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NHS
South West London

Evaluation of the South West London Hearing Health Pathway Pilot

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Health Innovation Wessex

CONTENTS

The evaluation of the South West London Hearing Health Pathway pilot has been delivered by NHS South, Central and West Commissioning Support Unit (NHS SCW) for, and on behalf of, NHS England. NHS SCW also partnered with Health Innovation Wessex (formerly Wessex Academic Health Science Network) for a proportion of the evaluation to develop the evaluation protocol, provide qualitative thematic analysis and synthesise findings.

1 EXECUTIVE SUMMARY

Hearing is one of our most precious senses, and it is essential for connecting with our surroundings, socialising with others, and learning.

NHS South West London Integrated Care Board (NHS SWL ICB) has recognised that there is a lack of equitable and free NHS hearing health services in the area. This can lead to patients facing long waiting times, health inequalities, and increased secondary care backlogs. It can also mean that senior ear, nose and throat (ENT) clinicians' time and skills are not being used as efficiently as possible.

To address this need, NHS SWL ICB developed and implemented a 12-month hearing health pilot pathway in September 2022. This was delivered across 21 community pharmacy sites located in the boroughs of Merton, Wandsworth and parts of Richmond[1].

The pathway offered the opportunity for patients with hearing health issues to be referred to their local participating pharmacy by their general practice. The pilot has utilised an innovative three-in-one otoscopy device, allowing trained pharmacy staff to perform digital otoscopy, earwax removal and hearing checks on patients. The ear, nose and throat (ENT) Clinical Network, which involves leadership and collaboration with primary and secondary care, Acute Provider Collaborative and NHS SWL ICB, have supported this pathway.

NHS England has followed the pilot closely to determine whether this model could be applied suitably by other ICBs. NHS England appointed NHS South Central and West Commissioning Support Unit (NHS SCW) to conduct an independent evaluation which explores the key learnings, findings and impacts of the pilot.

Pilot – Key outcomes

7,648 patients

Were referred by 72 general practices to the overall 21 community pharmacies during the pilot.

5,353 patients

(70% of referrals) completed treatment in community pharmacies during the pilot over 5,783 appointments.

85%

(4,531) of patients treated received an ear canal examination, followed by earwax microsuction and/or hearing check.

36%

Of patients were seen within one week, while 87% were seen in less than four weeks.

193

(3%) of patients completing appointments resulted in a recommendation for the patient to be referred on to secondary care, either ENT or Audiology, through their general practice.

[1]21 pharmacies selected in to the pilot and were trained on the device, with 18 pharmacies participating in the full 12 months of the pilot

Evaluation Framework and Approach

The evaluation framework has been underpinned by a set of five evaluation dimensions to provide a systematic and objective assessment of the pilot, detailed in this report.

Acceptability

Feasibility

Usability

Sustainability

Safety

The key insights to each of these evaluation themes are summarised below.

Acceptability

Reflecting the extent to which the relevant stakeholders, and patients, consider the service to be appropriate and acceptable.

- The pilot service has been widely accepted by the majority of professional staff and stakeholder teams involved and most importantly, patients.
- Staff stakeholders accepted the benefits for patients to access free and local hearing health services, as well as increased job satisfaction and upskilling of pharmacy roles.
- 95% of all professional stakeholders responding to the temperature check surveys rated their experience as 'Very Good' and 'Good', and the majority would recommend the service if commissioners were considering implementing the service elsewhere.
- Patient experience of the service was very positive. 99% of patients reporting they were happy with the service received and 98% would recommend this service to family and friends.
- 100% of patients surveyed agreed that pharmacy staff clearly explained the procedures that were carried out, and 98% agreed that the staff clearly explained what will happen after the appointment.
- The average patient waiting time from general practice referral to their first contact from community pharmacy was 14.4 days. This was found to be acceptable by patients. 90% of patient survey respondents agreed with the statement: "I was offered an appointment in pharmacy sooner than I expected."
- Both staff and patients were impressed by the innovation of the device and its capabilities.

Usability

Exploring the ease of use and the extent to which the pilot service has been used by referred patients and staff. This includes the technology, effectiveness, efficiency and satisfaction.

- Staff stakeholders have generally found both the pathway and technology (device and IT systems) straightforward to use, without disrupting established workflows.
- Improvements were suggested for mechanisms to further increase patient choice and access. This is through enabling referring general practices visibility of waiting times, or appointment slots, at different pharmacies.
- Secondary care staff felt that the small number of referrals seen so far from this pilot were appropriate. At this time, the impact on primary and secondary care waiting lists cannot be identified in the activity data to understand whether activity is being diverted and latent demand is not being generated.
- Health inequalities impacts could not be examined due to limitations in the available data during this pilot evaluation.
- Both community pharmacy and general practice staff rated the training highly, finding it helpful and effective in delivering the service.

Safety

Examining the safety of the overall pathway and technology.

- The development and implementation of governance processes has been of central importance to the SWL project team in ensuring the pathway is delivered safely.
- Triage processes appeared to have worked well and there is evidence that the quality reporting processes and feedback loops have been effective.
- Ongoing improvements are recommended to the referrals process, including training. This will ensure consistent understanding, and application of, the inclusion and exclusion criteria, to support minimisation of red flags and inappropriate referrals.
- From a patient safety perspective, there has been no evidence to suggest that patients are coming to harm from non-registered professional staff performing earwax removal during this pilot.
- The evaluation has not identified any digital safety incidents or near-misses during the pilot.

Feasibility

Looking at the key practicalities and enablers of implementing a hearing health service and associated technology within a community pharmacy setting.

Insights gathered as part of the evaluation have illuminated both the critical success factors and potential challenges of implementing the service. These findings provide valuable guidance for future endeavours and highlight the importance of adaptability and continuous improvement in service implementation.

Enablers to implementation

- Collaboration and communication
- Ease of resolving operational issues
- Engagement
- Planning and practice delivery
- Governance, roles and responsibilities
- The role of data
- Systems and processes
- Organisational change

Sustainability

Assessing the long-term viability and sustainability of the service by focusing on the financial, workforce and environmental factors when considering future roll outs and at scale commissioning.

- The hearing health pilot delivered in the community settings has shown to be sustainably worthwhile and effective. The advantages for the local patient populations and health care systems are noted in the feedback received.
- Key aims of the pilot have been supported in anecdotal feedback, as outlined in the Usability section. Ongoing monitoring will be required to ensure the quantitative data aims summarised below are achieved.
    - Diversion of activity from general practices and secondary care.
    - Reduction in health inequalities.
- Initial analysis suggests the pilot may have seen a positive impact in providing care closer to home and reducing travel times for patients and associated CO2 emissions. This will require further monitoring over time to ensure indicative benefits are realised and sustained.
- There has been shared optimism around opportunities to develop the pharmacy workforce and delivering additional services within a community pharmacy setting.
- The pilot has generated potential cost savings (non-cash releasing) when compared with delivering similar activity in secondary care. There is potential to generate further cost savings if available capacity is utilised effectively.
- Current payment structures should be reviewed to ensure they remain viable for supporting community pharmacy participation.

Report Conclusions

Overall, the evidence suggests that the pilot appears to be a worthwhile and effective service, that is beneficial for local patients hearing health needs. Patient demand for the service is high, with 70% of total referrals resulting in completed treatments. Community pharmacy appeared to have suitable capacity to deliver the service, providing that nominated staff were sufficiently trained. The benefits for patients, and advantages of delivering this service within a community setting, have been widely accepted by most professional staff and stakeholder teams.

The evaluation captured several opportunities for ongoing improvement of the pathway for NHS SWL ICB, noting that many of the issues raised, and opportunities for improvement, are likely to be reflective of embedding a new service. A number of detailed recommendations are set out in the 'Recommendations' section for NHS SWL ICB to consider. Key recommendations for ongoing improvement include:

- Improve clarity and application of the referral process to avoid issues around inappropriate referrals.
- Ensure governance and quality reporting processes continue to be robust.
- Continue to monitor the workforce model's safety and quality for patients. Ensure effective assurances are in place, with clearly defined roles and responsibilities.
- Consider ways in which the capacity can meet the demand more efficiently, to ensure community pharmacy utilisation is as high as possible. This will support minimisation of patient waiting times and support patient choice of pharmacy location.
- Consider the detailed recommendations set out below.

A larger activity data set is required to evidence several key aims of the pilot. It is recommended that NHS SWL ICB continue to monitor service performance, including the following key metrics below.

- If activity does reduce in general practices and in secondary care.
- If health inequalities are reduced.

In terms of overall value for money and financial sustainability comparing the pre- and post-pilot delivery models, the pilot has generated potential cost savings (non-cash releasing). The net savings per patient who would otherwise have received treatment in an acute setting was £49.01 (total £262,079 across the pilot period) and the net savings per patient who would otherwise have received treatment in a general practice was £2.01 (total £10,770 across the pilot period).

Utilisation across pharmacy sites has varied during the pilot period and the cost savings could potentially be greater if available capacity at the active pharmacy sites were fully utilised. Scenario modelling assuming a best-case scenario of 85% utilisation across the pharmacy sites, would show a unit cost saving of £36.81 per appointment compared to treatment in a general practice, and a unit cost saving of £68.16 per appointment compared to treatment in an acute setting of care.

Overall, the pilot pathway has appeared to benefit the local health and care system; and is a service which can be rolled out sustainably moving forward, 94% of professional stakeholders responding to the temperature check surveys reported that they would recommend the service if it were to be implemented elsewhere.

Recommendations

A series of recommendations are set out below for consideration by NHS SWL ICB, and for NHS England, and by ICS commissioners considering implementing a pilot or at scale commissioning model of a hearing health pathway in community pharmacy. The themes of recommendations for ICS's/at scale commissioning are summarised below.

Recommendation themes for ICS's/at scale commissioning

Culture and relationships

Create a sense of community and purpose to foster innovation and creativity.

Design of a local model

Ensure governance processes, pathways and oversight are tailored to the needs of the system and the population it serves.

Information sharing and data

Support professionals by ensuring quality information sharing, and patient visibility of waiting times, to support and enhance patient choice.

Safety, governance and workforce model

Develop the local workforce model, supported by robust and effective governance processes.

Commissioning and contracting

Processes, tariffs and payment structures that are realistic and viable.

Set up of a pilot / service model

Service mobilisation and establish commissioner/provider responsibilities.

Implementation

Maintain strong collaboration and communication between stakeholders.
Embed a sustainable service model.

2 INTRODUCTION AND BACKGROUND

2.1 Introduction

Hearing is one of our most precious senses, and it is essential for connecting with our surroundings, socialising with others, and learning. By 2030, hearing loss in the UK will overtake diabetes and cataracts in the top 10 disease burdens[3]. Recent studies have shown an increased risk between hearing loss and mental/cognitive health decline, as well as loneliness and social isolation, greatly impacting a person's quality of life. Proper management of hearing loss can help to reduce the risk of these outcomes and can prevent the onset of dementia[4].

NHS SWL ICB has recognised that there is a lack of equitable and free NHS earwax removal and hearing health check services in the area. Earwax removal treatments are provided in some general practices, but this has been variable due to capacity constraints and non-standardised local commissioning arrangements. Patients may often be referred onto an ear, nose and throat (ENT) consultant or audiologist within secondary care and consequently face long waiting times or may be directed to seek private treatment elsewhere at their own cost or may choose to seek private treatment to avoid waiting.

These gaps in service provision in South West London can often lead to patients facing long waiting times, health inequalities, and increased secondary care backlogs. It can also mean that senior ENT clinicians' time and skills are not being used as efficiently as possible. South West London Outpatient and Elective Care Recovery programme has identified ENT as one of the highest priority areas in NHS SWL ICB. In June 2021, there were 8,100 outpatients on the South West London patient treatment list (PTL) for ENT.

To address this need, NHS SWL ICB developed a new pilot pathway in community pharmacy settings, using an innovative three-in-one otoscopy device, allowing trained community pharmacy staff to perform digital otoscopy, earwax removal and hearing checks. An independent options appraisal was conducted by Health Innovation Network South London, and the ENT Clinical Network, which involves leadership and collaboration with primary and secondary care, Acute Provider Collaborative and NHS SWL ICB supported this pathway. The device chosen for the pilot was provided by TympaHealth Technologies and procured specifically because of its suitability for use by trained staff in community pharmacy settings.

The pilot pathway and related technology were both introduced in community pharmacies across three South West London boroughs: Merton, parts of Richmond, and Wandsworth, and the patient treatment was delivered by trained pharmacy staff.

The pilot supported NHS SWL ICB with fulfilling the ambitions set out in the NHS Long Term Plan particularly around bringing primary and community healthcare together, making use of innovative data and digital technologies, making better use of workforce in the community through training and upskilling, improving patient access, care and outcomes, and making best use of taxpayers' investment in the NHS. In addition, the pilot aligned with the National Institute for Health and Care Excellence (NICE) guidance on hearing health for adults, supporting with "providing earwax removal closer to home, in primary care or community ear care services, [which] will prevent the inappropriate use of specialist services" (NICE, 2018[5]).

[3]Archbold SL, B.;. 2016. The Real Cost of Adult Hearing Loss: Can We Afford to Wait. The Ear Foundation

[4]Livingston G, Sommerlad A, Orgeta V, Costafreda SG, Huntley J, et al. 2017. Dementia prevention, intervention, and care. Lancet (London, England) 390:2673-734

[5]https://www.nice.org.uk/guidance/ng98/chapter/Recommendations#assessment-and-referral

The primary goals of this pilot pathway are to reduce patient waiting times and alleviate the backlog of ENT and audiology cases in secondary care thus releasing capacity for ENT and audiology specialists in hospital settings to manage more complex patient referrals and procedures. Appendix A outlines the anticipated key benefits of launching the pilot service and how these benefits would be evidenced.

NHS England's Pharmacy Integration Programme has followed the pilot closely to determine whether this model could be suitable to be applied by other ICBs. Earwax removal is generally a non-regulated service when delivered in pharmacies or other community/high-street settings as a private service. The General Pharmaceutical Council (GPhC) regulate registered pharmacy premises. This regulation covers the delivery of clinical services via a set of high level standards. This pilot service would be an example of a clinical service. The GPhC also regulate pharmacy professionals (pharmacists and pharmacy technicians).

When GPhC inspectors inspect pharmacies, they look into the delivery of clinical services. They usually refer to the external recognised guidelines and or standards to aid them with this. In the case of an ear wax removal service, this would mean referring to standards developed by a relevant national body such as Improving Quality in Physiological Services (IQIPS) or the British Society of Audiology (BSA). Currently such standard is not available.

Audiology services in secondary care settings can be accredited with IQIPS which is a UKAS standard for physiological services. NHS England recommends IQIPS (IQIPS[7]) accreditation in secondary care. An equivalent of this IQIPS standard for community settings or pharmacies is not currently available.

In addition, the NHS Long Term Workforce Plan (June 2023[6]) states that pharmacists and pharmacy technicians are also increasingly working within primary care networks, to provide enhanced clinical services alongside general practices and a wider multidisciplinary team.

It is suggested that; "through proportionate regulatory reform, pharmacy technicians will be able to supply medicines and services through Patient Group Directions. This, combined with legislative changes will enable the NHS, and particularly community pharmacies, to make better use of the available skills mix and technology in pharmacies, will ensure pharmacy technicians can work most effectively as part of wider primary care teams and across the NHS" (NHS Long Term Workforce Plan, June 2023). Government intends to consult on these changes in due course.

This means key aspects of a model of hearing health treatment in a community/high street setting, including the governance, workforce model, quality assurance and compliance framework, will need to be key considerations of any scalable commissioning framework. The experiences of these areas in this pilot in South West London are reflected on in this report to inform next steps.

NHS England appointed NHS South Central and West Commissioning Support Unit (NHS SCW) to conduct an independent evaluation on this pilot to determine if there is a viable and scalable clinical pathway, with specific aims to:

- Explore the impact of the service on patients and professional stakeholders.
- Capture key findings and learnings to determine the viability of the service.
- Understand the realised benefits of launching a new innovative hearing health service.
- Set out key recommendations for future implementations by integrated care systems.

NHS SCW has partnered with Health Innovation Wessex (formerly Wessex Academic Health Science Network) for a proportion of the evaluation for their expertise and additional capacity in developing the evaluation protocol, developing interview guides, providing qualitative thematic analysis and synthesising findings.

[6] https://www.england.nhs.uk/wp-content/uploads/2023/06/nhs-long-term-workforce-plan-v1.2.pdf

[7] IQIPS: Improving Quality in Physiological Services https://www.ukas.com/accreditation/standards/iqips/

2.2 Evaluation Design and Methodology

This evaluation examines five evaluation dimensions, through which to consider and evaluate the pilot. Each evaluation dimension has been derived from the detailed evaluation specification and underpinned by a series of key lines of enquiry (KLOEs) that set out specific criteria for assessment. The evaluation specification is set out in Appendix A. Each of the five evaluation dimensions, singularly and together, offer a lens through which to consider all of the evidence and insight gathered during the evaluation.

