16 432 All pharmacists reported a lack of funding as a major barrier to LISTEN UP. They were concerned  
17 433 about the amount of time the consultations would take, the lack of remuneration for the trial and no  
18 434 clear funding pathway for subsequent service provision.

20 435 *Taking into consideration our hourly rate and if you don't actually sell anything...no*  
21 436 *remuneration would be a big barrier. (P6 – Pharmacist)*

23 437 The **compatibility** of the service with rural practice was reliant on the number of pharmacists available  
24 438 at the pharmacies. Evidence of consumers being asked to come back at a time when more pharmacists  
25 439 were available was reported. This was compounded by the lack of remuneration associated with the  
26 440 trial and thus the priority being placed on services that were profitable such as vaccinations, or  
27 441 dispensary tasks.

29 442 *If there were just two [pharmacists], then we're stretching it a bit. And we just definitely*  
30 443 *wouldn't offer it if there was just the one pharmacist. If they came in on a weekend, we'd*  
31 444 *ask them to come back during the week. (P4 – Pharmacist)*

33 445 Consumer and community support was highlighted as an enabler for the trial. The pharmacists  
34 446 expected that their local communities would be highly receptive of the service and they were  
35 447 pleased that the local GPs were also supportive of the trial and happy to be involved. After the trial  
36 448 pharmacists reported that they felt the service built trust, rapport and confidence from consumers.

#### 40 449 **Future directions**

41 450 Integration of the documentation process into existing dispensary software was not achieved for this  
42 451 trial however would be a focus for future services.

43 452 *If we could have it incorporated into our workflow to make it easier, part of a*  
44 453 *platform we already use, that would be cool, because technology makes things easy*  
45 454 *for us, and integrated technology is even better. (P4 – Pharmacist)*

46 455 The importance of the direct referral pathway with guaranteed appointment availability was also  
47 456 expected to be a major enabler for the trial however it is highly unlikely this could be a permanent  
48 457 feature of future service models given the burden this places on an already stretched GP workforce.  
49 458 However, maximising digital technologies could further enhance timely medical assessment. Images  
50 459 and results provided by the pharmacists would enable GPs to conduct a telehealth appointment for  
51 460 the consumer for an immediate diagnosis and treatment.

52 461 *You would have done all the work, because the only barrier to effectively diagnosing a*  
53 462 *consumer with an ear problem by telehealth is not having a look in the ear. But if we are*

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3 463 *presented with the photo ... then absolutely you will be able to make a diagnosis and treat*  
4 464 *the consumer effectively by telehealth using this model. (GP1 – General Practitioner)*

6 465 When asked about whether LISTEN UP should be rolled-out as a **national strategy**, all pharmacists  
7 466 agreed that it is a service community pharmacists can and should be providing, taking into  
8 467 consideration discussed barriers that this service would address. There was focus placed on the  
9 468 greater need in rural and remote settings and an uncertainty about how the service would be  
11 469 received in metropolitan settings.

13 470 *I think every pharmacist should be able to have the skills and knowledge to be able*  
14 471 *to look in someone's ear and decrease doctor's visits and ED referrals if it's a simple*  
15 472 *wax impaction or something like that. (P3- Pharmacist)*

## 17 473 **DISCUSSION**

19 474 Exploring the feasibility, accessibility and acceptability of an ear health intervention from a health  
20 475 system, pharmacist and consumer level is integral to considering future expanded practice services  
21 476 for rural community pharmacy. This study has provided the first insight into the challenges and  
22 477 motivators for pharmacists to provide an ear care service and offers considerations for  
23 478 implementation of this and other expanded services going forward.

### 26 479 **Health System Level**

27 480 WHO has recognised the major health burden ear disease presents for rural and remote  
28 481 communities and has called for change to be made to ensure all people have equal access to quality  
29 482 ear and hearing care across the life course.(1) Access to health providers trained in ear health has  
30 483 been identified as a major barrier to ear care previously, with difficulty increasing with distance from  
31 484 metropolitan areas.(2) This study has found that consumers having difficulty accessing GP  
32 485 appointments consequently present to emergency departments for ear complaints. In addition,  
33 486 pharmacists prior to the intervention reported regularly referring consumers to emergency  
34 487 departments, due to an inability to access timely GP appointments. In a study of GP-type  
35 488 presentations to emergency departments undertaken at one of the ear trial sites, it was found that  
36 489 half of all presentations over a six month period were GP-appropriate problems.(22)

40 490 LISTEN UP has provided the improved access to ear care by upskilling permanent and highly  
41 491 accessible health professionals, local community pharmacists. Consumers also reported the  
42 492 immediate access and the integrated pathway of GP referral as a major benefit to the service. GPs  
43 493 reported the referrals they received were appropriate and most consumers were able to be  
44 494 managed by pharmacists with analgesia and reassurance. The provision of a screening and referral  
45 495 service within local community pharmacies is an effective model to redirect ear complaints from  
46 496 emergency departments to appropriate settings.

### 49 497 **Pharmacist Level**

51 498 The provision of expanded services is an emerging area for Australian pharmacists.(23) To date no  
52 499 formal protocols have been developed to support pharmacists to provide expanded services, despite  
53 500 major developments for pharmacists' scope of practice internationally.(7) Research has reported  
54 501 rural pharmacists are supportive and interested to provide expanded services with expectation that  
55 502 such services would improve health outcomes and could address current gaps in healthcare.(10, 12)  
56 503 LISTEN UP has confirmed that pharmacists were motivated to provide an expanded ear health  
57 504 service. They described a lack of options currently available to manage ear complaints in community  
58 505 pharmacy and the regularity of referring consumers to emergency departments. After completing

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3 506 the formal training for the service, pharmacists reported improved confidence in managing ear  
4 507 complaints, but uncertainty in identify pathology and making prescribing recommendations. They  
5 508 expected their confidence would improve with practice and thus suggested longer trialability of the  
6 509 service to further develop their skills. They also reported wanting a very detailed protocol to be  
7 510 provided to guide them to provide the service.  
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10 511 This lack of confidence in clinical abilities has been reported to be a major barrier to advancement of  
11 512 the pharmacy profession previously.(24) The culture of feeling inadequately prepared for unfamiliar  
12 513 tasks and fear of making definitive decisions has been linked to pharmacists' personality traits and  
13 514 thus the profession needs to make a transition from scientist to consumer-centred practitioner to  
14 515 successfully work in an expanded scope of practice.(24)

16 516 In addition concern has been raised that expanded practice may not be feasible for rural practice as  
17 517 those pharmacies are already short-staffed and under-resourced.(25) Findings from LISTEN UP align  
18 518 with this, with recognition that three pharmacists are required to be able to offer expanded services  
19 519 and many rural and remote community pharmacies are unable to recruit and maintain that number  
20 520 of pharmacists. In addition, the time required to complete documentation was identified as a major  
21 521 barrier to the service implementation, mostly due to the pharmacists receiving no funding to provide  
22 522 the service with no cost to consumers. These challenges were reflected in the smaller than expected  
23 523 sample size and consequently the shorter duration of the trial. This smaller sample size also reduces  
24 524 the transferability and generalisability of the findings of this trial and reinforces the importance of a  
25 525 larger remunerated trial with more participating pharmacies in future studies. Without a dedicated  
26 526 professional practice pharmacist, consumers were unable to be offered the LISTEN UP service, thus  
27 527 limiting feasibility and defeating the purpose of expanded practice for rural community pharmacy.