- **Acceptability** – reflecting the extent to which the relevant stakeholders, including and patients, consider the service piloted to be appropriate and acceptable.
- **Usability** – exploring the ease of use and the extent to which the pilot service has been used by referred patients and staff, including the technology, measuring its effectiveness, efficiency, and satisfaction.
- **Safety** – examining the safety of the overall pathway and technology.
- **Feasibility** – looking at the key practicalities (the enablers and barriers) of implementing a hearing health service and associated technology within a community pharmacy setting.
- **Sustainability** - assessing the long-term viability and sustainability of the service by focusing on the financial, workforce and environmental factors when considering future roll outs and at scale commissioning.

Evaluation Approach

This evaluation incorporated a mixed methods approach, using both qualitative and quantitative research methods to effectively measure and assess the service model pilot, based on the five key evaluation dimensions listed above. Providers of the quantitative datasets are listed below. These datasets were used by the evaluation team to review and analyse the impact of the pilot service both numerically and statistically.

- **PharmOutcomes** provided data about the number of referrals, patient attendance rates, tier 1, and tier 2 procedures, follow-up appointments and waiting times. The data also included referrals sent from and to general practices using the EMIS IT system interacting with PharmOutcomes used in community pharmacies.
- **TympaHealth** offered remote review service data.
- **Secondary Uses Service (SUS)** provided referrals data to and from secondary care.
- **NHS SWL ICB Baseline business case and financial data** was obtained to inform the financial aspects of this evaluation.
- **Travel Times analysis** was completed using TravelTime software to plot the road network (not straight-line distance), between locations. Carbon calculations were then calculated using "Business Travel – Land" for Car by Size (Average Car) in miles, for a Petrol vehicle where (@Value(site_Distance (Miles))*0.26379).

Primary and qualitative data collection methods involved regular surveys, online focus groups and one-to-one interviews to gather in-depth insights and experiences of the pilot from professional staff, stakeholders and patients. Online surveys were managed using NHS SCW's Join the Conversation engagement platform from January to September 2023.

- **Patient surveys** (online link sent via text message or paper copy) sought to understand and quantify patients' satisfaction and experience of the pilot service, following a completed pharmacy appointment. A series of 17 non-compulsory closed-ended questions were asked, along with an optional open-ended question to leave a review of the service, which were analysed to identify key themes. A total of 551 patient surveys were completed, an overall response rate of 12% of those who completed the pathway.

- **Temperature check surveys** were conducted at quarterly intervals during the pilot to understand the overall experiences of the professional staff stakeholder groups involved in the pilot. The third and fourth survey included additional questions to the pharmacy staff, specifically exploring the duration of individual appointments. A total of 105 submissions were received across the four surveys.

- **A series of seven focus groups** were held between March and May 2023 with the professional staff stakeholder groups involved in delivering the pilot, including community pharmacy and general practice staff, IT provider, device provider and the SWL project team. Open-ended questions were asked to stimulate discussion and reflections on levels of confidence in the service, the implementation and operational processes, challenges commonly faced, and benefits to patients. The outputs of the sessions were thematically analysed by the evaluation team.

- **Targeted one-to-one interviews** were conducted between May and August 2023. Using purposive sampling methodology, nine general practice, one secondary care, and nine community pharmacy staff members involved in the pilot provided in-depth insights and opinions about the delivery, acceptability, usability, safety and sustainability of the service. Each 30-minute semi-structured interview was conducted and recorded using Microsoft Teams. Anonymised transcripts from the open-ended questions and the responses were thematically analysed by Health Innovation Wessex using the Braun and Clark method. In addition to the interviews there were two instances where participants were unable to commit to an interview session (one general practice and one secondary care staff member). In both cases, online surveys were produced in accordance with the general practice and secondary care interview questions and sent to participants for their feedback.

2.3 Evaluation Limitations

Four specific limitations are associated with this evaluation, outlined below

Data Quality

Community pharmacy is a front-line healthcare service which often operates in a highly pressurised environment, and much of the data collected during this pilot has relied heavily on data inputted by staff who are already delivering multiple services to patients. It is therefore expected that the quality of some of the data received has not been high, compared to the datasets which had designated clinical coders. Pharmacy staff may also not be experienced in recording patient interactions and had to develop familiarity with using a bespoke data input form. For example, challenges were noted during the pilot around understanding the exact number of patients who did not attend (DNA) their appointment, and a larger than expected number of DNAs were recorded. Subsequently, a list of drop-down reasons for DNAs were included in the latter stages of the pilot and a review of the free text fields collected earlier in the pilot was conducted by the evaluation team to understand the numbers and reasons for a recorded DNA. This allowed the evaluation to differentiate between DNAs and other reasons for a patient not completing treatment, for example if the pharmacy was unable to contact the patient.

Data Gathering

The opportunity to assess impact of the pilot pathway in primary and secondary care was limited due to the lack of a local clinic code and the COVID-19 pandemic. We were unable to accurately identify patients within the target cohort for the pilot and instead opted to measure the number of earwax removals being completed in both general practice and secondary care outpatient appointments in a pre-pandemic baseline period (2019/20 financial year) versus the equivalent months of the pilot. COVID-19 had, and continues to have a significant impact on clinical services in all settings. Therefore, it is recognised that it is difficult to attribute any change in activity levels to a single intervention.

Additionally, the evaluation faced challenges in obtaining patient postcode information due to information governance procedures. For this reason, geospatial analysis was conducted using a patient's registered general practice location as a proxy for their location. While this is often considered a sensible proxy, in densely populated urban areas such as South West London, it has its limitations. This absence of demographic and other data means there was a limited opportunity to assess the health inequalities impacts of the pilot.

Finally, there were challenges in obtaining qualitative feedback from all stakeholder groups. While efforts were made to engage with all general practices and community pharmacies involved in the pilot, a number of external factors may have impacted the ability of stakeholders to participate in the evaluation. The evaluation recognises that the representation in the qualitative feedback does not cover all participants.

Unconscious Bias

Some healthcare professionals providing qualitative feedback may be individuals who actively hold different roles within the healthcare system, or have previous experience which may influence their views and opinions. This risk was recognised and mitigated to some degree by seeking feedback from a range of perspectives and anonymising responses.

Patient Feedback

The patient survey was only available in English, meaning some patients who may not be confident in their English language skills may have struggled to respond, or required help from family or friends. Additionally, only patients who completed the pathway were asked to complete the survey, meaning no feedback is available from those who did not. Analysis of dropped/rejected referrals has helped to unpick reasons for referrals not progressing or completing the pathway, but this cohort of patients remain a further evaluation opportunity, to understand what would enable them to better access the service or to complete the pathway.

2.4 Background

Pilot Set Up

NHS SWL ICB commenced planning and preparation for a hearing health pathway pilot in community pharmacies in Spring 2021 with a subsequent business case process and training of local pharmacy staff in Summer 2022. The 12-month pilot commenced in September 2022 in three boroughs in South West London. NHS SWL ICB selected the community pharmacy model as the preferred delivery option because they were able to mobilise quickly and at scale. Furthermore, it appeared to be acceptable to patients and there were already successful examples of the model being used in community pharmacies that demonstrated proof of concept.

A number of community pharmacies expressed an interest in participating in the pilot and a number of factors were considered in the selection process. For example, considering health inequalities, deprivation across the boroughs, and if the pharmacy could offer any additional communication skills/languages at the interested sites, as well as ensuring pharmacies could provide the required resources and infrastructure to deliver the service. A total of 20 community pharmacy sites were selected to take part in the pilot, across three boroughs: 10 from Wandsworth, 6 from Merton and 4 from Richmond. Early in the pilot, one of the original sites in Richmond withdrew their participation and was replaced by another pharmacy in the same borough, which had previously expressed an interest in joining.

The TympaHealth hearing health device was chosen for this pilot because of its innovative three-in-one functionality to perform digital otoscopy, earwax microsuction and hearing health check. A total of 20 TympaHealth devices were purchased and provided to the participating pharmacies for the 12-month period. TympaHealth provided online and face-to-face training to a nominated pharmacist, pharmacy technician and/or pharmacy assistant in each of the participating pharmacies over a six-week period and were provided certification, accredited by British Society of Audiology (BSA), ENT UK and The British Society of Hearing Aid Audiologists. The accredited training enabled the pharmacy teams covered by the indemnity that they hold with the National Pharmacy Association (NPA) to be updated. This enabled teams, including pharmacy technicians and assistants, to undertake the hearing health pathway procedures under the supervision of a pharmacist. Ongoing support was also provided throughout the pilot.

PharmOutcomes is a clinical web-based platform to capture outcomes data for local pharmacy services and was utilised to deliver the overarching IT and referral systems for the pilot. Additional training was provided around the data and IT aspect of the service.

Clinical members of the NHS SWL ICB project team also provided information to general practice staff involved in the pilot, regarding the referral criteria and process.

A NHS SWL ICB task and finish group referred to as SWL project team in this report was set up to oversee and implement the new service using the TympaHealth hearing health device. Clear governance routes to the South West London Outpatient Transformation Programme and the SWL ENT Clinical Network were incorporated.

The SWL project team comprised a range of stakeholders and met at least weekly throughout the pilot setup, implementation and delivery phases.

Membership of the SWL project team incorporated: a secondary care consultant and a GP as the co-clinical leads; SWL ENT Clinical Network pharmacist and transformation manager; Local Pharmaceutical Committee leadership and project management; technology and device supplier representation from PharmOutcomes and TympaHealth; NHS SWL ICB quality representative; and NHS England Pharmacy Integration representative.

The role of the SWL project team evolved through the course of the pilot, from inception and delivery of the pilot set-up, through to data tracking and operational issue resolution, and incorporated decision-making and escalation responsibilities.

Pre-pilot Pathway

The primary entry point for the pre-pilot hearing health pathway in South West London was a patient contacting their GP. This resulted in being provided with an information leaflet, with advice to use pharmacy supplied ear drops for 10 to 14 days, before seeking further treatment is the problem persisted. The patient would typically then revisit their GP. If the general practice did not provide an earwax removal treatment the patient would be referred to a secondary care ENT specialist. NHS SWL ICB analysis determined that patients may also be advised to seek private services for earwax removal, although this is unaffordable for many requiring treatment.

Otoscopy, earwax removal and hearing checks were generally performed in secondary care outpatient appointments. When referred to secondary care, the ENT consultant would initially investigate and provide the appropriate earwax removal treatment but if a patient was experiencing hearing loss, they would be referred onwards to an audiologist. If earwax was identified during an audiology appointment, the patient would be rebooked for an earwax removal appointment by the audiologist or referred to an ENT consultant or to a general practice. Please refer to appendix B for a diagram of the pre-pilot pathway.

Pilot Referral Pathway

A new referral pathway was designed for the pilot service, allowing local general practices to refer patients into the service based on pre-defined inclusion and exclusion criteria. Subsequently, community pharmacies could update patient records or provide recommendations back to the patient's GP following the appointment, ensuring continuity of appropriate care.

The pilot pathway specifies that once a patient has been identified as suitable for the service by the general practice, they are required to consent for the community pharmacies to access their patient records and triage for suitability, prior to any consultation taking place. Where patients did not consent, they could not progress into the pilot service and are referred back to their general practice. Patients were provided self-care guidance and were advised to use earwax softening agents for 10 to 14 days (such as olive oil) prior to their appointment at the community pharmacy. During the pharmacy consultation, digital otoscopy was conducted to examine the patient's ear canal and to identify if earwax is present. Where earwax was found to be obstructing over 50% of the ear drum, a microsuction procedure was performed by the trained community pharmacy staff member (pharmacist, pharmacy technician, pharmacy assistant). Follow-up appointments were offered if necessary and the use of earwax softening drops recommended as required. If these measures proved ineffective, patients were referred to their GP for further consultation. Successful treatment resulted in the patient being discharged. A record of the consultation was sent to the patients GP electronically via the NHS.net email system, to allow the patients EMIS medical record to be updated. EMIS is the electronic patient record clinical system used locally in general practice.

If no earwax had been found but the patient reported hearing loss, a hearing check was performed by the trained staff member. Where the hearing check highlighted abnormalities, the images captured from the TympaHealth device and audiometry results were shared with the GP for review, along with an electronic record of the consultation. Where urgent issues were identified requiring escalation, patients were encouraged to make an appointment with their GP or to call 111. If the situation was urgent, the patient was advised to attend their local emergency department.

Pharmacy staff also had an option to access remote review support provided by TympaHealth to get advice or a second clinical opinion.

The community pharmacy receives payment for patients based on a two-tier system, as outlined below.

Tier 1: Pharmacy initial clinical assessment performed for every patient, consisting of:

- a consultation (a patient interview)
- and an ear canal(s) examination (an otoscopy procedure) using the TympaHealth device (as appropriate based on consultation outcome).

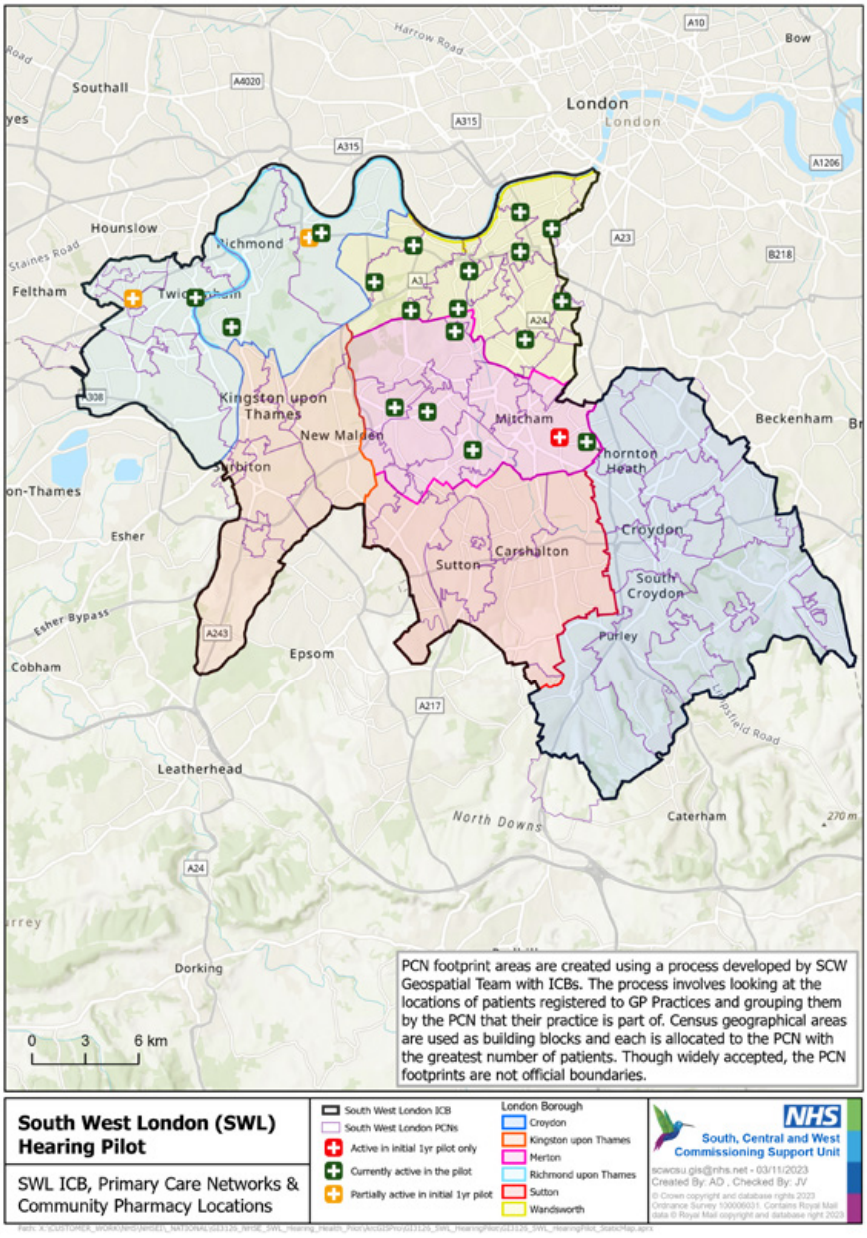
Tier 2: Following the examination, the patient may require:

- earwax removal from one or two ears (microsuction via the TympaHealth device)
- a hearing check
- a referral back to their general practice if the problem could not be resolved at the community pharmacy. The general practice may then decide to treat the patient or refer them to secondary care, depending on the presenting condition.