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32 528 The value of a collaborative model of care for expanded practice must be considered for rural  
33 529 practice. Community pharmacists historically have worked independently of other professions,  
34 530 however literature indicates that collaboration between health professional and community  
35 531 pharmacists is expected to improve health outcomes, particularly in chronic disease  
36 532 management.(26)

### 38 533 **Consumer Level**

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40 534 Findings from this study have highlighted a high level of acceptance from consumers with reports of  
41 535 trust and confidence from consumers for their local pharmacists. It has reported high levels of  
42 536 consumer satisfaction and a willingness to return for the service in future. Consumers have also  
43 537 reported a willingness to pay for the service due to the convenience and accessibility it provides.  
44 538 This willingness to pay for expanded services has been previously identified, however there is also  
45 539 recognition that those who are most vulnerable are likely not to be able to pay for the service and  
46 540 thus alternative funding models need to be considered.(8)

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49 541 This study provides first insight into the feasibility, accessibility and acceptability of expanded  
50 542 practice for rural community pharmacists and identifies challenges that need to be addressed for  
51 543 this expanded pharmacy practice to be a sustainable model of health care delivery for rural and  
52 544 remote communities. It provides new knowledge to an area of unmet need in rural community and  
53 545 highlights challenges to ear care from consumer, health professional and pharmacist perspectives. A  
54 546 larger trial with multiple sites is needed to further consider this model of care, including  
55 547 sustainability, patient outcomes, and collaborative integration in rural and remote communities.  
56 548 However adequate funding is essential to ensure high quality training, sufficient pharmacist numbers  
57 549 and low cost provision for consumers.  
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3 550 **CONCLUSION**  
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5 551 Hearing is key to human function and its loss impacts the whole society. Ear care in rural community  
6 552 pharmacy is often fraught with uncertainty and referral to emergency departments. LISTEN UP  
7 553 provides a feasible protocol for trained pharmacists to provide immediate ear care with an  
8 554 accessible integrated pathway to general practice if needed. This model has been developed and  
9 555 accepted with extensive consultation and provides an initial framework for similar expanded services  
10 556 to be modeled on in the future. Rural community pharmacists remain motivated to provide  
11 557 expanded services, however sufficient funding and a paradigm shift for the pharmacy profession is  
12 558 essential for expanded services to be sustainable and thus contribute to improving healthcare in  
13 559 rural and remote communities.  
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20 562 Figure 1: Process diagram of LISTEN UP study.  
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24 564 Figure 2: Thematic map illustrating the themes and codes for qualitative analysis of GP and  
25 565 Pharmacist Interviews.  
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3 569 **DECLARATIONS**  
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5 570 **Ethics approval and consent to participate**  
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7 571 This project has been approved by the Human Research Ethics Committee, James Cook University.  
8 572 (Reference number: H8187) Informed consent obtained from study participants is in written form.  
9

10 573 **Data availability statement**  
11

12 574 The authors welcome any correspondence or requests for further details about this study. The  
13 575 datasets used and/or analysed during the current study are available from the corresponding author  
14 576 on reasonable request.  
15

16 577 **Competing interests**  
17

18 578 The authors declare that they have no competing interests.  
19

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21

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23 581 The study has been reviewed by the Centre for Rural and Remote Health and an advisory panel  
24 582 consisting of key stakeholder organisations including Pharmaceutical Society of Australia, Pharmacy  
25 583 Guild of Australia, Gidgee Healing (Aboriginal Medical Service), and Australian Primary Health  
26 584 Network.  
27

28 585 **Authors' contributions**  
29

30 586 ST, AC, and BG contributed to the design of the study. ST conducted the data management with  
31 587 secondary assistance from BG. ST prepared the first draft of the manuscript, which was reviewed  
32 588 and edited by AC and BG. All authors read and approved the final manuscript.  
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34

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665 **ENDNOTE AUTOMATED REFERENCE (Please disregard)**

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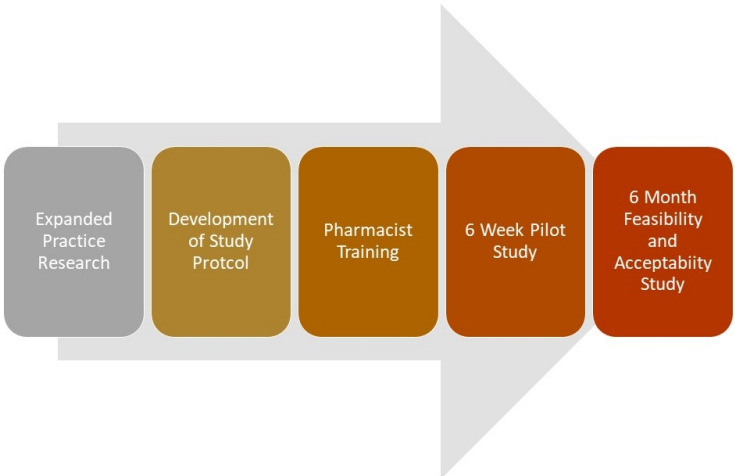


Figure 1: Process diagram of LISTEN UP study.

338x190mm (96 x 96 DPI)

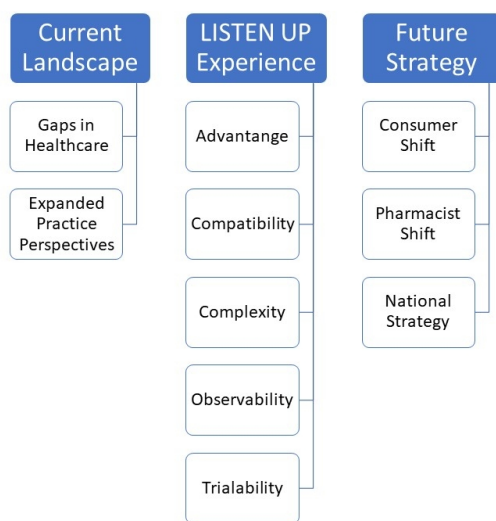
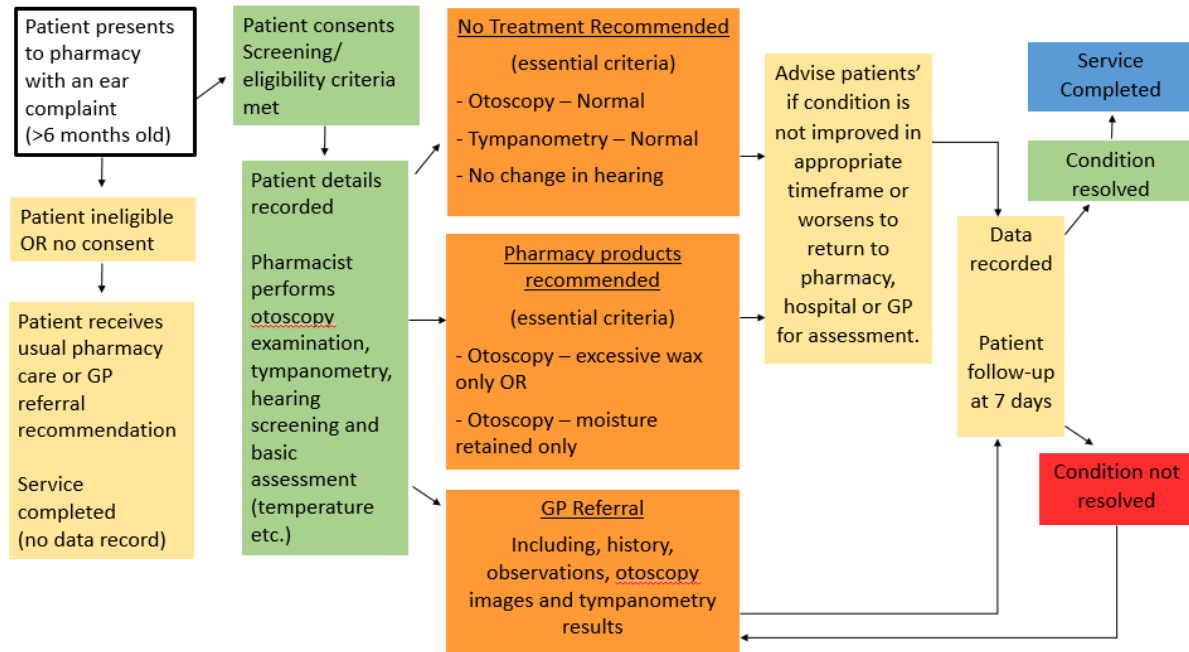


Figure 2: Thematic map illustrating the themes and codes for qualitative analysis of GP and Pharmacist Interviews.

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



## SERVICE SUMMARY DOCUMENT

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

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

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

Attach images and results

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

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

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

## 1. Introduction of self and purpose of the call.

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

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

## 2. Demographics

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

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

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

Page/line no(s).

### Title and abstract

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

### Introduction

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

### Methods

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

1 2 3 4 5	<b>Data collection instruments and technologies</b> - Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	181-190
6 7 8	<b>Units of study</b> - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	245-254
9 10 11 12	<b>Data processing</b> - Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/de-identification of excerpts	218-232
13 14 15 16	<b>Data analysis</b> - Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale**	218-232
17 18 19 20	<b>Techniques to enhance trustworthiness</b> - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	227-232

### Results/findings

23 24 25 26	<b>Synthesis and interpretation</b> - Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	485-489
27 28 29	<b>Links to empirical data</b> - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	286-483

### Discussion

32 33 34 35 36 37 38	<b>Integration with prior work, implications, transferability, and contribution(s) to the field</b> - Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	484-554
39	<b>Limitations</b> - Trustworthiness and limitations of findings	61-71

### Other

42 43 44	<b>Conflicts of interest</b> - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	584-585
45 46	<b>Funding</b> - Sources of funding and other support; role of funders in data collection, interpretation, and reporting	586-591

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

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\*\*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

For peer review only

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

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

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



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

**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**

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3 Loss of the ability to perform other tasks or meet other responsibilities resulting from the diversion  
4 of resources needed to introduce, test, or sustain a particular [improvement](#) initiative  
5  
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### 7 **Problem**

8 Meaningful disruption, failure, inadequacy, distress, confusion or other dysfunction in a healthcare  
9 service delivery [system](#) that adversely affects patients, staff, or the [system](#) as a whole, or that  
10 prevents care from reaching its full potential  
11

### 12 **Process**

13 The routines and other activities through which healthcare services are delivered  
14  
15

### 16 **Rationale**

17 Explanation of why particular [intervention\(s\)](#) were chosen and why it was expected to work, be  
18 sustainable, and be replicable elsewhere.  
19

### 20 **Systems**

21 The interrelated structures, people, [processes](#), and activities that together create healthcare services  
22 for and with individual patients and populations. For example, systems exist from the personal self-  
23 care system of a patient, to the individual provider-patient dyad system, to the microsystem, to the  
24 macrosystem, and all the way to the market/social/insurance system. These levels are nested within  
25 each other.  
26  
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### 28 **Theory or theories**

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

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

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Secondary Subject Heading:	Health services research, Pharmacology and therapeutics
Keywords:	Adult otolaryngology < OTOLARYNGOLOGY, Paediatric otolaryngology < OTOLARYNGOLOGY, PRIMARY CARE

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3 1 **Feasibility, accessibility and acceptability a pharmacist-led ear health intervention at rural**  
4 2 **community pharmacies (LISTEN UP): a mixed-methods study in Queensland, Australia**  
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30 26 Word Count: 5489

## 29 ABSTRACT

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

35 **Design:** Prospective pre- and post-intervention mixed-methods study. An ethnographic lens of rural  
36 culture was applied to the descriptive qualitative component of the study.

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

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

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

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

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

57 **Study registration:** ACTRN12620001297910.

58

### 59 Strengths and limitations of this study

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

64

## 65 INTRODUCTION

66 The ear, when working well, is a complex organ with receptors that respond 100,000 times every  
67 second, which allows hearing, a sense through which humans communicate, express thoughts, gain  
68 an education and engage socially.(1-3) Disadvantage resulting from hearing loss is well recognised

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

72 The World Health Organization (WHO) has identified that globally 1.5 billion people experience some  
73 decline in their hearing throughout their life course, with many more at risk of hearing loss due to  
74 preventable causes.(1) WHO has proposed an integrated people-centred approach to ear and  
75 hearing care service provision to provide a coordinated service across the continuum of care.(1) The  
76 provision of a comprehensive, safe, effective, timely, efficient and acceptable service by a motivated  
77 and skilled workforce operating in a supportive environment is expected to provide equal access to  
78 quality ear and hearing care.(1) This overarching approach is a gold standard to work towards,  
79 however in current practice, limited trained health professionals in ear health, a lack of resources  
80 and barriers to accessing ear care services impacts ear health, especially in rural and remote  
81 communities .(2)

82 In Australia, one in six people experience some form of hearing impairment with an expected  
83 increase as the population ages.(4) Australia has a first world healthcare system, however reports  
84 rates of chronic ear disease as high as 50% for remote Indigenous communities in Northern and  
85 Central Australia.(2) This enormous burden of ear disease is expected to worsen with an estimated  
86 900 million people to be affected worldwide by 2050 if no change to care is made.(2)

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

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

109 Despite rural community pharmacists' knowledge and embedded role in community, pharmacy ear  
110 care service provisions are limited without any structured service model. A scoping review of  
111 pharmacists' involvement in ear health care interventions found eleven articles worldwide, including  
112 pharmacies partnering with audiometry services for hearing screening, an otoscopy pilot study, a  
113 pharmacy-based ear clinic and targeted education for undergraduate pharmacy students.(8)  
114 Pharmacists in Australia did not provide ear services, instead they reported audiometry services  
115 offering hearing screening through the pharmacy.(8)



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3 117 Internationally, rural pharmacists are expanding their scope of practice and providing innovative  
4 118 services to meet the needs of communities for improved health outcomes.(9) Expanded services  
5 119 including immunisations, screening and management of chronic and infectious diseases have  
6 120 reported positive outcomes in rural practice, where access to health professionals are limited.(9)  
7 121 Recent research into the perspectives of consumers, pharmacists, health professionals and  
8 122 stakeholders regarding rural pharmacists providing expanded services has highlighted support for  
9 123 these expanded services, despite some reservation from the medical profession.(10-14) In response  
10 124 to this, a community pharmacy-based ear health service model was developed and trialled in two  
11 125 rural pharmacies in Australia.(15) The aim of this study is to determine the feasibility, accessibility  
12 126 and acceptability of the service model.(15)  
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## 127 128 **METHODS**

17 129 The PRECEDE-PROCEED model was used to provide a framework to develop the research protocol  
18 130 for this study, LISTEN UP (**L**ocally **I**ntegrated **S**creening and **T**esting **E**ar **a**nd **a**Ural **P**rogram). LISTEN  
19 131 UP is a community pharmacy-based intervention to improve the management of ear health in rural  
20 132 community in Australia.(15, 16) The PRECEDE component included an assessment of the  
21 133 predisposing, reinforcing and enabling constructs to support practice change through a scoping  
22 134 review; stakeholder surveys and interviews (piloted); and consultation with health professionals  
23 135 (including general practitioners (GPs) and ear nose and throat (ENT) specialists) and relevant  
24 136 authorities.(16) The PROCEED segment incorporated the evaluation of a six week service pilot and  
25 137 informed planned implementation, process, impact and outcome evaluation of the service.(16) The  
26 138 SQUIRE guidelines have provided a framework to report the new knowledge from this study.(17)  
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### 30 139 **Study design**

31  
32 140 The prospective pre- and post-intervention mixed-methods study is described in Figure 1. The  
33 141 descriptive qualitative component of the study was undertaken through an ethnographic lens of  
34 142 rural culture. The researchers are all located in regional, rural and remote locations, with extensive  
35 143 experience in rural health both globally and locally from a clinical and academic perspective.

36  
37 144 Prior to the study commencing, the two participating pharmacies collected usual care data as a  
38 145 comparator for 8 weeks beginning November 2020.

39  
40 146 The intervention was then piloted for six weeks at each pharmacy (16) before the six month study  
41 147 was conducted from February – July 2021.

### 42 148 **Ethics approval**

43  
44 149 This project has been approved by the Human Research Ethics Committee, James Cook University  
45 150 (reference number: H8187).