At the start of the pilot, a total of 20 pharmacies had been selected and trained on the service and device, each offering up to 10 appointments a week from September 2022. In early 2023, two sites stopped taking part in the pilot pathway, including one site who had not been offering any slots for patients to be referred to. One additional pharmacy joined the pilot. Therefore, in total, 21 pharmacies received training to provide the service over the lifetime of the pilot. 19 pharmacies were still active by the end of the pilot (12 September 2023) and18 pharmacies participated in the full 12-month pilot.

The map to the right shows SWL borough boundaries and the location and status of the pharmacy sites at the end of the pilot period, noting those currently active, and those either partially or fully active in the initial 12 month pilot.

As part of an ongoing capacity and demand review, during month 6 of the pilot (March 2023) the SWL project team supported the active sites to increase their available appointments from 10 per week to 15 per week per pharmacy.



2.5 What Happened in the Pilot – Key Data Findings

Referrals

During this pilot, activity data showed that:

- 7,648 patients were referred by 72 general practice to the 21 community pharmacies during the pilot. (note: the sites participating varied during the course of the pilot. 19 sites were actively involved in accepting referrals at the end of the first 12-month pilot.
- The volume of referrals to this pilot pathway increased over the course of the pilot (Figure 1), enabling more patients to access treatment.
- The average number of weekly referrals received by each pharmacy site ranged between 0.8 to 16.8, as shown in Figure 2.

Figure 1: Referrals received by participating community pharmacies each month.

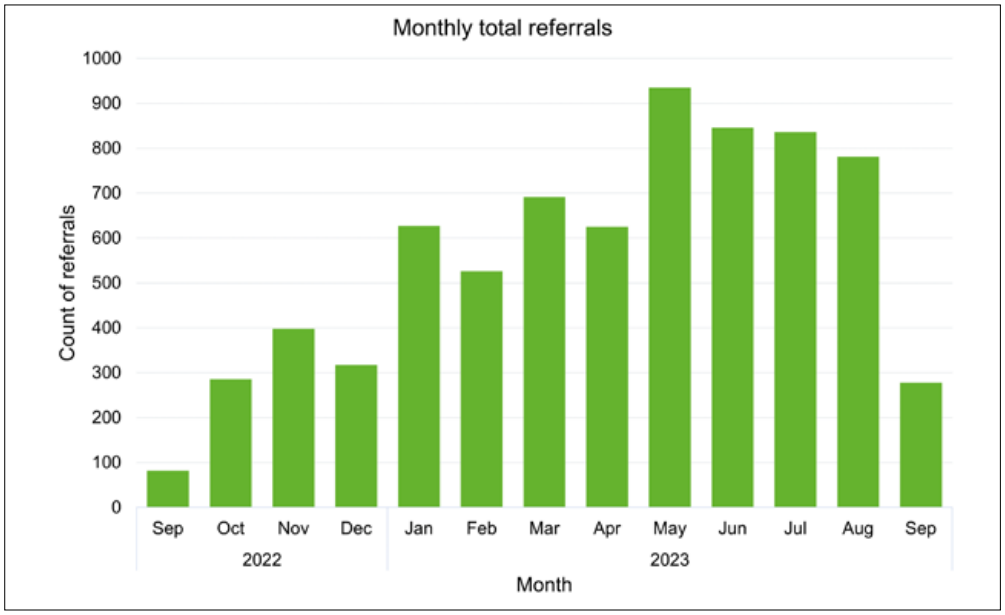
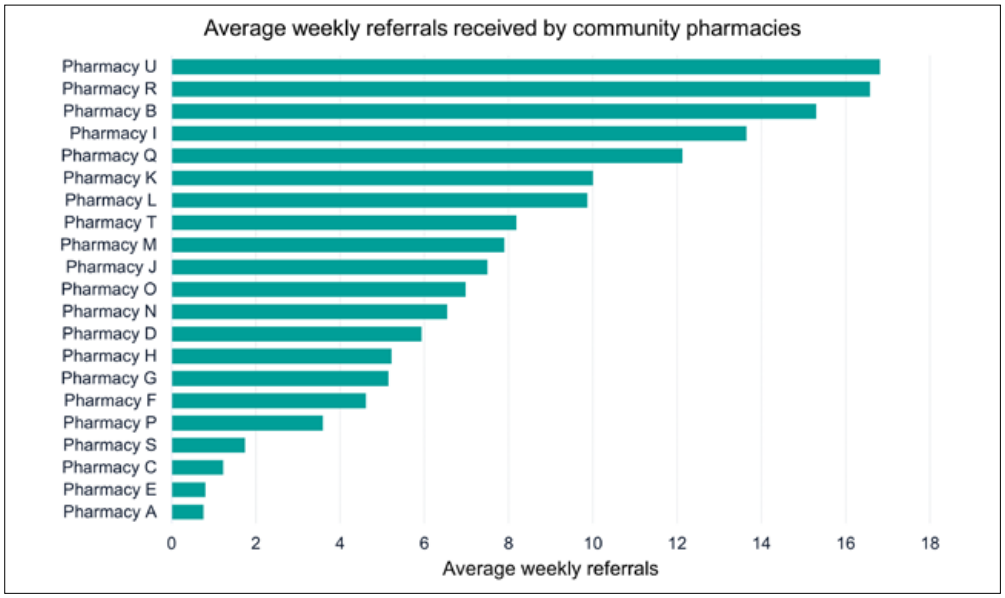


Figure 2: Average number of weekly referrals received by pharmacy sites.

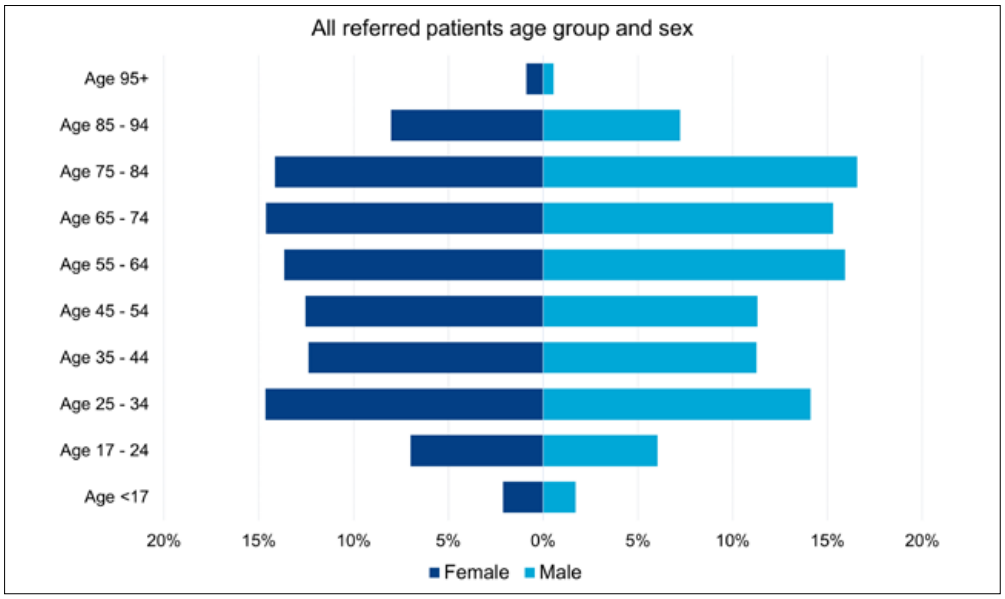


Patient Demographics

Gender: Both male and female patients were referred to the pilot service, with the split between patients who stated their gender being approximately 50% male and 50% female.

Age: Figure 3 shows the split by age group and gender, showing over half of patients (53%) were aged 55 or older. Despite the service not being intended for patients aged under 16 years, there have been a small number of patients aged under 16 who have been incorrectly referred into the service and in most cases these patients have been referred back to the general practice.

Figure 3: Breakdown of the age group and sex of patients referred to the pilot.

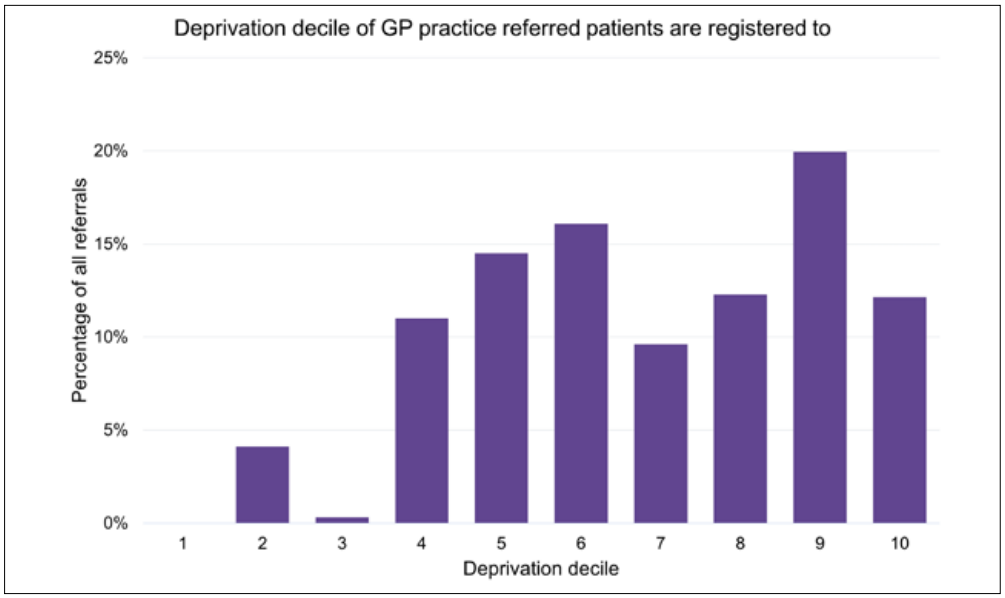


Ethnicity: 31% of patients identified as white and 8% identified as all other ethnic groups. Ethnicity was not disclosed by the majority of patients (61%), therefore it was not possible to produce any further analysis and this data should be treated with caution.

Deprivation: The geographical area covered by the pilot does not have large areas of significant deprivation, however there are some pockets of deprivation within the pilot area. This has been reflected in the patients being referred to the pilot service.

4% of all patients referred to the service are registered with a general practice that sits in an area in 20% most deprived areas nationally. Figure 4 outlines the percentage of all referred patients who are registered with a general practice at different deprivation deciles. However, is it important to note that this is based on the location of a general practice and may not be an accurate reflection of a patient's circumstances and any associated deprivation.

Figure 4: Deprivation decile of the general practices which patients referred to the pilot are registered with (1 is most deprived).



There were no obvious trends in patient outcomes in relation to the deprivation decile of their general practice, with the percentage of patients referred completing treatment and the tier of treatment remaining fairly stable for all deprivation deciles. Further comment on health inequalities can be found in Usability section 4.2: The Suitability of the Pathway.

Appointment and Treatment Data

- 5,353 patients (70% of total referrals) completed treatment in community pharmacies during the pilot over 5783 appointments.
- 1,920 referrals (25% of total referrals) were dropped or rejected by pharmacies. See additional information on dropped and rejected referrals further down in this section.

Figure 5 shows the breakdown of the number of tier 1 and tier 2 appointments for patients who completed treatment, by month, during the pilot.

Tier 1 appointments: 15% of patients (826) received a tier 1 ear canal examination consultation only.

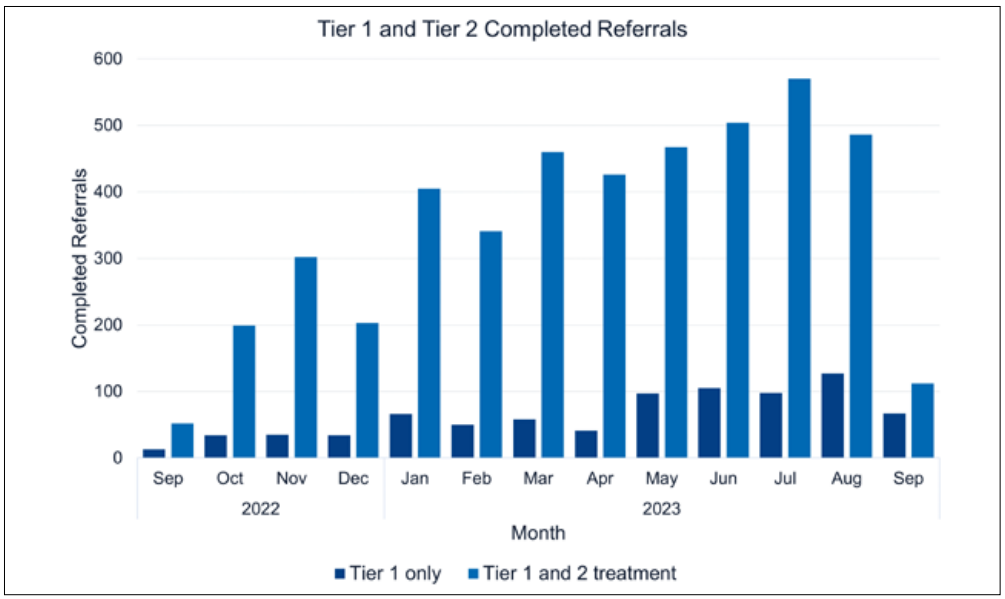
Tier 2 appointments: 85% (4527), of patients treated received a tier 2 treatment, which involved an initial tier 1 examination followed by earwax microsuction and/or hearing check.

Of the 4,527 (85%) of patients who received tier 2 treatment;

- 3,663 (81%) received microsuction only
- 199 (4%) received a hearing check only
- 665 patients (15%) received both microsuction and hearing check.

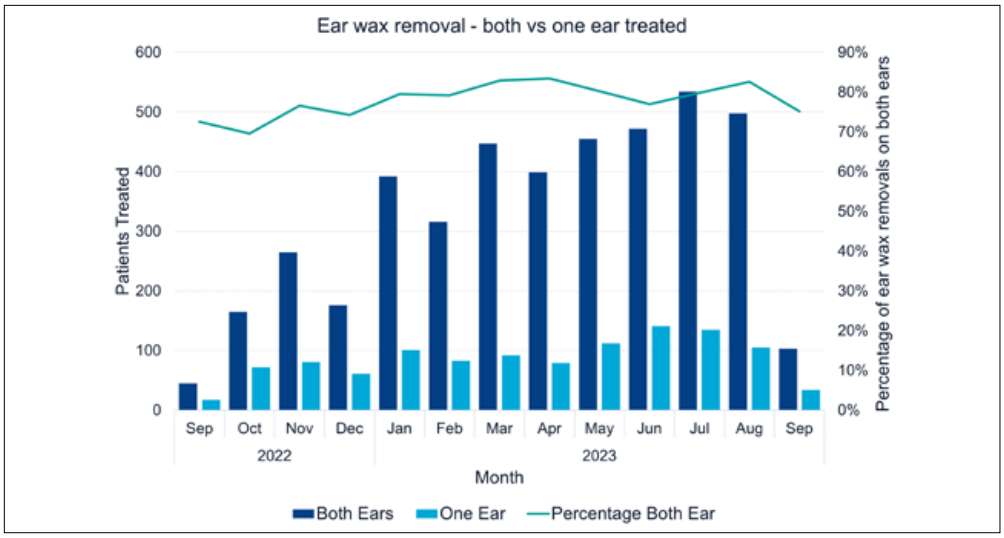
Referred back to general practice: 99 (11%) tier 1 appointments resulted in a referral back to general practice. 216 (4%) tier 2 appointments resulted in a referral back to general practice for further review.

Figure 5: Number of tier 1 compared to tier 2 appointments completed.



Earwax removal one or both ears: Patients could receive earwax removal treatment for one or both ears during their tier 2 appointment. Figure 6 shows that most patients have been treated for both ears during the pilot, and the number has slightly increased over time from 73% in September 2022 to 83% in August 2023. This could possibly imply improved practitioner confidence in providing this treatment.

Figure 6: Breakdown of both vs one ear treated for earwax at appointment.