### 46 151 **Setting and recruitment**

47  
48 152 Pharmacies that had participated in previous research on rural expanded pharmacy practice were  
49 153 invited to express an interest to participate in the LISTEN UP study.(10, 12, 14) Two community  
50 154 pharmacies (Modified Monash Model (MMM) category 6 – remote community, population 18,000  
51 155 and MMM category 4 – medium rural town, population 6000) expressed interest and were enrolled  
52 156 in the study. General practitioner (GP) practices at the intervention sites were invited to participate  
53 157 and one practice at each of the sites volunteered. An invitation to participate with an information  
54 158 sheet and informed consent form was provided to each pharmacist at the participating pharmacies  
55 159 and each GP at the participating general practice. Participating pharmacies met eligibility criteria  
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160 including being classified as rural or remote by the Modified Monash Model classification system  
161 categories 4-7.(15, 18)

162 Each participating pharmacist undertook nationally credentialed training in ear health including  
163 otoscopy and tympanometry. This training was delivered via mixed modes with online and face-to-  
164 face components over 55 hours including two full days of workshops provided by the Benchmarque  
165 Group.(15) The training addressed the following units of competencies: EHHPEH002 - Promote,  
166 educate and manage ear health, EHHAEH001 - Assess ear health, EHHPEA004 – Paediatric ear health  
167 assessment and TYMPTY001 - Perform Tympanometry.

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

### 173 Data collection

174 Data were collected from consumers, pharmacists and GPs (Table 1). Data relating to the feasibility  
175 (the extent of the service to be provided viably), acceptability (the level of approval of the service)  
176 and accessibility (the extent of being easily able to receive/provide the service) of LISTEN UP were  
177 collected via multiple mixed methods (Table 1).

178 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]

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

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

### 184 Intervention

185 A study protocol (flow chart provided in Appendix 1) which pharmacists followed to provide the  
186 intervention involves trained pharmacists providing otoscopy and tympanometry assessments on  
187 consumers presenting to community pharmacy with ear complaints and includes an integrated  
188 direct referral pathway to local GP providers.(15)

189 Consumers who presented to the pharmacy with an ear complaint and met the eligibility criteria  
190 were invited to participate. To be eligible, participants were required to understand the English  
191 language at an appropriate level to provide informed consent, have no obvious major trauma to the  
192 ear and not be a high COVID19 risk consumer (e.g. travelled in a COVID19 hotspot within 14 days).  
193 Participants were then provided a written information sheet and returned a signed informed  
194 consent sheet.

195 Pharmacists used the 'service summary document' (Appendix 1) to record consumer demographics,  
196 and details relating to the current episode of care including the presenting complaint, duration of

1  
2  
3 197 the complaint and treatments tried. Pharmacist examination notes were recorded including  
4 198 temperature, otoscopy (normal/abnormal), tympanometry (normal/abnormal), brief notes and a  
5 199 clinical impression. Pharmacists completed a tick box list of usual recommendations and expanded  
6 200 practice recommendations. If consumers required a referral to a GP, the pharmacists made the  
7 201 appointment with the consumer for the same-day or next-day. Consumers were offered a brief  
8 202 satisfaction survey directly after their LISTEN UP consultation. All consumers were then followed-up  
9 203 with a phone call by a member of the research team at seven days (Interview Guide - Appendix 1). If  
10 204 their condition was unresolved, they were referred to the GP. Hearing screening via the *Sound*  
11 205 *Scouts* application with Sennheiser HD 300 headphones was also available, however no hearing  
12 206 screens were conducted during the study period. The MedRx video otoscope and Amplivox Otowave  
13 207 102 tympanometer were used in this study.

### 17 208 **Outcome and data analysis**

19 209 Demographic information, clinical characteristics (Appendix 1) and survey data were analysed using  
20 210 descriptive statistics, with qualitative data from consumer interviews analysed using content  
21 211 analysis. Pharmacist and GP interview data were analysed using a hybrid approach of inductive and  
22 212 deductive coding and theme development exploring specifically for feasibility, accessibility and  
23 213 acceptability data.(19) This style of thematic analysis incorporated both the data-driven inductive  
24 214 approach and the deductive priori template of codes approach.(19) Diffusion of innovation theory  
25 215 and categories adapted from 'Qualitative data analysis for applied policy research' were combined  
26 216 to form a thematic map which provided a framework for the analysis (Figure 2).(20, 21) NVivo 12  
27 217 software was used for all of the qualitative analysis.(22)

29 218 Transcriptions were read multiple times and an initial coding tree was created from the first four  
30 219 transcripts. Thematic analysis continued and codes which were conceptually similar were  
31 220 categorised into emerging themes, using an ethnographic technique of domain analysis.(23)  
32 221 Objectivity, assumed knowledge and bias were reduced by involvement of a second member of the  
33 222 research team who also analysed the first five interviews and any discrepancies were resolved. A  
34 223 member checking process was conducted with three participants to support validity of the data.

### 37 224 **Patient and Public Involvement**

39 225 There was no patient or public involvement.

41 226

## 43 227 **RESULTS**

44 228 To compare usual pharmacy ear presentations to those identified during the intervention, the  
45 229 pharmacists collected data pertaining to ear complaints for eight weeks prior to the intervention  
46 230 period. During this time 23 ear complaints were recorded as presenting to the pharmacy (child (8),  
47 231 adult (15)). These complaints were ear pain (35%) and ear wax (35%), swimmer's ear (17%), hearing  
48 232 loss (4%) and other (discharge, fever, insomnia, blocked ear, vertigo; 4%). These complaints and  
49 233 frequencies were comparable to those reported during the intervention period.

51 234 55 consumers participated in the study (mean age = 42 years). One in five participants were  
52 235 Aboriginal (10/55) and 95% (52/55) of participants were over 19 years of age (ethics approval for  
53 236 children younger than 13 was gained halfway through the study). The planned sample size for this  
54 237 study was calculated to be 203 consumer participants.(13) The sample size was calculated using the  
55 238 formula  $n = Z^2 P (1-P)/d^2$ , where  $n$ =sample size,  $Z$  is the critical value of the normal distribution at  $\alpha/2$   
56 239 for a confidence level of 95% where  $\alpha$  is 0.05 and the critical value is 1.96,  $P$  = expected prevalence  
57 240 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.

277 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%)
<b>Questions with Yes/No answer option</b>	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%)	
<b>Free Text Comments</b>		
"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"		

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

279

### 280 *Consumer Post-Intervention Data (Acceptability and Accessibility of Service)*

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

285 Data from these interviews were analysed using quantitative content analysis. Every participant  
 286 described their experience at the pharmacy with a positive term (e.g. marvelous, wonderful, better  
 287 than a doctors surgery) and these affirmations were recorded 89 times. Participants reported being  
 288 surprised that pharmacists were able to provide ear health services. More advertising and using the  
 289 video-otoscope to examine other parts of the body (e.g. throat) were the only two service  
 290 improvements recommended. Most participants (87% (48/55)) reported they would pay for this type  
 291 of pharmacy service, with suggested amounts ranging from AUD\$1-20 (33%), \$21-50 (33%). The  
 292 average value that participants were willing to pay was AUD\$33 with values of AUD\$100, \$150 and  
 293 \$200 also suggested.

294 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>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.</i>  <i>Was really helpful in explaining what the issue was and what she was treating me with that day.</i>

Confidence	Trust, comfortability and confidence of the pharmacists' skills and knowledge to provide the service.	41	<i>They were trained very well...very knowledgeable.</i>  <i>What the doctor does is less, the pharmacist was more thorough.</i>
Availability of local GP appointments	Difficulty in being able to make a GP appointment in an appropriate timeframe.	32	<i>When I need to book to see a GP it takes two weeks.</i>  <i>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.</i>
Willingness to pay	Explanations of participants' willingness to pay or not pay for the service.	30	<i>I would pay because it was so quick, easy and inclusive.</i>  <i>I don't pay for the doctors so I wouldn't pay for the pharmacist.</i>  <i>You have to pay at the doctors so I don't see a difference.</i>
Reassurance	A feeling of reassurance about the ear complaint.	29	<i>I felt more comfortable about why I was having pain and treatment.</i>  <i>Put my mind at ease so I didn't need to go to the doctor.</i>
Pharmacy convenience and accessibility	Positive associations with pharmacy accessibility and immediate service provision.	29	<i>It was convenient, you didn't have to book an appointment.</i>  <i>Going to the pharmacy was easier because if I need something for my ears you have it there already.</i>
Expanded scope for pharmacists	Support for pharmacists to provide other expanded services or an extension of this service (e.g. prescribing and syringing)	9	<i>If the pharmacists can see it's infected, they should be able to give me the drops (antibiotics).</i>  <i>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.</i>

295

296 As well as information presented in table 4, some consumers highlighted the opportunity to use  
 297 telehealth GP services with the imaging provided from the service to overcome some of the barriers  
 298 to accessing local GP services, including cost of appointments/lack of bulk-billing and distances to  
 299 access GPs of up to 600 kilometers.

300 *Pharmacist and GP Interview Data (Pre- and Post-) Feasibility and acceptability of service*

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3 301 Semi-structured interviews were conducted with participating pharmacists and GPs pre- and post-  
4 302 the intervention and analysed according to the thematic map, Figure 2. The interview duration  
5 303 ranged from 13 to 73 minutes with an average of 25 minutes.

7 304 Prior to the service trial, pharmacist and GP's expectation of the acceptability and feasibility of the  
8 305 service was explored in the context of **the current rural health landscape**.

10 306 Due to **gap in accessible healthcare** in the rural communities where the study was undertaken,  
11 307 consumer *acceptability* was expected by both participant groups.

13 308 Pharmacists described difficulty with accessing health professionals, wait lists in excess of two weeks  
14 309 for GP's and allied health professions as well as a lack of permanent health care providers and rapid  
15 310 turn-over of staff as having a negative impact on consumer care.

18 311 *Getting in to see a health professional is difficult, and then relationships as well, when*  
19 312 *they keep turning over, where our pharmacists seem to be pretty steady. A lot of remote*  
20 313 *areas that have visiting clinics, what happens when they're not visiting, who do they go*  
21 314 *and see? (P1 – Pharmacist)*

23 315 *There's a real scope for pharmacies to offer extra services, especially in rural areas*  
24 316 *...Purely geographically a lack of access to services, and I don't think just because you live*  
25 317 *in a rural area your health should be hindered. (P5 – Pharmacist)*

27 318 The pharmacists reported an **advantage** they expected of LISTEN UP was to increase rapport building  
28 319 with GPs through the direct referral process. GPs though, reported concerns about pharmacists taking  
29 320 work from junior doctors but recognised that in rural Australia the lack of health providers broadly  
30 321 means there is enough work for all.

33 322 *Providing services in rural communities across the board is very difficult, and anyone*  
34 323 *who can bring services where they aren't already should be encouraged. (GP6 – General*  
35 324 *Practitioner)*

37 325 After the study, GPs described the service and direct referral pathway as **compatible** with their current  
38 326 practice. They reported that all of the referrals they received were appropriate. GPs' perceived LISTEN  
39 327 UP to be an advantageous method of screening individuals who present to community pharmacy and  
40 328 setting them on a trajectory for GP care. They also expected young children to be more comfortable  
41 329 in the pharmacy setting.

44 330 *The foot traffic at a pharmacy is quite a lot on a daily basis. So the pharmacists are seeing*  
45 331 *people coming from different practices and bringing their prescriptions and whatever else*  
46 332 *they buy there. So having a good coverage of the community is an entry point for them to*  
47 333 *have that ear looked at. (GP2- General Practitioner)*

49 334 The pharmacists felt the structured approach and protocol supported the delivery and  
50 335 professionalism of the service.

52 336 *We don't have existing ear care services, so this model has all the advantages because*  
53 337 *it's actually a model and actually a service. (P2 – Pharmacist)*

55 338 GPs however, described a level of increased anxiety in consumers who had been referred and  
56 339 suspected this may be due to the language used by pharmacists when referring consumers.

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2  
3 340 Pharmacists identified enabling factors (*feasibility*) to the implementation of an ear health expanded  
4 341 practice model. These included the *willingness of pharmacists to develop expanded practice models*  
5 342 and their professional skills.

7 343 *We're familiar with the upskilling required, and we're enthusiastic about doing more*  
8 344 *application of health services, rather than hiding behind the dispensary. I think that the*  
9 345 *pharmacists coming through now are craving that and wanting that. (P1 – Pharmacist)*

11 346 There was an expectation that this expanded service may be a springboard for further service  
12 347 development and for both consumers and health professionals to be more accepting of an expanded  
13 348 scope for pharmacists.

16 349 *I am expecting advancement in our placement in the minds of the community that we*  
17 350 *service, of what we can actually achieve and what we can do as a pharmacist for them. (P1 –*  
18 351 *Pharmacist)*

20 352 *I hope it will bring about some results that will elicit a meaningful change in terms of*  
21 353 *broadening our scope of practice. (P5 – Pharmacist)*

23 354 Pharmacists reported the recent growth in professional service areas such as vaccinations had  
24 355 pharmacists feeling well placed to provide other expanded services for their communities. This was  
25 356 also identified as an enabler as some of the challenges of role conflict with GP's has already been  
26 357 addressed and relationships between the professional groups had adjusted to new service models.

29 358 *When we started the immunisation program, there was a lot of resistance there and now*  
30 359 *that it's a known kind of service, it's great, but at first, it was like we were taking from*  
31 360 *their role. (P8 – Pharmacist)*

33 361 After the study pharmacists continued to report a positive **pharmacist behaviour shift** towards  
34 362 expanded pharmacy broadly. Pharmacists described the study solidifying and extending their  
35 363 interest in working to their full scope.

37 364 *I really have enjoyed pushing that scope, learning something new, delving into a new*  
38 365 *domain. I think we need to keep doing it as pharmacists. We need to offer as much care*  
39 366 *as we can for people, and we need to push ourselves to do that, and not just rest on*  
40 367 *dispensing a script, especially if we want to be valued members of the healthcare system*  
41 368 *going forward. (P2 – Pharmacist)*

44 369 **Consumer behaviour shift** through increased confidence and knowledge of the potential for expanded  
45 370 pharmacy roles was a reported benefit of the study.

47 371 *People started to see us as actual health professionals that are available to the*  
48 372 *community, that you can actually touch and feel, that you have access to without an*  
49 373 *appointment. (P4-Pharmacist)*

51 374 Prior to the study, pharmacists reported advice on ear complaints was commonly sought by  
52 375 consumers with up to two presentations each day. They reported an overall lack of confidence with  
53 376 managing ear complaints based on symptomatic description from consumers and reported referring  
54 377 most ear complaints to a GP or hospital emergency department (ED). Pharmacists expected an  
55 378 improvement in their skills and knowledge in the management of ear complaints and the ability to  
56 379 provide better ear care in community.

58 380 *My conversation is always...I can't look in your ear. I can understand your symptoms,*  
59 381 *I'm hearing what you're saying, but it covers a lot of different things and I can't make*



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2  
3 382 *that decision on what you're telling me, and I also don't have much to offer you. (P5-*  
4 383 *Pharmacist)*

5  
6 384 After the study pharmacists reported increased **observability** and increased confidence in managing  
7 385 ear complaints as a result of having more information (otoscopy and tympanometry results) for  
8 386 decision making. The imaging of the ear canal was one of the most valued aspects of the service,  
9 387 improving pharmacist and consumer confidence in the service. Pharmacists were able to provide  
10 388 reassurance to patients and explain the anatomy and pathophysiology to consumers in real time.