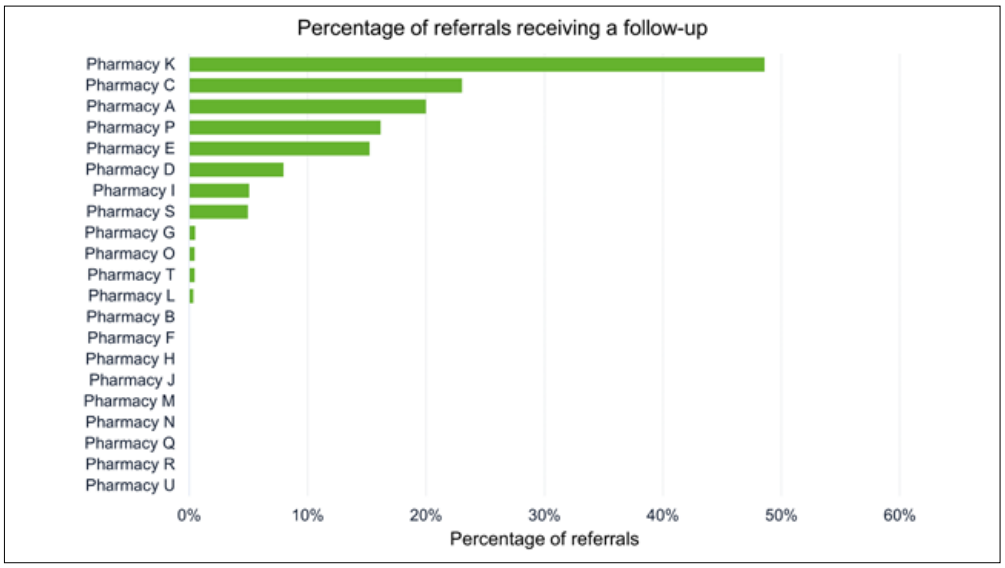


Follow-up appointments: Some pharmacies offered follow-up appointments, where required, to support a patient, however follow-up appointments were not marked to attract additional payment for pharmacies in the payment structure.

During the pilot, 951 patients (18%) that were seen in community pharmacy were flagged as requiring a follow-up appointment, with 301 of these patients subsequently receiving a follow-up appointment; the remaining 650 did not have a follow-up appointment. Additionally, 90 patients were recorded as not requiring a follow-up appointment despite receiving one.

Figure 7 shows a variation in the percentage of follow-up appointments offered by each pilot pharmacy. In one pharmacy, almost half of their referrals (49%) incurred a follow-up appointment.

Figure 7: Percentage of referrals receiving a follow-up appointment.



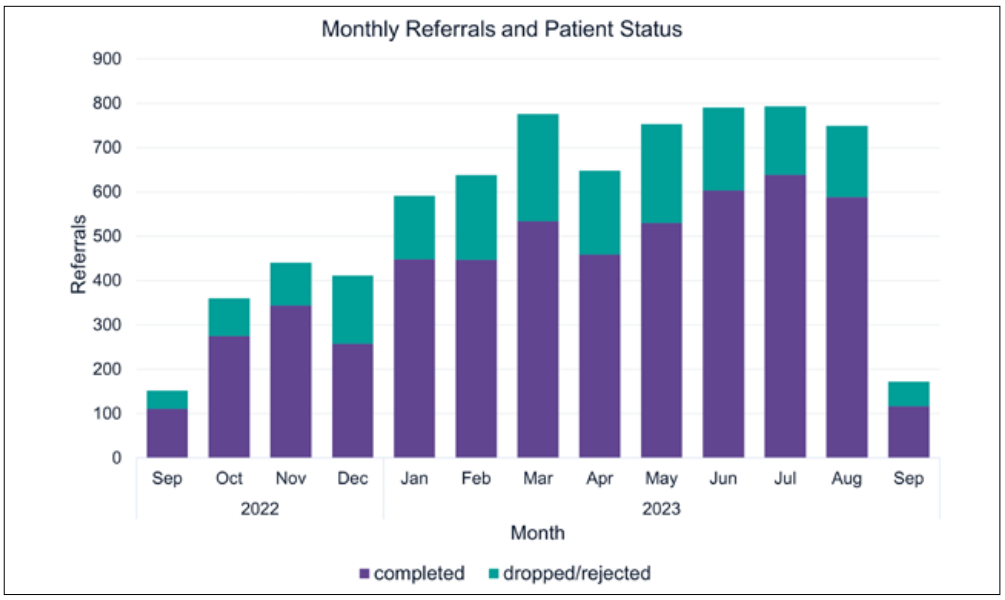
Dropped and Rejected Referrals

Figure 8 shows that out of the total 7,648 referrals, 1,920 referrals were dropped or rejected by pharmacies:

- 834 (11%) of all referred patients did not attend their appointment
- 348 (5%) of all referred patients rejected the offered appointment
- 264 (3%) of all referred patients could not be contacted despite three separate attempts.
- Referrals marked as 'dropped or rejected' in the data set also included 317 inappropriate referrals. 64 patients who canceled their appointment and 93 'other'.

Dropped and rejected rates are explored in more detail in the Safety section under the referrals and general practice triage in more detail.

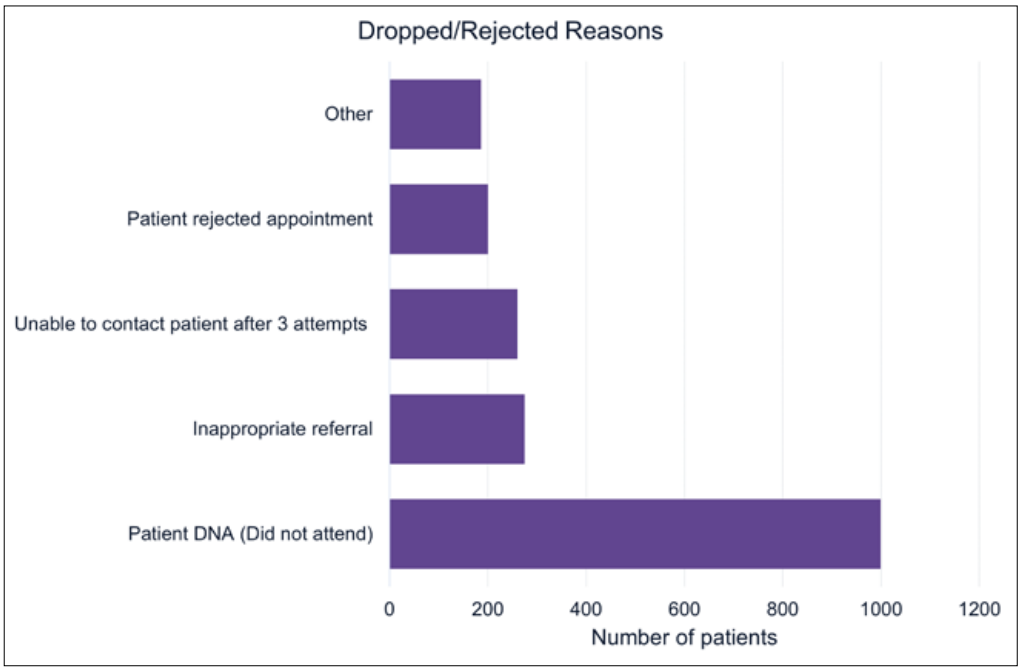
Figure 8: Breakdown of referrals (patients waiting for treatment excluded).



Did Not Attend (DNA) Rates: It is important to note that until August 2023 the dataset did not include a list of specific drop-down reasons for referrals being dropped or rejected by a pharmacy. Pharmacy staff often marked the referral status as 'did not attend' (DNA) when this may not have been not the case, and sometimes used the optional free text field to provide additional information. For example, a patient was under 16, therefore the referral was inappropriate rather than an actual DNA.

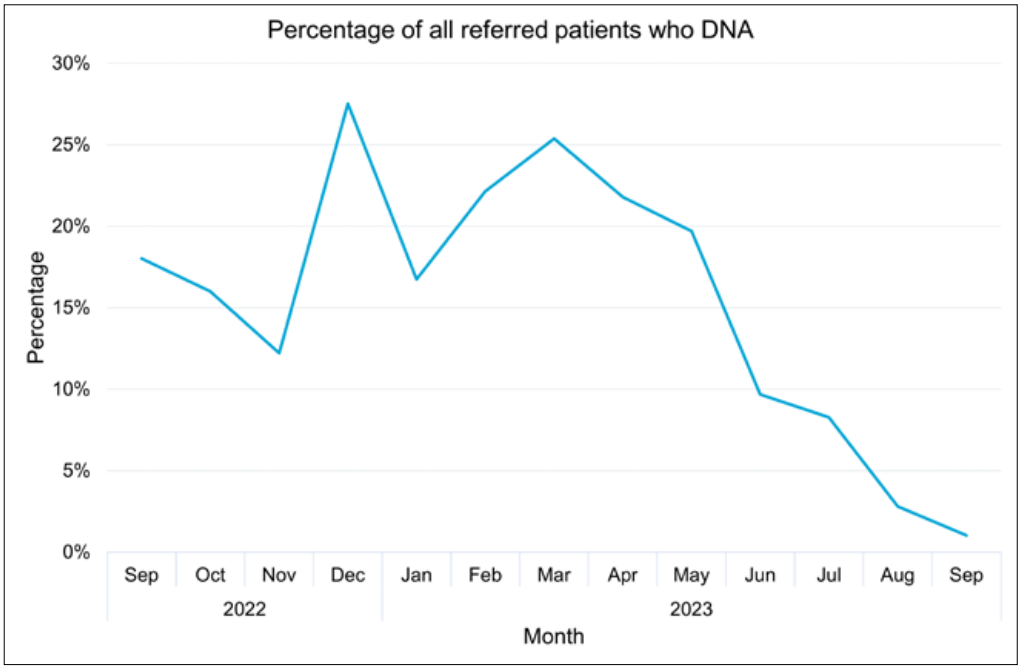
The evaluation team conducted a coding and analysis exercise of the referral statuses marked as DNA and the free text fields where these were completed to determine the dropped or rejected reasons. Referral statuses recorded as DNA, with no additional information in the free-text field are included in the DNA total. (Figure 9).

Figure 9: Number of patients recorded in each dropped/ rejected sub-category.



Patients who rejected an appointment or who were recorded as 'did not attend' may have been exercising patient choice and may have chosen to be treated elsewhere, and this cannot be determined from the dataset.
When the list of drop-down reasons for dropped or rejected referrals was implemented in August 2023, the number of referrals recorded as DNAs drastically reduced. The analysis of the dataset found that the volume of patients who 'did not attend' (DNA) their appointments fell continually from 25% in March to 3% in August 2023, as shown in figure 10.

Figure 10: Percentage of patients referred who are recorded as did not attend their appointment.



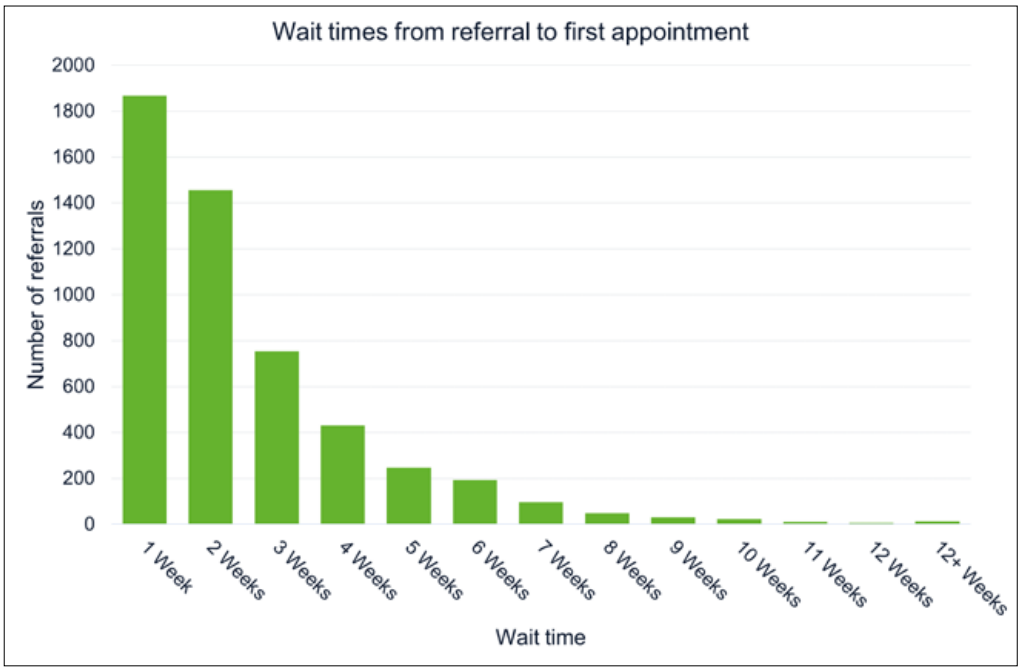
Note: The list of drop-down reasons for dropped or rejected referrals was implemented in August 2023.

Waiting Times Data

There were known data quality issues[8] within the appointment activity dataset which have impacted the recording of dates, and subsequently the calculation of waiting times. To support appropriate analysis of this data, records which showed a first appointment date before the referral date (39 records, 0.7% of complete referrals) were removed. A small number of patients (17, 0.3% of completed referrals) were shown to have a calculated waiting time of more than 12 weeks. It has not proved possible to ascertain any clear reasons for the long waiting times, or whether these may have been a result of data quality issues.

Figure 11 details the breakdown of patient waiting times from general practice referral to first pharmacy appointment however, it should be noted that the pathway recommends a two-week wait between referral and appointment with the patient advised to use eardrops to soften their earwax ready for microsuction.

Figure 11: Waiting times from referral to first appointment.

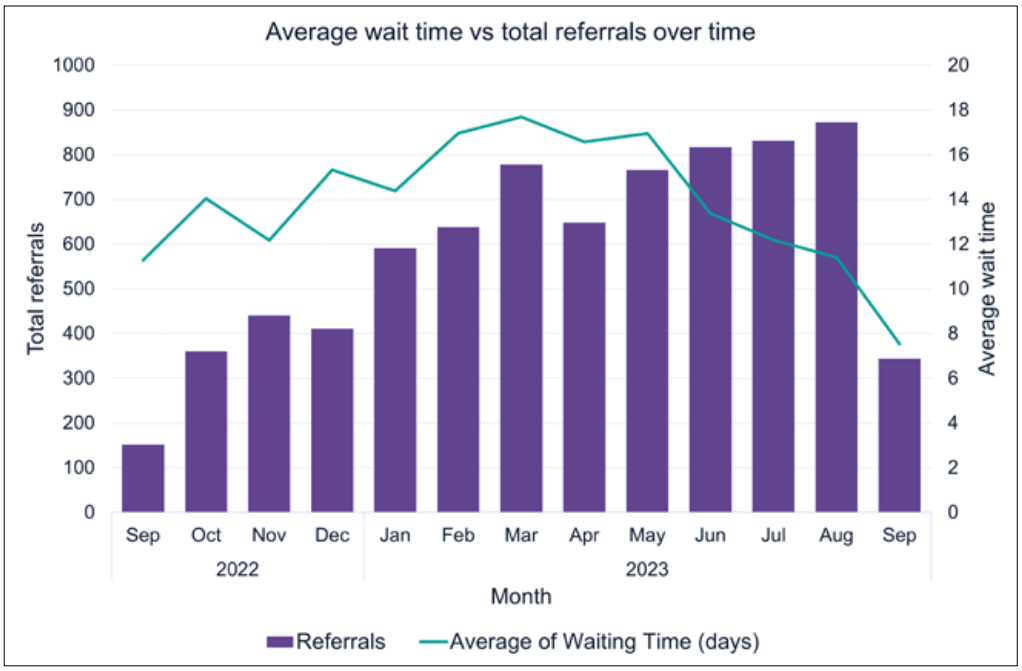


- The data indicates that the average patient waiting time from general practice referral to their first appointment with a community pharmacy was 14.4 days.
- Patients who required a follow-up appointment (18%) also appeared to have had a shorter average waiting time of 11.9 days versus 15 days. There is the possibility that a shorter waiting time for an appointment impacts the length of time a patient may use ear drops, potentially reducing their effectiveness in softening the patient's earwax, and therefore reducing the likelihood of a patient being treated successfully in a single appointment. local guidelines state that ear drops should be used for 10 to14 days before earwax removal is attempted.
- The data also indicated that 36% of patients were seen within one week, while 87% were seen in less than four weeks.

[8]Data quality issues have been noted in the Evaluations Limitations of this report.

- 375 patients were waiting for treatment by the end of the 12-month pilot. Of those patients awaiting treatment, the longest had been waiting six months, with 27 waiting three months or more. However, it is a known data quality issue that some community pharmacies may not update records for patients who turn down appointments or who have not been contactable. It is also important to note that NHS SWL ICB has chosen to extend the pilot beyond the 12 months in scope for this evaluation, so these patients will be transferred into the pilot extension.
- The average patient waiting time between each of the pharmacies ranged from 5.9 to 30.1 days.
- Patient waiting times reduced slightly to 13.7 days on average in the latter months of the pilot after pharmacies increased the number of weekly appointments from 10 to 15.
- The overall patient waiting times ranged from a minimum of 0 days to a maximum of 189 days. Long waiting times were more common in the earlier months of the pilot, with no patients waiting more than 90 days from April 2023 onwards. Throughout the pilot, nine patients who completed treatment are recorded as having waited for longer than 90 days for an appointment. It has not been possible at this time to determine the cause of these or if they have been impacted by data quality issues.
- The average weekly referrals received does not correlate to the average waiting time, although anecdotally community pharmacies referenced the impact of the increasing number of referrals on their waiting times (figure 12).