11  
12  
13 389 *It's really nice showing them what their eardrum looks like, and explaining to some why*  
14 390 *they don't need antibiotics. (P2 – Pharmacist)*

15  
16 391 *Anything that we can get more data to help us be more definitive and clear in our referral*  
17 392 *pathways is helpful. (P2-Pharmacist)*

18  
19 393 Pharmacists reported being comfortable with recommending wax dissolvent and drying agents, but  
20 394 identified a barrier of the service model was the restriction of not being able to prescribe antibiotics  
21 395 or medicines only available with a doctor's prescription. There was optimism that the study would  
22 396 positively influence more products to be down-scheduled to become available for pharmacists to  
23 397 provide.

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25  
26 398 *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*  
27 399 *more. (P4 – Pharmacist)*

28  
29 400 After the study the pharmacists reported that the skills learnt during LISTEN UP, including the training  
30 401 improved their confidence in managing ear complaints from below average to 7+ out of 10.

31  
32 402 The training alone however was not deemed enough to improve confidence. Pharmacists discussed  
33 403 the **complexity** of the training provided and suggested that more face-to-face case studies were  
34 404 needed in addition to more content related to clearly identifying various pathology (**trialability**). Some  
35 405 pharmacists who had not conducted many consultations during LISTEN UP felt the training needed to  
36 406 include a greater volume of case examples to improve their confidence to provide the service.

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38  
39 407 *I don't have the confidence for a diagnosis at all and it's just purely from not doing enough*  
40 408 *and not getting feedback. (P3-Pharmacist)*

41  
42 409 Confidence however, improved with clinical experience and an enabler was the structured LISTEN UP  
43 410 protocol, supporting decision-making. Pharmacists reported needing to conduct at least ten  
44 411 consultations in the community pharmacy before feeling confident to provide the service  
45 412 independently.

46  
47 413 *I think I needed the first five to ten hours of practice, mainly just to get comfortable with*  
48 414 *actually how to talk to consumers and look inside the ear and all the techniques. But after*  
49 415 *that, I felt very comfortable. (P4-Pharmacist)*

50  
51 416 The flexibility and capacity of the current pharmacy service model was seen as both an enabler and  
52 417 barrier to LISTEN UP. Pharmacists expected the study to fit into the current no-appointment necessary  
53 418 workflow with strategies such as having additional pharmacists available to focus on professional  
54 419 services, advising consumers of longer wait times for prescriptions and asking consumers to come  
55 420 back to collect medicines.

1  
2  
3 421 *I'm very confident that there's going to be no problem with that. You just need to*  
4 422 *change your operational flow to support more hands-on time with the clients. (P1 –*  
5 423 *Pharmacist)*

7 424 After the study, workflow demands however were identified as a barrier to both the study and  
8 425 expanded practice generally. It was highlighted that a number of consumers received a consultation  
9 426 by a pharmacist but the occasion was not documented for the study. Time required for the  
11 427 documentation process and competing dispensary demands were reported as the reasons for this  
12 428 occurring. In addition, it was noted that as influenza vaccinations increased, the availability of the  
13 429 consultation room was limited and this inhibited the ability to offer LISTEN UP.

15 430 *I'd say there's double the number of people who we probably could have done, that we*  
16 431 *haven't done, because it wasn't the right time, we were too busy. (P8-Pharmacist)*

18 432 The length of the consultations were also raised as a potential barrier, with concerns when only one  
19 433 pharmacist was on-duty and expectation that it would be difficult to be able to offer the service  
21 434 during those times.

23 435 *Time is the biggest factor, we are often under the pump with the supply role so I think the*  
24 436 *clinical service can press you that little bit further. (P7 – Pharmacist)*

26 437 All pharmacists reported a lack of funding as a major barrier to LISTEN UP. They were concerned  
27 438 about the amount of time the consultations would take, the lack of remuneration for the study and  
28 439 no clear funding pathway for subsequent service provision.

30 440 *Taking into consideration our hourly rate and if you don't actually sell anything...no*  
31 441 *remuneration would be a big barrier. (P6 – Pharmacist)*

33 442 The **compatibility** of the service with rural practice was reliant on the number of pharmacists available  
34 443 at the pharmacies. Evidence of consumers being asked to come back at a time when more pharmacists  
35 444 were available was reported. This was compounded by the lack of remuneration associated with the  
36 445 study and thus the priority being placed on services that were profitable such as vaccinations, or  
37 446 dispensary tasks.

40 447 *If there were just two [pharmacists], then we're stretching it a bit. And we just definitely*  
41 448 *wouldn't offer it if there was just the one pharmacist. If they came in on a weekend, we'd*  
42 449 *ask them to come back during the week. (P4 – Pharmacist)*

44 450 Consumer and community support was highlighted as an enabler for the study. The pharmacists  
45 451 expected that their local communities would be highly receptive of the service and they were  
46 452 pleased that the local GPs were also supportive of the study and happy to be involved. After the  
47 453 study pharmacists reported that they felt the service built trust, rapport and confidence from  
48 454 consumers.

#### 51 455 **Future directions**

52 456 Integration of the documentation process into existing dispensary software was not achieved for this  
53 457 study however would be a focus for future services.

55 458 *If we could have it incorporated into our workflow to make it easier, part of a*  
56 459 *platform we already use, that would be cool, because technology makes things easy*  
57 460 *for us, and integrated technology is even better. (P4 – Pharmacist)*

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2  
3 461 The importance of the direct referral pathway with guaranteed appointment availability was also  
4 462 expected to be a major enabler for the study however it is highly unlikely this could be a permanent  
5 463 feature of future service models given the burden this places on an already stretched GP workforce.  
6 464 However, maximising digital technologies could further enhance timely medical assessment. Images  
7 465 and results provided by the pharmacists would enable GPs to conduct a telehealth appointment for  
8 466 the consumer for an immediate diagnosis and treatment.

9  
10  
11 467 *You would have done all the work, because the only barrier to effectively diagnosing a*  
12 468 *consumer with an ear problem by telehealth is not having a look in the ear. But if we are*  
13 469 *presented with the photo ... then absolutely you will be able to make a diagnosis and treat*  
14 470 *the consumer effectively by telehealth using this model. (GP1 – General Practitioner)*

15  
16 471 When asked about whether LISTEN UP should be rolled-out as a **national strategy**, all pharmacists  
17 472 agreed that it is a service community pharmacists can and should be providing, taking into  
18 473 consideration discussed barriers that this service would address. There was focus placed on the  
19 474 greater need in rural and remote settings and an uncertainty about how the service would be  
20 475 received in metropolitan settings.

21  
22  
23 476 *I think every pharmacist should be able to have the skills and knowledge to be able*  
24 477 *to look in someone's ear and decrease doctor's visits and ED referrals if it's a simple*  
25 478 *wax impaction or something like that. (P3- Pharmacist)*

## 26 479 **DISCUSSION**

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29 480 Exploring the feasibility, accessibility and acceptability of an ear health intervention from a health  
30 481 system, pharmacist and consumer level is integral to considering future expanded practice services  
31 482 for rural community pharmacy. This study has provided the first insight into the challenges and  
32 483 motivators for pharmacists to provide an ear care service and offers considerations for  
33 484 implementation of this and other expanded services going forward.

### 34 485 **Health system level**

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38 486 WHO has recognised the major health burden ear disease presents for rural and remote  
39 487 communities and has called for change to be made to ensure all people have equal access to quality  
40 488 ear and hearing care across the life course.(1) Access to health providers trained in ear health has  
41 489 been identified as a major barrier to ear care previously, with difficulty increasing with distance from  
42 490 metropolitan areas.(2) This study has found that consumers having difficulty accessing GP  
43 491 appointments consequently present to emergency departments for ear complaints. In addition,  
44 492 pharmacists prior to the intervention reported regularly referring consumers to emergency  
45 493 departments, due to an inability to access timely GP appointments. In a study of GP-type  
46 494 presentations to emergency departments undertaken at one of the ear study sites, it was found that  
47 495 half of all presentations over a six month period were GP-appropriate problems.(24)

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50  
51 496 LISTEN UP has provided the improved access to ear care by upskilling permanent and highly  
52 497 accessible health professionals, local community pharmacists. Consumers also reported the  
53 498 immediate access and the integrated pathway of GP referral as a major benefit to the service. GPs  
54 499 reported the referrals they received were appropriate and most consumers were able to be  
55 500 managed by pharmacists with analgesia and reassurance. The provision of a screening and referral  
56 501 service within local community pharmacies is an effective model to redirect ear complaints from  
57 502 emergency departments to appropriate settings.

### 58 503 **Pharmacist level**

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3 504 The provision of expanded services is an emerging area for Australian pharmacists.(25) To date no  
4 505 formal protocols have been developed to support pharmacists to provide expanded services, despite  
5 506 major developments for pharmacists' scope of practice internationally.(9) Research has reported  
6 507 rural pharmacists are supportive and interested to provide expanded services with expectation that  
7 508 such services would improve health outcomes and could address current gaps in healthcare.(12, 14)  
8 509 LISTEN UP has confirmed that pharmacists were motivated to provide an expanded ear health  
9 510 service. They described a lack of options currently available to manage ear complaints in community  
10 511 pharmacy and the regularity of referring consumers to emergency departments. After completing  
11 512 the formal training for the service, pharmacists reported improved confidence in managing ear  
12 513 complaints, but uncertainty in identify pathology and making prescribing recommendations. They  
13 514 expected their confidence would improve with practice and thus suggested longer trialability of the  
14 515 service to further develop their skills. They also reported wanting a very detailed protocol to be  
15 516 provided to guide them to provide the service.

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19 517 This lack of confidence in clinical abilities has been reported to be a major barrier to advancement of  
20 518 the pharmacy profession previously.(26) The culture of feeling inadequately prepared for unfamiliar  
21 519 tasks and fear of making definitive decisions has been linked to pharmacists' personality traits and  
22 520 thus the profession needs to make a transition from scientist to consumer-centred practitioner to  
23 521 successfully work in an expanded scope of practice.(26)

24  
25 522 In addition concern has been raised that expanded practice may not be feasible for rural practice as  
26 523 those pharmacies are already short-staffed and under-resourced.(27) Findings from LISTEN UP align  
27 524 with this, with recognition that three pharmacists are required to be able to offer expanded services  
28 525 and many rural and remote community pharmacies are unable to recruit and maintain that number  
29 526 of pharmacists. In addition, the time required to complete documentation was identified as a major  
30 527 barrier to the service implementation, mostly due to the pharmacists receiving no funding to provide  
31 528 the service with no cost to consumers. These challenges were reflected in the smaller than expected  
32 529 sample size and consequently the shorter duration of the study. This smaller sample size also  
33 530 reduces the transferability and generalisability of the findings of this study and reinforces the  
34 531 importance of a larger remunerated study with more participating pharmacies in future studies.  
35 532 Without a dedicated professional practice pharmacist, consumers were unable to be offered the  
36 533 LISTEN UP service, thus limiting feasibility and defeating the purpose of expanded practice for rural  
37 534 community pharmacy.

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42 535 The value of a collaborative model of care for expanded practice must be considered for rural  
43 536 practice. Community pharmacists historically have worked independently of other professions,  
44 537 however literature indicates that collaboration between health professional and community  
45 538 pharmacists is expected to improve health outcomes, particularly in chronic disease  
46 539 management.(26)

#### 47 48 49 540 **Consumer level**

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51 541 Findings from this study have highlighted a high level of acceptance from consumers with reports of  
52 542 trust and confidence from consumers for their local pharmacists. It has reported high levels of  
53 543 consumer satisfaction and a willingness to return for the service in future. Consumers have also  
54 544 reported a willingness to pay for the service due to the convenience and accessibility it provides.  
55 545 This willingness to pay for expanded services has been previously identified, however there is also  
56 546 recognition that those who are most vulnerable are likely not to be able to pay for the service and  
57 547 thus alternative funding models need to be considered.(10)  
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3 548 This study provides first insight into the feasibility, accessibility and acceptability of expanded  
4 549 practice for rural community pharmacists and identifies challenges that need to be addressed for  
5 550 this expanded pharmacy practice to be a sustainable model of health care delivery for rural and  
6 551 remote communities. It provides new knowledge to an area of unmet need in rural community and  
7 552 highlights challenges to ear care from consumer, health professional and pharmacist perspectives. A  
8 553 larger study with multiple sites is needed to further consider this model of care, including  
9 554 sustainability, patient outcomes, and collaborative integration in rural and remote communities.  
10 555 However adequate funding is essential to ensure high quality training, sufficient pharmacist numbers  
11 556 and low-cost provision for consumers.

## 14 557 **CONCLUSION**

16 558 Hearing is key to human function and its loss impacts the whole society. Ear care in rural community  
17 559 pharmacy is often fraught with uncertainty and referral to emergency departments. LISTEN UP  
18 560 provides a feasible protocol for trained pharmacists to provide immediate ear care with an  
19 561 accessible integrated pathway to general practice if needed. This model has been developed and  
20 562 accepted with extensive consultation and provides an initial framework for similar expanded services  
21 563 to be modeled on in the future. Rural community pharmacists remain motivated to provide  
22 564 expanded services, however sufficient funding and a paradigm shift for the pharmacy profession is  
23 565 essential for expanded services to be sustainable and thus contribute to improving healthcare in  
24 566 rural and remote communities.

## 28 567

## 29 568 **DECLARATIONS**

### 30 569 **Ethics approval and consent to participate**

31 570 This project has been approved by the Human Research Ethics Committee, James Cook University  
32 571 (reference number: H8187). Written informed consent was obtained from the study participants.

### 33 572 **Data availability statement**

34 573 The authors welcome any correspondence or requests for further details about this study. The  
35 574 datasets used and/or analysed during the current study are available from the corresponding author  
36 575 on reasonable request.

### 37 576 **Competing interests**

38 577 The authors declare that they have no competing interests.

### 39 578 **Funding**

40 579 This study is funded by the Department of Health through the Centre for Rural and Remote Health.  
41 580 The study has been reviewed by the Centre for Rural and Remote Health and an advisory panel  
42 581 consisting of key stakeholder organisations including Pharmaceutical Society of Australia, Pharmacy  
43 582 Guild of Australia, Gidgee Healing (Aboriginal Medical Service), and Australian Primary Health  
44 583 Network.

### 45 584 **Contributors**

46 585 ST, AC, and BG were involved in the conceptualisation and development of the study. ST and BG  
47 586 conducted the analysis. ST drafted the initial manuscript. AC and BG supervised the research, edited  
48 587 and reviewed the final manuscript.

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 591 their time and contribution to this study.

592

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667 **Figure 1: Process diagram of LISTEN UP study**

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

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676 **ENDNOTE AUTOMATED REFERENCE (Please disregard)**

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Figure 1: Process diagram of LISTEN UP study.

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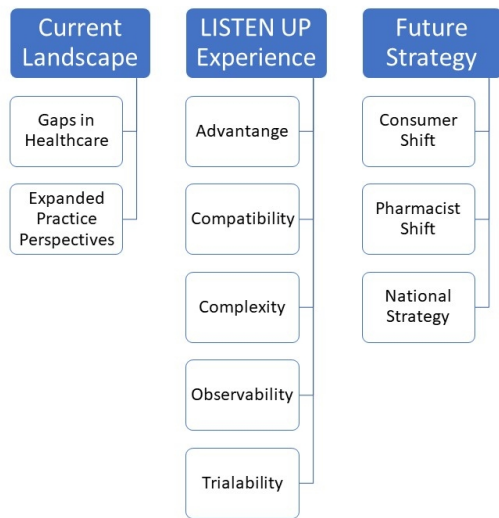


Figure 2: Thematic map illustrating the themes and codes for qualitative analysis of GP and Pharmacist Interviews.

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

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

Page/line no(s).