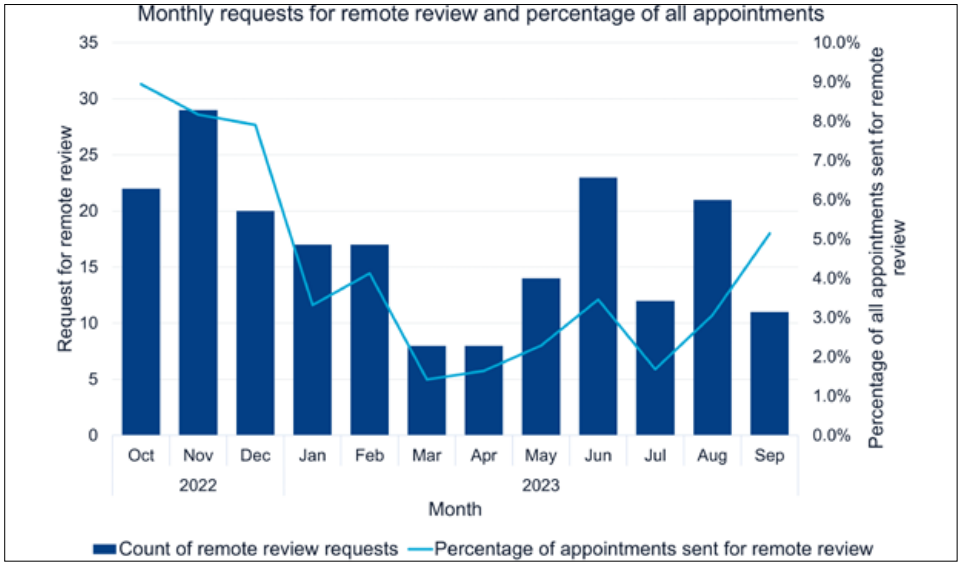
Figure 12: Total number of referrals and average waiting time experienced from referral to first appointment by month.



Remote Review Service Data

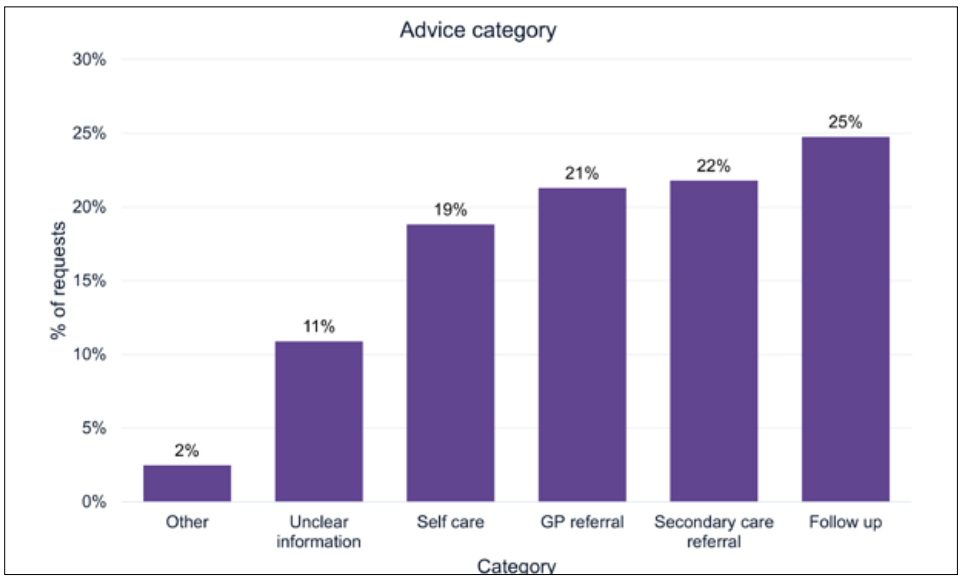
- The device supplier offered a remote review service which allowed pharmacies to exchange information, along with images and videos, if they required a second clinical opinion. The first request would be sent to TympaHealth's audiologists with a 24hr response time, and this could be escalated to an ENT consultant for further advice with a 5 day response time. 3.5% of all appointments were escalated for a remote review.
- 9% of appointments were escalated for a remote review in the first month of the pilot and this percentage steadily decreased to its lowest in March 2023 (1.4%), although this slightly increased again following an event held in May 2023 which promoted the use of the remote review service. By the end of the pilot, 5.1% of appointments were escalated, as shown in figure 13. The small increase in the percentage of all appointments making use of the remote review service from July 2023 onwards may signify the importance of staff engagement, however there are no visible trends identified at this stage.
- On average, 22% of remote reviews were escalated to an ENT consultant. This ranged from 38% to 4% per month but does not appear to follow a trend over time.

Figure 13: Number of monthly remote review requests.



Advice provided by the remote review service has been categorised into larger groups for analysis, as illustrated in figure 14.

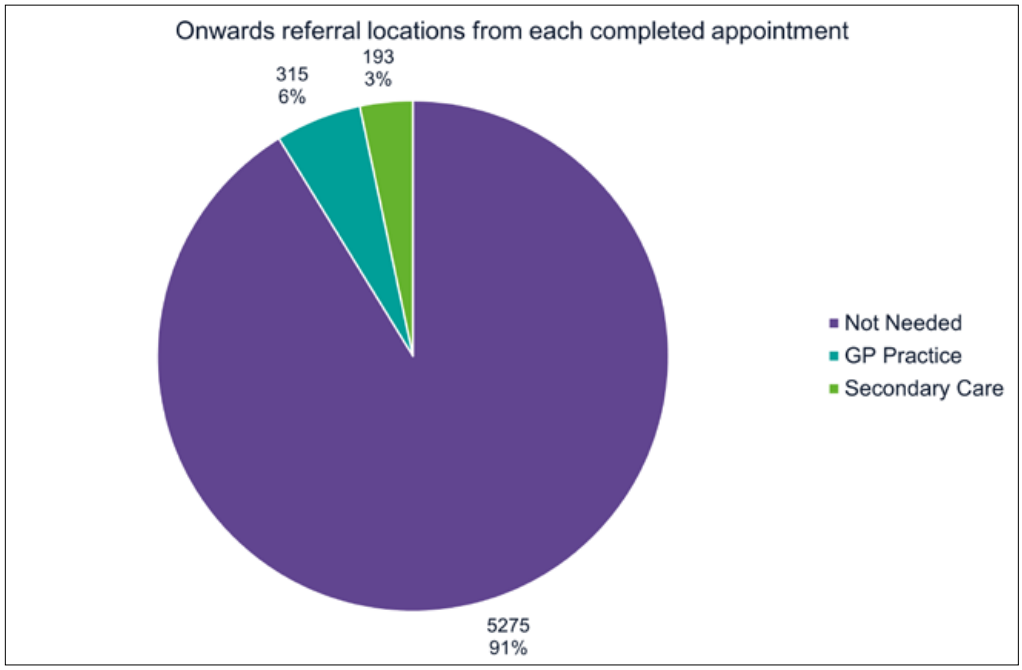
Figure 14: Number of remote review requests by advice category.



Onward Referrals to Primary and Secondary Care

Figure 15 shows the low number of onwards referrals to a general practice or to secondary care following a pharmacy appointment.

Figure 15: Location of onward referrals, where further consultation was recommended.



Impact on general practice: 315 onward referrals (6% of 5,783 completed appointments) were made directly to general practice during the pilot (99 following tier 1 consultations; 216 following tier 2 consultations).

Impact on secondary care: A low number of onward referrals (193, 3% of 5,783 completed appointments) were made to secondary via a general practice, following a pharmacy appointment (15 following tier 1 consultations; 178 following tier 2 consultations).

3 KEY FINDINGS: ACCEPTABILITY

This section reflects the extent to which stakeholders, including patients consider the pilot service to be appropriate and acceptable.

3.1 Patient Experience and Satisfaction

Patient experience was captured using a patient survey and the feedback was overwhelmingly positive throughout the pilot. The survey response rate was 12% overall, and of those who completed the pathway:

99% of patients were happy with the service received.

100% of patients agreed or strongly agreed that pharmacy staff clearly explained the procedures to be carried out.

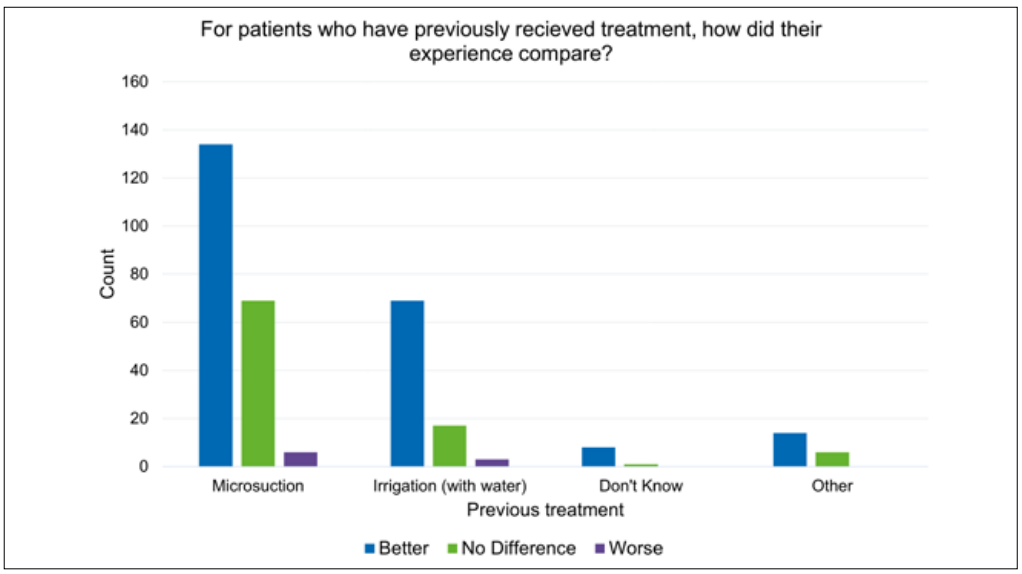
98% would recommend this service to family and friends if they needed to use it.

98% agreed that the staff clearly explained what would happen after the appointment.

Patient survey data revealed that 62% of patient respondents had previously been treated for earwax removal. The majority had received microsuction, the next largest proportion had been treated using water irrigation, with a few patients recorded as 'unsure' or 'other'. 66% of patients rated their experience in the community pharmacy setting as better than their previous experience, 27% stated there was no difference and 3% reported it was worse.

Figure 16 shows there was no difference between those who rated their experience as worse than before (3%), compared to those who had previously had earwax removal using microsuction or water irrigation methods.

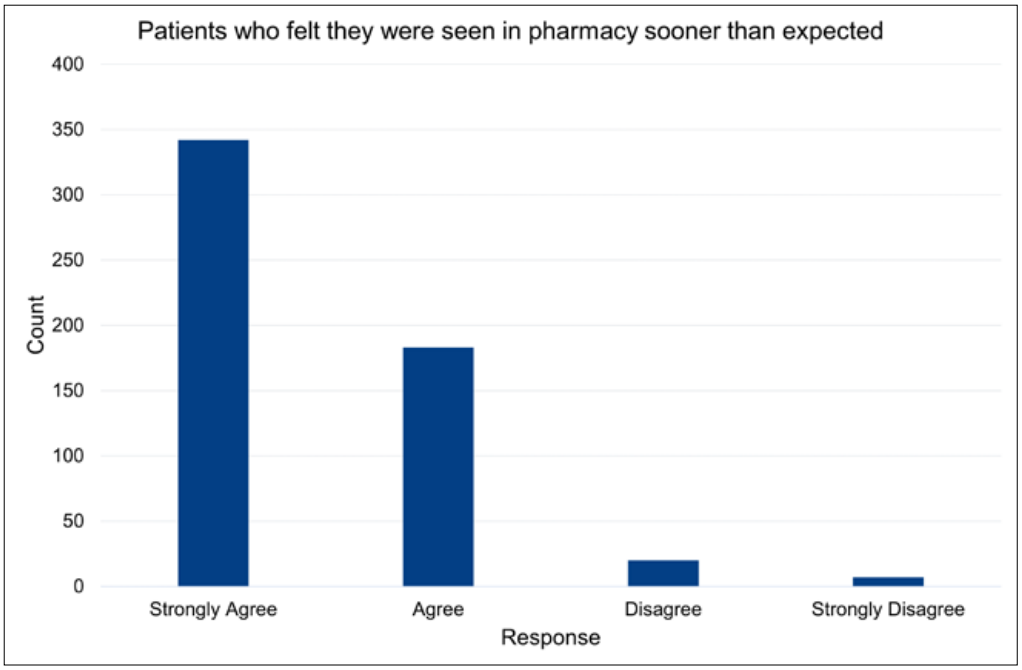
Figure 16: For patients who have previously received treatment, how did their experience compare? (Source: patient survey data).



Only 5% of survey responders disagreed with the statement "It was explained to me by my general practice surgery that I would be referred to a pharmacy". This suggested that most patients felt the information provided by the practice was sufficient to understand the purpose of the service and make an informed decision to use it.

Patients were asked about their waiting time in comparison to their expectation and 90% agreed with the statement: "I was offered an appointment in pharmacy sooner than I expected" (figure 17). Patients noted their satisfaction with the waiting time in the free text responses, indicating a quick turnaround time for receiving an appointment compared to being referred to specialist audiology or ENT services.

Figure 17: Patient survey.



"I was offered an appointment in pharmacy sooner than I expected"

Patient survey respondent

The overwhelming majority of patients who left a review of the service made very positive comments about the service (approximately 97% of comments were rated positively). The key themes from the feedback included:

- Staff were very professional, caring and accommodating.
- Patients would highly recommend the service.
- Patients were satisfied with the outcome of the microsuction treatment.
- Patients would use the service again.
- Patients experienced short waiting times.

> *"Very efficient and explained the process fully. It was also more local and much quicker than going to hospital, so very convenient. The staff were fantastic. The equipment and facilities were great. Would highly recommend to everyone."*
>
> **Patient survey respondent**

> *"The microsuction procedure was excellent. Thoroughly explained, quick, totally comfortable, and effective. 10+ out of 10!"*
>
> **Patient survey respondent**

A very small number of patients noted they had experienced some difficulties with the service, for example, commenting that the room was small, it was not private, or they could hear other customers, which the respondents perceived may have affected their hearing check. A couple of patients preferred the ear syringing procedure, with one respondent commenting:

> *"I would have preferred to be at general practice surgery in a more clinical surrounding with a nurse. My ears were very sore following treatment."*
>
> **Patient survey respondent**

One patient reported an excellent service within the pharmacy, however experienced delays in seeking further treatment due to the GP not being able to view the video of their ear.

Although the survey data shows that patients felt they were seen quickly in pharmacy, one patient noted the waiting times for the pharmacy appointment took weeks and was not ideal.

3.2 Professional Stakeholder Experience

General practice staff feedback from interviews stated they felt there had been a positive impact on general practice. Perceptions of the pilot included fewer face-to-face appointments freed up time and capacity to reduce overall demand within general practice, allowing them to deal with more complex referrals.

> *"I think it's been a useful service to have… because we don't do them anymore [earwax removal] in our practice and it's a useful service for patients to be able to access in pharmacies"*
>
> **General practice staff interviewee**

The data from the quarterly temperature check surveys shows that 95% of all professional stakeholders involved in the pilot (general practice, pharmacy, SWL project team, device, and IT supplier respondents) rated their experience as 'very good' and 'good', with 94% of respondents reporting that they would recommend the service if commissioners were considering implementing the service elsewhere.

Respondents noted a smooth, timely service providing positive health outcomes for patients, especially those who were elderly and at risk of developing dementia. The service being delivered in a pharmacy also allows patients the opportunity to access other crucial pharmacy services at the same time. They commented that the pilot pathway added value to pharmacy roles and job satisfaction, freed up GP and ENT consultants' time to deal with more complex cases, and reduced secondary care referrals and hospital waiting times. This sentiment was also strongly echoed in the one-to-one interviews with community pharmacy and general practice staff and focus groups with the SWL project team.

> *"It is definitely needed to relieve pressure on GP… We can save our appointments for complex patients".*
>
> **General practice staff interviewee**

> *"There have been huge clear positive outcomes for patients' health and for overstretched ENT departments. This pilot has raised our profile among local healthcare providers and proved that we can deliver on more complex services."*
>
> **Community pharmacy staff, Temperature Check survey respondent**

It was also recognised in the stakeholder survey that the service may not be suited for those patients who are very vulnerable and may struggle to use the pharmacy-based service, suggesting that the service should be delivered by general practice instead for this group of patients. One community pharmacy staff member suggested adding home visit appointments to this service, which could improve access for very vulnerable patients. Secondary care feedback also highlighted preference for this service to sit under community pharmacy.

> *I think community focus is definitely the right place to do it rather than in secondary care."*
>
> **Secondary care staff interviewee**

Referral systems: Most general practice staff found the referral and triage processes worked well. They reported them to be straightforward and appreciated the opportunity to add information in the free text box, which integrated well with their workflows.

> *"The referral process is easy, the form is easy to fill out…it's very easy for primary care to refer into the pharmacy"*
>
> **General practice staff interviewee**

Several suggestions for improvements were made by general practice and pharmacy staff to streamline the referral and booking processes, with the aim of reducing waiting times further. These suggestions are summarised in the Usability section.

Pharmacies receiving referrals: While many community pharmacy staff expressed satisfaction with the referral process, some respondents acknowledged they had received batches of referrals simultaneously, which led to difficulties in scheduling timely patient appointments.

While the increase of pharmacy appointments to 15 per site per week did appear to improve this and showed a reduction in the average waiting time for patients, a very small number of patients (14) still experienced long waiting times of over eight weeks. It is important to note that the SWL project team took action to address long wait times by temporarily switching off referrals for a pharmacy to allow them to catch up.

Several pharmacy staff also commented on the rate and source of their referrals, indicating that not all participating surgeries were making referrals, and they would welcome more referrals to improve patient access as well as utilise their capacity.

> *"We're not getting as many referrals as some of the other pharmacies that are in the programme We probably only see around 15 to 20 patients a month."*
>
> **Community pharmacy staff interviewee**

Referral criteria: Whilst in the minority, feedback from pharmacy staff and the SWL project team indicated some issues understanding the inclusion and exclusion referral criteria amongst general practice staff, as evidenced in the analysis of the 'dropped or rejected' data, due to 317 (4%) referrals being inappropriate i.e., under 16's, ear pain, infection.

Pharmacy staff recognised that errors may often be due to staff familiarising themselves with the new pathway, or the impact of staff turnover leading to inconsistent training. One pharmacy respondent noted that patients with more serious conditions were wrongly referred to them, rather than being immediately signposted to the correct service. This may indicate a need for more training, and clear communications between general practice staff and pharmacies to ensure appropriate referrals are being made and there is continuous improvement, throughout the life of a pilot or service model.

The SWL project team provided self-care and eardrops guidance for all participating general practices to incorporate into their triage processes, although several pharmacy staff felt that further improvements could be made with the information to patients about their referral, expectations from the service and waiting times.

Appointments: Feedback from secondary care clinicians noted that the number of appointments provided in community pharmacies had been encouraging to see.

Waiting times: Overall, staff stakeholders were positive about the patient waiting times, noting that they are considerably shorter compared to previous primary or secondary care waiting times.

> *"Benefits for patients is the quick access to microsuction, whereas referral to secondary care could take six months..."*
>
> **General practice staff interviewee**

Pharmacy staff feedback noted varying experiences in the number of referrals received, with some suggesting that a high number of referrals led to longer patient waiting times. However, this trend was not visible when analysing the data shown in figure 12.

Furthermore, pharmacy staff felt that offering only 10 appointments each week was leading to longer waiting times and prior to April 2023, the average waiting time from referral to first appointment was 15.2 days.

> *"Ten appointments per week isn't good enough, people are saying the wait is too long."*
>
> **Community pharmacy staff, focus group respondent**

When pharmacy appointment capacity increased to 15 per week per site in April 2023, the average waiting time reduced to 13.7 days suggesting that the increase in appointment capacity was successful in reducing patient waiting times.

Device: Pharmacy staff were impressed by the otoscopy device and its capabilities, along with the training received to help operate and set it up, and appreciated the support received from the SWL project team and the device supplier.

> *"I think it's really good [device]. It's nice that we can film inside the ear and take pictures... some customers are generally curious and want to see what's going on."*
>
> **Community pharmacy staff interviewee**

While most of the general practice staff had not used or seen the device as part of this pilot, one general practice gave very positive views about the technology, and several general practice staff members suggested it could be deployed in practices for nurses or healthcare assistants to deliver the service and increase patient accessibility.

> *"I think it's important that general practice does it, I don't mind if pharmacists do it and I don't mind referring, but I think every contact counts."*
>
> **General practice staff interviewee**

Onward referrals: Although the number of onward referrals from community pharmacy to general practice was low as shown in Figure 15, in the latter months of the pilots a small number of general practices staff survey respondents noted that they would not recommend this service due to many patients being referred back to them because pharmacy could not fully perform the microsuction treatment, indicating that the service seemed reliant on local skills. In contrast to this, the two secondary care respondents noted that they had anecdotally seen a low number of onward referrals from general practices, which they felt were appropriate.

In terms of the quality of information received back from pharmacies, a general practice staff member, and a secondary care respondent mentioned that simplification of the feedback document, or prioritisation of the images/video links in the documentation received from a general practice, would be better to understand the patient's management and outcome.

> *"Simplify the documents…if you can, because ultimately, I need to know what happened and what was the outcome. I think those are the two key things and I'll be reading through a lot of documents in a day."*
>
> **General practice staff interviewee**

> *"[ensuring the images/video links are at the top of the referral] that would probably speed up the data efficiency at the end when I'm triaging."*
>
> **Secondary Care staff interviewee**

3.3 Acceptability: Conclusions

Generally, there was a strong uptake of community pharmacy appointments delivered during the pilot, with 70% of the total referred patients completing treatment. Although general practice staff found the referral and triage processes to pharmacy worked well, there is a need for ongoing training information about the inclusion and exclusion referral criteria to mitigate the number of inappropriate referrals, as well as advise on the use of eardrops ahead of appointments. Waiting times for the service were viewed positively by both patients and staff stakeholders, noting that they were considerably shorter compared to previous primary or secondary care waiting times.

It can be determined that this pilot service has been widely accepted by the majority of professional staff and stakeholder teams involved, and most importantly, by the patients. They particularly accepted the service's benefits for patients to access free, local hearing health services, as well as their own increased job satisfaction and upskilling of pharmacy roles. Furthermore, patient experience of this service was especially positive and a large proportion of the patients who used the service thought that the staff were very professional, explained procedures well, were satisfied with the microsuction treatment they experienced and would highly recommend the service. Both staff and patients were also impressed by the innovation of the device and its capabilities, and some pharmacy staff expressed an interest for more staff to be trained to use it.

4 KEY FINDINGS: USABILITY

This section of the report explores the ease of use and the extent to which the pilot service has been used by referred patients and staff, including the technology, measuring its effectiveness, efficiency, and satisfaction.

4.1 The Referral Process

The referral process was supported by most general practice and pharmacy staff. Several communications and training took place during the pilot, however feedback gathered during the evaluation also noted that further guidance and training will be required to ensure a common understanding of triage and referral criteria. This may be linked to staff turnover and reliance on general practice to disseminate information that is received about the pathway.

At referrals stage, patients can choose which of the participating pharmacies they wish to be referred to.

> *"[It] Would still be helpful if general practices could tell patients realistic waiting times."*
>
> **Community pharmacy staff, Temperature Check survey respondent**

Some suggestions were noted for improvements to streamline the booking and referral system and processes, with the ambition to reduce waiting times and enhance a fair distribution of referrals and appointments across pharmacies.

The ideas for improvements included:

- The ability for general practice or pharmacy staff to redirect referrals from one pharmacy to another if there is a substantial patient waiting time, which could save further time and resource rather than creating a new referral for another suitable pharmacy site.
- An option to access and book into pharmacy appointment slots for general practice staff or patients via a self-booking system, to further increase patient choice and access. This could potentially minimise pharmacy time and resource that would otherwise be spent phoning patients to book appointments, and thus reduce the number of patient referrals being dropped or rejected from pharmacies because they were unable to contact them (it was identified that 264 of referrals were dropped or rejected because of no telephone contact).
- Patient self-referral to a pharmacy – could be considered as a way to further increase patient choice. But will need careful consideration to ensure an effective triage is maintained, which is crucial to ensure patients are suitable for the service. Digital access needs should also be considered to ensure a digital barrier is not put in place.

Patient choice is considered further in the Sustainability section.

4.2 The Suitability of the Pathway

Generally, the available evidence suggests that the intended population are being treated in line with the service specification in NHS SWL ICB. This means patients with gradual hearing loss and impacted wax are receiving earwax removal and a hearing check in a pharmacy setting. Whilst a number of incorrect referrals have been observed in the quantitative data, this is likely to be reflective of a new service being embedded.

It should be noted, that due to limitations in the data available for analysis it has not been possible to fully reflect the two following key aims of the pilot with regards to the intended population.

- Alleviate the pressures faced in primary and secondary care by reducing ENT backlogs and appointments. This is discussed further below in 'Impact on Workload'.

- Reduce patient health inequalities by improving patient access and experience to free hearing health services.

Impact on health inequalities - Although this was not a specific area of investigation within the pharmacy and General practice staff interviews, several respondents commented on the role of the new hearing health pathway in addressing health inequalities. General practice staff stressed the importance of promoting good hearing health, otherwise it can have wider implications if not managed. A simple treatment can lead to a significant impact on a patient's life, especially for those with co-morbidities and certain protected characteristics.

> *"It reduces disability…wax-related hearing loss can be very disabling if you've got a history of dementia or you're frail. If you lose your hearing, it can lead to other problems - you can fall over, become socially isolated and lonely, so it's a simple treatment which can have huge repercussions…"*
>
> **General practice staff interviewee**

As discussed elsewhere, limitations in the available data such as an absence of demographic information meant that it is not possible to identify whether any patient groups were unable to access the service. It was also not possible to identify health inequality trends in patient experience and outcome. It is therefore a key consideration of future rollouts to assess and evaluate whether the pilot is reaching those most at risk of experiencing health inequalities. However, it can be assumed that this pilot is enabling a wider cohort of patients to access treatment in a timely manner. This is evidenced by both the short average wait times for patients and the average 2.67 mile reduction in travel distance when compared to treatment in assumed secondary care location.

4.3 Technological Infrastructure

Many participants in this evaluation highlighted the crucial role of technology, particularly robust IT systems, in the successful implementation of the pilot programme. However, there were some digital challenges that affected the pilot's execution for example, certain general practices faced delays when activating the TympaHealth referral function due to the email address verification process. While this issue seems to have been resolved, some participants recommended the inclusion of a contingency plan for patient referrals in case of technical glitches with electronic referrals. Despite these challenges, general participants acknowledged that electronic referrals provide a safer and more secure method for submitting referrals to pharmacies. The initiation of the NHS SWL ICB hearing health pilot pathway required EMIS as an IT system in general practices, and PharmOutcomes as an IT provider in participating pharmacies. A lack of wider system interoperability indicated a limiting factor in the general practices, and pharmacies who were able to take part in the pilot.

Another technological issue identified during the evaluation is that patient records are not automatically updated with treatment outcomes, or the need for further general practice appointments. Currently, general practices, rely on electronic documents sent via NHS mail, which is not deemed the most efficient solution. Given the requirement for manual updating of records between the PharmOutcomes and TympaHealth systems, there are potential risks to consider in relation to information accuracy and timely recording of patient outcomes as with any health record system, however this was not raised in the feedback by participants during the evaluation and is not apparent in the quantitative data beyond the noted limitations of the data. Community pharmacy staff also reported a satisfactory level of support from technology providers however, some participants noted that when technical issues did arise with the PharmOutcomes system, their only option for raising queries was through an online system, which often resulted in delays. To address this, it was suggested to establish a telephone helpline or a similar immediate support mechanism for busy clinics.

Most pharmacy staff members in interviews and focus groups found the TympaHealth device user-friendly without encountering any major difficulties. Only a small minority experienced issues which were promptly addressed.

"…it's really, really good…the actual equipment. Being able to show patients a visual and explain to them what's going on, what we're looking at makes them much calmer and appreciative because they understand what you're doing."

Community pharmacy staff interviewee

"…this is an amazing piece of kit. It's like this is far better than what we were offering to patients [previously]"

General practice staff interviewee

The ability to save and share a video allows for a comprehensive examination of the ear, however capturing a picture may not adequately convey concerns or anomalies for diagnostic accuracy and safety. In a few instances, participants have reported Wi-Fi issues causing problems with image and video uploads and device crashes, but this seems to have affected only a minority of those in the pilot.

Numerous pharmacy staff have expressed a preference for utilising iOS devices over Android counterparts, partly due to the smoother performance and superior image quality. Early in the pilot phase, technical problems arose with the iOS devices, leading the supplier to replace them with Android devices, causing some confusion and frustration among pharmacy staff. It has since been resolved, emphasising the need to standardise the platform for future service rollouts in pharmacies.

> *"I've I had a few problems with the Android system. Picture quality was one of the issues…they looked a lot grainier…the difference in picture quality [compared to iOS] is quite vast."*
>
> **Community pharmacy staff interviewee**

4.4 Impact on Workload

Feedback from general practice staff regarding workload has been predominantly positive. The referral process, as previously mentioned, seemed to be functioning smoothly without introducing any significant delays.

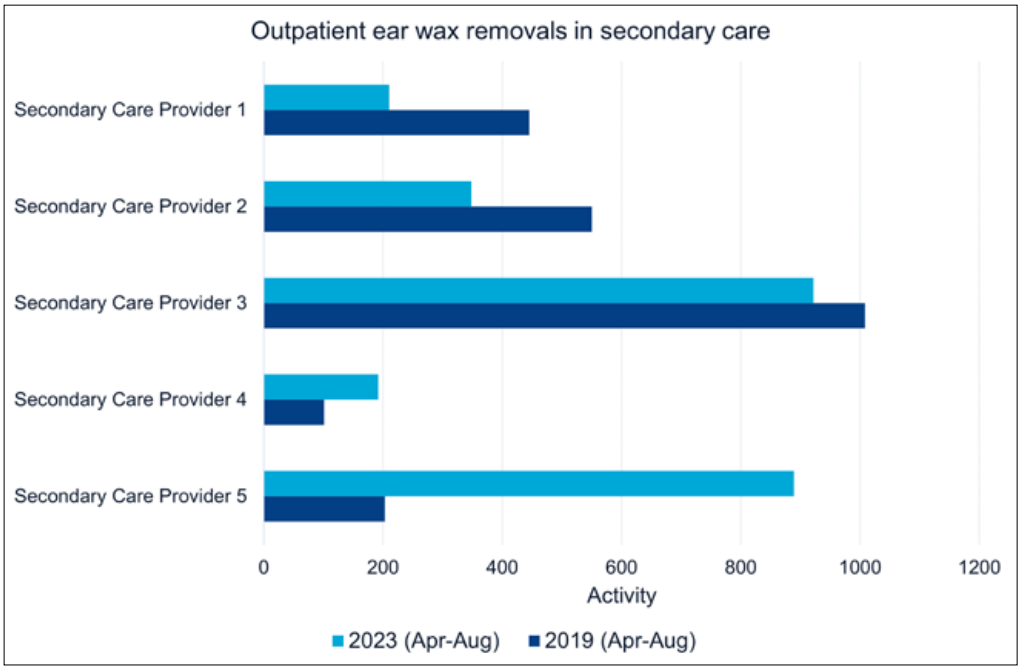
As referenced above in suitability of the pathway, it has not been possible to fully reflect on the pilot aim of alleviating the pressures faced in primary and secondary care by reducing ENT backlogs. The data from the pilot has shown that most patients referred to this service had their hearing health needs met in community pharmacy, with activity data showing that 3% of appointments including a hearing check went on to result in a recommendation for the patient to be referred to secondary care services, either specialist audiology or ENT. This would therefore appear to demonstrate that most patients treated within community pharmacy do not require secondary care services, and so the assumption could be made that these patients would otherwise have been treated in primary or secondary care, and therefore this pilot pathway is redirecting activity away from secondary care settings towards the community.

It is not possible to quantify the amount of activity which has been reduced in primary or secondary care as a result of this pilot. During the 2019/20 financial year (prior to pilot), 8,635 earwax removal treatments were performed in primary care and 3,141 in secondary care. When looking at the number of earwax removals being completed in secondary care in 2019 compared to during the pilot in 2023, three secondary care providers with SWL general practice registered patients being regularly referred to them experienced a reduction in activity being completed between April and August in 2019 (baseline year) and 2023 as shown in figure 18.