### Title and abstract

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

### Introduction

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

### Methods

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

1 2 3 4 5	<b>Data collection instruments and technologies</b> - Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	181-190
6 7 8	<b>Units of study</b> - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	245-254
9 10 11 12	<b>Data processing</b> - Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/de-identification of excerpts	218-232
13 14 15 16	<b>Data analysis</b> - Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale**	218-232
17 18 19 20	<b>Techniques to enhance trustworthiness</b> - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	227-232

### Results/findings

23 24 25 26	<b>Synthesis and interpretation</b> - Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	485-489
27 28 29	<b>Links to empirical data</b> - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	286-483

### Discussion

32 33 34 35 36 37 38	<b>Integration with prior work, implications, transferability, and contribution(s) to the field</b> - Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	484-554
39	<b>Limitations</b> - Trustworthiness and limitations of findings	61-71

### Other

42 43 44	<b>Conflicts of interest</b> - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	584-585
45 46	<b>Funding</b> - Sources of funding and other support; role of funders in data collection, interpretation, and reporting	586-591

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

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\*\*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

For peer review only

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

## 1. Introduction of self and purpose of the call.

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

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

## 2. Demographics

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

## SERVICE SUMMARY DOCUMENT

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

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

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

Attach images and results



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

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

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

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

5. <b><u>Rationale</u></b>	Informal or formal frameworks, models, concepts, and/or <a href="#">theories</a> used to explain the <a href="#">problem</a> , any reasons or <a href="#">assumptions</a> that were used to develop the <a href="#">intervention(s)</a> , and reasons why the <a href="#">intervention(s)</a> was expected to work
6. <b>Specific aims</b>	Purpose of the project and of this report
<b>Methods</b>	<i>What did you do?</i>
7. <b><u>Context</u></b>	Contextual elements considered important at the outset of introducing the <a href="#">intervention(s)</a>
8. <b><u>Intervention(s)</u></b>	<ul style="list-style-type: none"> <li>a. Description of the <a href="#">intervention(s)</a> in sufficient detail that others could reproduce it</li> <li>b. Specifics of the team involved in the work</li> </ul>
9. <b>Study of the Intervention(s)</b>	<ul style="list-style-type: none"> <li>a. Approach chosen for assessing the impact of the <a href="#">intervention(s)</a></li> <li>b. Approach used to establish whether the observed outcomes were due to the <a href="#">intervention(s)</a></li> </ul>
10. <b>Measures</b>	<ul style="list-style-type: none"> <li>a. Measures chosen for studying <a href="#">processes</a> and outcomes of the <a href="#">intervention(s)</a>, including rationale for choosing them, their operational definitions, and their validity and reliability</li> <li>b. Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency, and cost</li> <li>c. Methods employed for assessing completeness and accuracy of data</li> </ul>
11. <b>Analysis</b>	<ul style="list-style-type: none"> <li>a. Qualitative and quantitative methods used to draw <a href="#">inferences</a> from the data</li> <li>b. Methods for understanding variation within the data, including the effects of time as a variable</li> </ul>
12. <b>Ethical Considerations</b>	<a href="#">Ethical aspects</a> of implementing and studying the <a href="#">intervention(s)</a> and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest
<b>Results</b>	<i>What did you find?</i>
13. <b>Results</b>	<ul style="list-style-type: none"> <li>a. Initial steps of the <a href="#">intervention(s)</a> and their evolution over time (e.g., time-line diagram, flow chart, or table), including modifications made to the intervention during the project</li> <li>b. Details of the <a href="#">process</a> measures and outcome</li> <li>c. Contextual elements that interacted with the <a href="#">intervention(s)</a></li> <li>d. Observed associations between outcomes, interventions, and relevant contextual elements</li> <li>e. Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the <a href="#">intervention(s)</a>.</li> <li>f. Details about missing data</li> </ul>
<b>Discussion</b>	<i>What does it mean?</i>
14. <b>Summary</b>	<ul style="list-style-type: none"> <li>a. Key findings, including relevance to the <a href="#">rationale</a> and specific aims</li> <li>b. Particular strengths of the project</li> </ul>

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

**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**

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3 Loss of the ability to perform other tasks or meet other responsibilities resulting from the diversion  
4 of resources needed to introduce, test, or sustain a particular [improvement](#) initiative  
5  
6

### 7 **Problem**

8 Meaningful disruption, failure, inadequacy, distress, confusion or other dysfunction in a healthcare  
9 service delivery [system](#) that adversely affects patients, staff, or the [system](#) as a whole, or that  
10 prevents care from reaching its full potential  
11

### 12 **Process**

13 The routines and other activities through which healthcare services are delivered  
14  
15

### 16 **Rationale**

17 Explanation of why particular [intervention\(s\)](#) were chosen and why it was expected to work, be  
18 sustainable, and be replicable elsewhere.  
19

### 20 **Systems**

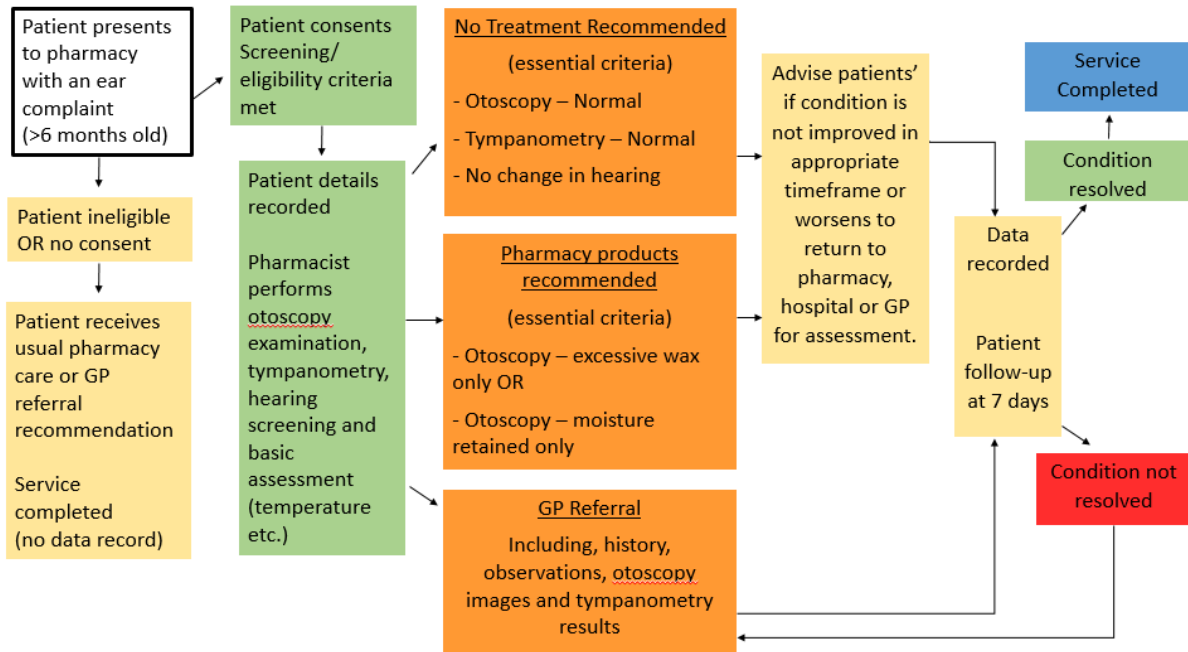
21 The interrelated structures, people, [processes](#), and activities that together create healthcare services  
22 for and with individual patients and populations. For example, systems exist from the personal self-  
23 care system of a patient, to the individual provider-patient dyad system, to the microsystem, to the  
24 macrosystem, and all the way to the market/social/insurance system. These levels are nested within  
25 each other.  
26  
27

### 28 **Theory or theories**

29 Any “reason-giving” account that asserts causal relationships between variables (causal theory) or  
30 that makes sense of an otherwise obscure [process](#) or situation (explanatory theory). Theories come  
31 in many forms, and serve different purposes in the phases of [improvement](#) work. It is important to  
32 be explicit and well-founded about any informal and formal theory (or theories) that are used.  
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Clinical characteristics Table (N=55)

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



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