Two secondary care providers experienced an increase in activity however, this could be caused by changes in earwax removal provision post COVID-19 pandemic. Due to the lack of a local clinical code to support identification, patient referral numbers could only be obtained to speciality level which would be influenced by a number of initiatives and difficult to attribute any change to this pilot alone.

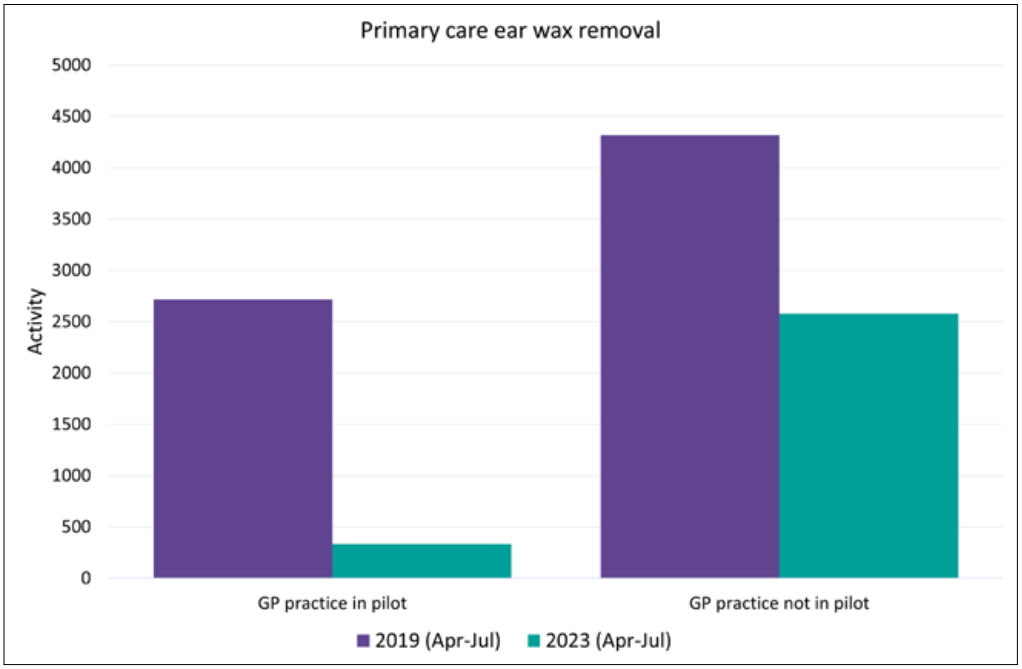
Additionally, it was recognised by pilot stakeholders that there is a significant waiting time and patient backlog for earwax removal in secondary care, meaning the full impact of the pilot in redirecting activity may not yet be realised.

Figure 18: Outpatient earwax removal activity in secondary care providers in 2019 (baseline, pre-pilot) vs 2023.



A key consideration to note is that it is important to ensure that the service does in fact redirect demand away from other settings and does not just simply increase the overall demand by generating latent demand which had not existed previously. It is not clear whether some patients being seen by the pilot are accessing earwax removal for lifestyle reasons, and there is anecdotal evidence of patients suggesting that they will seek private treatment for reasons such as an upcoming flight and are therefore showing new demand rather than redirected activity. This is corroborated by outcomes data indicating that in a number of instances patients have chosen to not progress with this pathway, but to pay privately for earwax removal. This forms a key recommendation for NHS SWL ICB and other commissioners considering an at scale / rollout of this pathway.

Figure 19: Earwax removal activity in primary care in 2019 (baseline, pre-pilot) vs 2023.



Initial data from primary care shows a reduction in earwax removal activity between the baseline period of 2019 and 2023 during the pilot for all general practices in the South West London geography. However, there is a larger percentage decrease observed (-88%) by practices who fall inside the pilot geography in Richmond, Merton and Wandsworth compared to those outside (-40%). Additionally, insight from the interviews and focus groups suggested that the pilot did have an impact in freeing up valuable time for general practice and secondary care consultants. The general practice respondents felt that the pilot programme has the potential to alleviate the demand for hearing health-related appointments and associated clinician time, particularly that of general practice nurses, allowing them to address other medical issues and conditions more effectively.

> *"[It's a] Very good service - patients are being seen quicker than if referred to the hospital."*
>
> **General practice staff, Temperature Check survey respondent**

4.5 Ensuring a Sustainable Workload

While community pharmacies initially had doubts about the impact of introducing a new service to their already busy schedules, it appears that these concerns were not realised by the sites that continued with the pilot programme. During focus group discussions, pharmacy staff expressed a positive view of offering this service within a community setting. When asked about their perceptions regarding delivering this service alongside their current workload, they considered factors like the number of referrals and the time required for each appointment.

While they acknowledged that it could sometimes be challenging to balance the hearing health service with other pharmacy tasks, they also indicated that it was manageable based on the referral load they received. It is worth noting that some pharmacy staff mentioned receiving relatively few referrals. This may reflect a self-selecting sample, as those who had the time for interviews might represent pharmacies that found the referral workload manageable, which may not be universally applicable - a point acknowledged by some respondents.

Further details regarding task duration and its impact on processes are discussed in the Sustainability section below.

If a problem could not be resolved for a patient in community pharmacy, a referral is made back to general practice, so there is potential of a perceived increase in demand / workload for general practices. General practices respondents were broadly positive about the workload impacts, also noting the increased nursing appointment capacity.

> *"We have now got more nurses appointments available for other conditions."*
>
> **General practice staff, focus group respondent**

Secondary care staff reflected that they had seen fewer but more appropriate referrals, where pharmacies were not able to remove the earwax and required advanced examination and skills. A small number of general practice staff in the latter months of the pilot noticed an increase in referrals and would therefore not recommend the service. It is recommended that the number of onwards referrals received from pharmacies, to both general practices and secondary care, are monitored to ensure a sustainable workload for all stakeholders.

> *"They [community pharmacy staff] tried several times to remove the earwax and couldn't do it"*
>
> **Secondary care staff interviewee**

4.6 Effectiveness of the Training

The quality of the training has gathered widespread support from general practice and pharmacy staff, noting that it was outstanding and sufficient in preparing them for service delivery. Participants from the general practice staff focus group noted that the training at the launch of the pathway was helpful and participants from the pharmacy staff focus group rated the effectiveness of the TympaHealth training high, scoring it at 4.2 out of 5.

> *"TympaHealth [training], the theory, the practical and the commissioning when they come in and sign you off...100% brilliant. To my mind they've hit the mark."*
>
> **Community pharmacy staff interviewee**

Members of the SWL project team responsible for managing the training implementation emphasised the extensive research they conducted to ensure the microsuction training for pharmacy staff met high standards. They stated that it was the most comprehensive training available, akin to medical school education, covering both classroom instruction and practical learning, site assessments with a post-course mentored clinic, logbook submission and ongoing support.

The training also received favourable feedback when compared against other privately provided training packages for similar services. Technology providers noted that they didn't receive many support requests from pharmacy staff, attributing this to a well-thought-out and effective training programme.

The regular training events were perceived to have operated smoothly, with a maximum of 12 attendees per session which enabled the SWL project team to promptly address questions and issues while adjusting the course as necessary. There was also a consideration for training on data protection and information governance, due to potential differences in data handling between community pharmacies and general practices.

A recurring concern voiced by community pharmacy staff, both in focus groups and interviews, was the limitation on the number of staff from a pharmacy who could receieve training. Respondents felt that this occasionally led to capacity and delivery challenges, especially during busy periods.

> *"The quality of the training has been good and comprehensive, but we could do more of it in terms of training more members of staff."*
>
> **Community pharmacy staff, focus group respondent**

Furthermore, those responsible for training occasionally received inquiries and concerns from healthcare professionals regarding clinical effectiveness and professional liability. Participants acknowledged these concerns, recognising the need for reassurance due to this new community service delivered by non-specialists. It was recommended that this issue be further addressed within the training programme. Additionally, peer support, particularly through regular Multidisciplinary Teams (MDT) forum, where queries could be addressed, was deemed crucial for ongoing learning. Participants found feedback from the MDTs valuable, whereby discussions were held from both a clinical and operational perspective, i.e., standard operating procedures on the otoscopy device, DNA patients, learning from 'Make a Difference' alerts and triage. Further aspects related to quality and safety are explored in the Safety section below.

A training audit conducted during the course of the pilot led to the SWL project team reviewing the requirements for registration and revalidation training in the subsequent pilot extension. Example of changes included setting clear time frames for completion and sign-off of training log books, and setting out clear requirements for wider certification for example on safeguarding and information governance.

4.7 Usability: Conclusions

Participants in the pilot have generally found both the pathway and the underlying technology, to be straightforward to use, without disrupting established workflows. The overall referral process seems to function effectively and is well-integrated with general practice systems. Although the general practices received supplementary guidance on referral processes, further improvements can still be made to ensure communications and training is disseminated to new general practice staff in order to follow a standardised procedure. Moreover, some suggestions were noted for improvements to streamline booking and referral system and processes, with the ambition to reduce waiting times and enhance a fair distribution of referrals, and appointments, across pharmacies, as well as improve patient choice.

The impact on health inequalities of this pilot cannot be made in the data at this stage. It is a key recommendation both for next steps, and for others e.g., other ICSs to implement this pilot pathway / for this service to be commissioned at scale, to assess and evaluate whether the pilot is reaching those most at risk of experiencing health inequalities.

General practice and secondary care activity including waiting lists should also be monitored to test if activity is being diverted, to better understand whether there has been a reduction in primary and secondary care appointments and backlog, and ensure latent demand is not being created.

Mechanisms to increase patient choice and access have also been suggested, such as enabling patients the visibility of appointments at general triage stage, or allowing patients to self-book an appointment. These should be considered and explored in future implementations.

Community pharmacy staff reported finding the system easy to use, with only minor initial issues that were promptly resolved. General practice staff were also keen to automate patient information flows from pharmacy to general practices.

Both community pharmacy and general practice staff highly rated the training, finding it helpful and effective. Regular training events were well-received. Some pharmacies expressed the need for more staff training and potential backfill support. The introduction of certification to formalise the training process was seen as a way to enhance credibility. Pharmacy staff members also appeared satisfied with the impact on their workload.

5 KEY FINDINGS: SAFETY

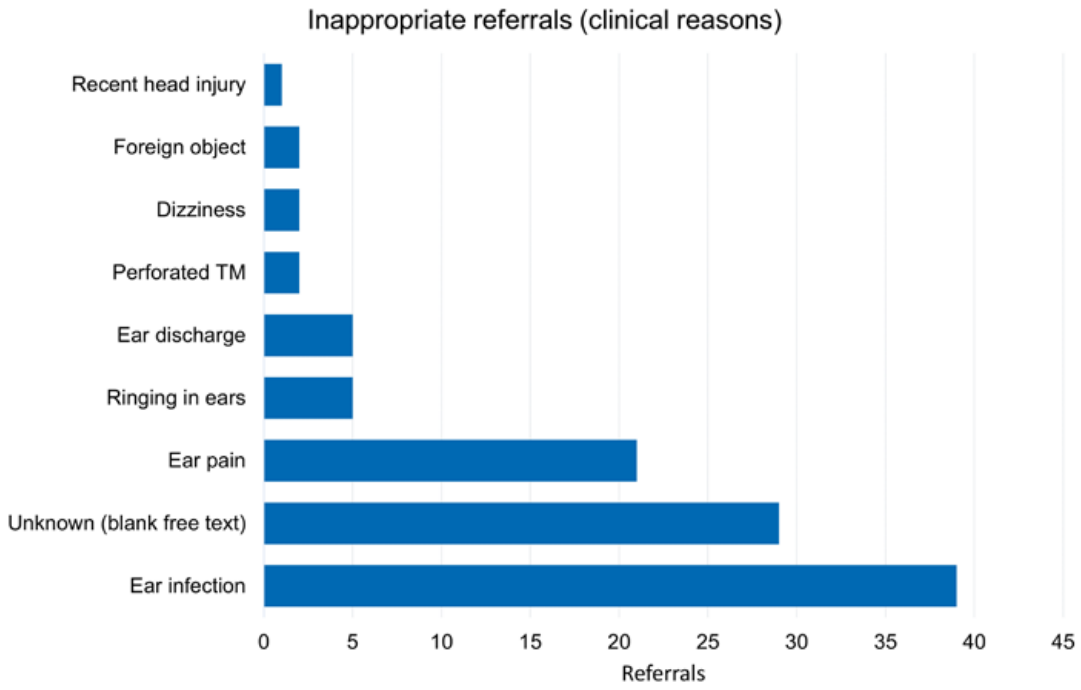
This section examines the safety of the overall pathway and technology.

5.1 Referral and General Practice Triage

The pilot adopted a pragmatic approach to general practice triage. The pilot was rolled out with existing triage processes in place across general practices, which encompassed a range of approaches including the use of navigators, care coordinators and clinicians. To ensure that appropriate red flags were identified and self-care advice given, staff were provided with comprehensive training and clear guidance on the pathway. It was suggested by a number of stakeholders that ongoing training on the pathway was important, as shown in the small number of patients aged under-16 who had been incorrectly referred into the service. Healthcare professionals in primary care could utilise the NHS SWL ICB 'Make a Difference' incident reporting system, which was used to report the quality concern around under 16 referrals. As a result, targeted communication was disseminated to relevant practices to prevent recurrence.

The qualitative feedback and the dropped / rejected / DNA data suggested that a number of people were referred to the pathway inappropriately. Patients whose referrals were deemed inappropriate for medical reasons were most commonly referred with an ear infection or ear pain as shown in figure 20. Generally, this was considered an accepted risk that could be flagged through the general practice triage process, as is typical of general practice triaging in general. This risk was mitigated, though not completely, through initial and cyclical training.

Figure 20: Inappropriate referrals and their clinical reasons for exclusion.



5.2 Pharmacy Triage and Procedures

Within the pilot, clear protocols were in place to ensure that red flags were checked for and appropriate self-care was applied at pharmacy triage. If there was evidence of an acute problem, such as an ear infection, pharmacies were instructed to contact the general practice and speak to the duty doctor. There is evidence from the pilot that this feedback loop had been effective. For more serious presentations, such as if the ear was bleeding, patients would be signposted to accident and emergency services.

The service excluded patients under 16 referred onto the pathway, and in most cases underage referrals were sent back to the general practice. It is recommended that the SWL project team continually monitor the age profile of patients being referred and that all general practices adhere to the inclusion and exclusion referral criteria consistently to ensure inappropriate referrals are minimised.

The data from the remote review service shows that this service has been utilised by pharmacies to acquire a second clinical opinion, see Figure 15, which, if necessary, could be escalated to an ENT consultant for further advice. Whilst there is no preferred or acceptable level for remote reviews being requested, for any extension of the pilot or commissioning in other areas, consideration will need to be given the monitoring of the remote referrals in order to ensure a level of consistency across pharmacies.

5.3 Workforce

Microsuction in community pharmacy is a non-regulated service and questions had been raised during the initial pilot set up stage around the appropriateness of pharmacy assistants, as non-registered professionals, performing earwax removal.The clinical leads from the SWL project team considered the workforce model and decided to enable pharmacists and pharmacy technicians (as registered professionals) and pharmacy assistants (as non-registered professionals) to be trained to deliver the hearing health service under the supervision of an on-site pharmacist. Throughout the 12-month pilot time period, 55% of appointments were delivered by a pharmacist, 10% by a pharmacy technician and 33% by a pharmacy or dispensary assistant. 2% of appointments were delivered by a staff member who subsequently left the pilot and therefore their job role was unknown. See further information on wider workforce considerations in the 'Introduction' and 'Developing a Sustainable Workforce' sections. Ultimately, the accountability for any procedure lies with the clinical pharmacist and thus, it is important that appropriate workforce model is assessed locally and considered within the context of the maturity of local governance processes.

5.4 Governance

From a governance perspective, the SWL project team pilot has encouraged pharmacies to use the ICB quality reporting process, Make a Difference[9], to feedback on inappropriate referrals from general practices or other issues relating to quality. There is evidence from the SWL project team of this reporting process being used effectively, particularly when under 16 referrals were being made and subsequent targeted communication was undertaken with the relevant practices to prevent recurrence.

Clinical pharmacy is an expanding field, with some challenges still being addressed. This includes making sure that pharmacy business models align with the overall aims and values of the NHS and strengthening overall governance processes. Clinical safety is a key priority and the clinicians leading the NHS SWL ICB pilot have provided intensive support to participating pharmacies, including in person attendances to assure themselves of clinical safety aspects. As a national governance model is not in place for treating hearing health in community pharmacy, other systems will need to consider what an appropriate support and assurance mechanisms looks like, taking in to account their local geography and other system factors. See further reflections in the Feasibility and Sustainability sections regarding recommendations to support successful implementation.

[9]Make a difference
https://www.southwestlondon.icb.nhs.uk/contact/make-a-difference/

5.5 Digital Clinical Safety

Published under the Health and Social Care Act 2012, the DCB0129 information standard provides a set of requirements to ensure the effective application of Clinical Risk Management by organisations responsible for the development and maintenance of Health IT Systems for use within the health and care environment. The TympaHealth system application therefore is required to comply with this DCB0129 standard.

The DCB0160 information standard is broadly similar to DCB0129, but instead applies to organisations which deploy or use a Health IT system. Within this DCB0160 standard is requirement 2.5.1 which states: "In the procurement of a Health IT System the Health Organisation must ensure that the Manufacturer and the Health IT System complies with DCB0129." The scope of DCB0129 and DCB0160 was extended in 2018 to include functionality classified as a 'Medical Device', where that functionality is 'implemented' in a 'Health IT system'.

A review of documentation provided by TympaHealth to support DCB0129 compliance was undertaken by a Clinical Safety Officer, with a number of observations noted in the review of the documentation. To the knowledge of the evaluation team and Clinical Safety Officer undertaking this review, there have been no safety incidents or near-misses reported during the pilot related to any of the digital clinical aspects. The system itself may well be considered safe by the manufacturer, however in terms of Digital Clinical Safety and DCB0129 compliance, it is recommended that further review of the documentation is conducted by TympaHealth to ensure there are no areas of doubt when it is presented to potential deployers or customers.

5.6 Safety: Conclusions

Overall, the development and implementation of governance processes has been of central importance to NHS SWL ICB ensuring the pathway is delivered safely. Triage processes appear to have worked well and there is evidence that the NHS SWL ICB quality reporting processes and feedback loops have been used effectively.

Ongoing development and improvements are recommended regarding consistent understanding and application of referral processes and inclusion and exclusion criteria to ensure red flags and inappropriate referrals to the service are minimised. The 'Make a Difference' quality alerts has apparently been successful so far as forming a key feedback and learning loop.

From a patient safety perspective, there has been no evidence to suggest that patients have come to harm from non-registered professional staff performing earwax removal during this pilot and NHS SWL ICB should ensure the workforce model and its impacts are closely monitored for safety and quality impacts for patients. See further discussion in the Feasibility section, subheading 'Governance, Roles and Responsibilities'.

Whilst governance aspects of the pilot have been used effectively in NHS SWL ICB, there are gaps in the current regulatory position as standards developed by a national body are not currently available for earwax removal in community pharmacies. There is opportunity to undertake work with national stakeholders to ensure that national governance processes support the successful implementation and delivery of these services at a local level. See 'Governance, Roles and Responsibilties' heading in the Feasibility section for further discussion.

In terms of digital clinical safety, NHS SWL have continued to consider their assurance requirements under the DCB0160 as the deploying organisation. For example, completing a review of the DCB0129 deliverables by the supplier by the deputy CCIO, including a clinical safety case document, to support consideration of pilot extension/rollout. NHS SWL ICB should continue to consider their requirement to ensure there are appropriate and considered mechanisms to review documentation and processes in accordance with Digital Clinical Safety and DCB0129 compliance standards for the supplier.

6 KEY FINDINGS: FEASIBILITY

This section looks at the key practicalities and enablers of implementing a hearing health service and associated technology within a community pharmacy setting.

6.1 Key Enablers to Implementation

Collaboration and Communication

Professional stakeholders, especially those in the SWL project team, emphasised that successful collaboration and communication across the pathway and organisational boundaries are vital for the pilot's success. Focus group participants highlighted the extensive collaboration that has taken place among all professional stakeholders involved, particularly between pharmacies and general practices. Positive relationships and effective communication have played a significant role in ensuring the swift resolution of issues arising.

> *"Collaborative working between community pharmacy and general practice is crucial and very, very important because we often find ourselves in situations whereby general practices understand one thing compared to community pharmacies and then the patient gets very naturally upset and goes back to the general practice and in some cases, they start to give up on the pilot. If someone else was taking on the pilot, they need to ensure comms are strong."*
>
> **SWL project team, focus group respondent**

Similarly, there seems to have been robust and cooperative working relationships between all project stakeholders through the SWL project team, which have greatly contributed to the successful execution of the pilot. This was considered crucial in fostering relationships to effectively implement the pilot and stimulating discussions regarding potential future collaborations.

Based on discussions held during focus groups, it is evident that key individuals involved in this project are highly motivated and enthusiastic about establishing a successful service. The pilot programme's creation was a collaborative effort, involving various stakeholders who explored alternative ways to alleviate pressure on the local secondary care ENT service. This dialogue among stakeholders, focused on reducing pressure and demand, nurtured an innovative culture that organically led to the pilot's development.

> *"…innovation was cultivated through teamwork and communication."*
>
> **SWL project team, focus group respondent**

Furthermore, it is worth noting that possessing relevant local knowledge will be crucial for the successful replication and nationwide rollout of this service. Different regions may present unique nuances and challenges, necessitating specific solutions and resolutions in each area.

Engagement

Engagement with clinical leads, primary care managers, and community pharmacies across the three boroughs has been instrumental in addressing potential issues and concerns. Providing support and guidance, such as resolving IT issues and hosting service launch webinars for clinical colleagues, has contributed to the pilot's success.

The Local Pharmaceutical Committee (LPC) role was also deemed significant in bridging the gap between the SWL project team and local pharmacies and offering support to local pharmacies when challenges arose.

The communication and engagement model is key to transitioning to a sustainable commissioning framework. It is important to make sure that dedicated resources are identified for at scale implementation, to coordinate key communication and engagement activities. This can ensure the flow of information across the programme and keep stakeholders informed and engaged, manage expectations, mitigate risks, and promote the project's benefits.

Some participants in the focus group pointed out that effectively communicating and engaging with various stakeholders has proven to be complex and challenging at times, due to the transient and time-constrained nature of the workforce. Consequently, this complexity has led to further issues related to education and ensuring that all staff share a common understanding of the pilot programme and its objectives. To address this, it has been suggested that offering regular supplementary training for staff would ensure consistency in knowledge and understanding.

Feedback has indicated that issues around communications and engagement can be mitigated, for example the SWL project have implemented high levels of engagement with the local stakeholders in each locality, including general practices and clinical leads. This has strengthened relationships to drive the implementation of the pilot and resolve operational issues.

> *"…my main piece of advice to any other ICS that is looking to commission it is to mirror the [SWL project team] structure, to make sure that we've got key people in within each stakeholder group that are responsible for moving those messages around between all of the people on the ground that are delivering it…"*
>
> **Technology provider, focus group respondent**

Governance, Roles and Responsibilities

Robust commissioning governance frameworks, clear processes, and a well-defined service specification have been crucial for effective service delivery.

> *"It is important to work within a robust governance framework so that there's clear processes to work from during roll out of the technology."*
>
> **Technology provider, focus group respondent**

A significant lesson learned from the pilot programme emphasises the importance of establishing proper clinical governance arrangements. This proved challenging, particularly in the early stages of the pilot, because community pharmacy contracts had not been decentralised to local ICBs, resulting in difficulties in crafting suitable local clinical governance structures (although local approaches are now in progress). It is noted that having a strong project team played a key role in developing these governance structures.

Additionally, it was observed that clarity in roles and responsibilities, particularly between the ICB and the Acute Provider Collaborative (APC), was crucial. As referenced in the Safety section, NHS SWL ICB and other commissioners will need to consider, set up and monitor appropriate local governance and assurance mechanisms. However, the difficulties faced in setting these up in NHS SWL ICB show there is opportunity for governance and assurance systems to be supported and enabled through development of, for example, a national standard for earwax removal in community pharmacy settings. Similar models of national standards and inspection in other settings work well, and it is recommended that NHS England work with national stakeholders to ensure that national governance processes support the successful implementation and delivery of services at a local level.

> *"The time that's been put in to deliver a service like this and bring it to fruition to manage the governance is really key."*
>
> **SWL project team, focus group respondent**

Ease of Resolving Operational Issues

Overall, communication among distinct groups and professionals involved in the pilot project appeared to function seamlessly, offering robust support in addressing operational challenges. Participants expressed satisfaction with this aspect, with no notable issues identified. Regular training events were deemed successful by the project team, enabling rapid responses to issues and questions, with adjustments made as necessary. Their collaboration was strong, extending beyond the pilot project.

Community pharmacy staff noted that peer support played a vital role in continuous learning. The MDT met monthly to discuss pilot issues, share and receive praise and recognition for providing valuable clinical and operational support, facilitated learning and shared experiences. While participants generally appreciated the support during the project, some found it challenging to attend MDT meetings due to competing commitments, suggesting that as the service matures, less frequent meetings might suffice.

> *"It does help learning from other people's experiences because everyone sees different things and learning how people are managing their time and what they're doing definitely did help."*
>
> **Community pharmacy staff interviewee**

Local collaboration between pharmacies and general practices operated effectively, with issues promptly addressed on a case-by-case basis. Participants highlighted the LPC project manager's strong relationship and support for local pharmacies as a crucial source of reassurance. A robust and regularly meeting project group with strong working relationships played a pivotal role in addressing and resolving issues promptly.

> *"The thing with pharmacies is they're really busy… I think it's just important to make them feel that you're just on the other end of the phone; they really appreciate the support."*
>
> **SWL project team, focus group respondent**

Planning and Practical Delivery

The pilot has generated valuable insights for those involved, particularly from the SWL project team focus group participants. They have primarily learned through practical experience and identified important lessons, for example, clarifying the training requirements at the pilot's outset to prevent confusion, and particularly agreeing the allocation of consumables to each site as part of the pilot as it could impact their costs significantly, potentially influencing their decision to join the pilot.

SWL project team recognised that the fixed pilot launch date placed considerable pressure to execute tasks, therefore have recommended sufficient rollout time to be planned in. Additional preparation could allow for more time to integrate the software into local systems and ensure that all relevant staff receive adequate training.

Systems and Process

Several focus group participants identified potential barriers within the ICB model's systems and processes. Given that this was the first hearing health project in a community pharmacy setting, challenges included; agreeing ownership and governance within NHS SWL ICB; comprehending necessary financial procedures to secure funding for the pilot; ensuring effective resource allocations for critical functions such as communication, project management, and contract management.

Participants observed that a substantial portion of the pilot setup and management relied the SWL project team, particularly their goodwill and adaptability in terms of roles and responsibilities. This approach is unsustainable in the long run. Therefore, for the pilot to successfully expand and roll out in the future, it is imperative to establish a well-defined resource plan and assign specific individuals to key delivery tasks.

Initially, the SWL project team experienced some difficulties with managing the contractual and finance aspects of the pilot, primarily around the finance and procurement processes. In particular, the processes were complex and the SWL project team had to work very hard to deal with the contract management internally and develop processes quickly.

Participants in the SWL project team expressed that properly executed contracting was viewed as a significant facilitator of success once initial barriers were overcome.

Organisational Change

The implementation faced hurdles due to organisational changes, notably emphasised by the SWL project team focus group. As the pilot expanded across boroughs, the need for a South West London process, rather than one tied to specific locations, presented its own set of challenges. Transitioning from a London Healthcare Partnership to an ICB added complexity, necessitating a thorough review and update of all financial elements related to the pilot.

Likewise, during the pilot's design and setup phases, shifts in commissioning models, from a Clinical Commissioning Group (CCG) to an ICS, and finally to an ICB resulted in changes in leadership. These changes, in turn, impacted the pilot's design and setup, adding to the workload of those already involved.

It is worth noting that at the time of writing this report the existing ICB is expected to undergo yet another restructuring, creating a period of uncertainty for the project team.

The Role of Data

Effectively managing data is a crucial aspect of implementing the service, ensuring its effectiveness can be measured. During the pilot phase, challenges arose in obtaining robust data across different aspects of the pathway, hindering the ability to showcase the service's impact and to actively monitor wait times without heavy reliance on manual processes.

Free-text data fields pose an increased risk to information governance and security of patient identifiable information. Where free-text data fields are required, it should be ensured that staff members are clear on the purpose of the dataset, and it's intended recipient to protect patient information.

> *"There's been a difficulty in getting robust, clear data to demonstrate the true impact of the service."*
>
> **SWL project team, focus group respondent**

6.2 Feasibility: Conclusions

In conclusion, the insights gathered from interviews and focus groups with the participants involved in the pilot project have illuminated both the critical success factors and potential challenges of implementing the service. By emphasising effective collaboration, clear governance, and meticulous planning, along with addressing issues such as ownership and staff turnover, systems can navigate the path to successful implementation. Additionally, the positive impact of clinical information sharing, and strong support and communications and engagement networks within the system underscore the potential for a successful outcome. These findings provide valuable guidance for future endeavours and highlight the importance of adaptability and continuous improvement in service implementation efforts.

7 KEY FINDINGS: SUSTAINABILITY

This section assesses the long-term viability and sustainability of the service by focusing on the financial, workforce and environmental factors when considering future roll outs and at scale commissioning.

7.1 Ensuring Financial Sustainability

Using data from the pilot, financial analysis was undertaken to test the assumptions made within the original NHS SWL ICB business case and understand the cost of providing the service, compared against the current secondary care payment structure to understand the potential for any net system cost savings. It is important to note that whilst the term "savings" has been used here for ease of understanding, any likely savings generated from implementing such a service are likely (and were expected by South West London) to be non-cash releasing in nature and are more likely to be considered in terms of cost avoidance.

The full details of the financial analysis have been circulated separately to NHS England and NHS SWL ICB.

It should also be noted that the implementation costs and modelling do not account for the significant amount of time, energy and goodwill contributed by members of the SWL project team, which have been a significant factor in the success of the pilot and will need consideration in any future extension of the pilot or at scale commissioning.

In terms of overall value for money and financial sustainability comparing the pre- and post-pilot delivery models, the pilot has generated potential cost savings (non-cash releasing). The net savings per patient who would otherwise have received treatment in an acute setting was £49.01 (total £262,079 across the pilot period) and the net savings per patient who would otherwise have received treatment in a general practice was £2.01 (total £10,770 across the pilot period).

Utilisation across pharmacy sites has varied during the pilot period and the cost savings could potentially be greater if available capacity at the active pharmacy sites were fully utilised. Scenario modelling assuming a best-case scenario of 85% utilisation across the pharmacy sites, would show a unit cost saving of £36.81 per appointment compared to treatment in a general practice, and a unit cost saving of £68.16 per appointment compared to treatment in an acute setting of care.

Greater cost savings could potentially be realised if capacity across all participating community pharmacy sites were to be fully utilised. It should be noted that whilst on average there was significant underutilisation across the participating community pharmacy sites, this belies the fact that there was significant variation in utilisation between the different community pharmacies sites participating in the pilot. There was also some variation across localities within the pilot geography. Reducing this variation in utilisation is likely to be important in ensuring sustainability of service provision going forward.

It is also important to consider the sustainability of the payment structure in incentivising community pharmacies to participate and provide the service. Whilst the overall income which the service generates for community pharmacies appears welcome, and the service is regarded as beneficial for patients and therefore worthwhile providing, there appears to be an element of concern amongst some community pharmacies that the current payment structures are potentially not enough to make the service financially worthwhile and sustainable for them in the long run.

> *"The service in itself is excellent - patient satisfaction is very high. However, this is not sustainable at [the current level of] renumeration."*
>
> **Community pharmacy staff, Temperature Check survey respondent**

The lack of payment for DNAs, despite the admin time and work still required, was also cited as a potential hindrance to community pharmacies participating in providing the service (this is discussed further in the next section). There also appeared to be some confusion amongst pharmacies, particularly at the start of the pilot, as to exactly what costs would be covered including future expectations around whether community pharmacies would need to pick up the cost of consumables post pilot. This includes arrangements for any backfill when attending training, even though the pilot did provide payment to cover backfill for training. Ensuring any payment structure is set at an appropriate and affordable level will be important in any rollout of such services to ensure sustainability.

7.2 Ensuring a Sustainable Workload

The key to assessing the sustainability of workload in this pilot pathway is to evaluate whether the referral levels are appropriate, and if appointment duration and the associated workload is appropriate and sustainable.

In relation to workload sustainability, pharmacy staff indicated that, based on their current referral levels, it was feasible to manage. Importantly, those pharmacies that responded reported receiving manageable or relatively low referral volumes. It is worth noting that the sample of pharmacies who provided feedback as part of the interviews may have been self-selecting, with those able to spare time for interviews representing those feeling referrals were manageable, a situation that may not apply universally, as recognised by some respondents.

The interviewees acknowledged that less well-resourced pharmacies might struggle to meet the service demand, which is an important factor in considering longer term viability of the model. Some respondents suggested that having more trained personnel would enhance service capacity and continuity, while others highlighted the additional administrative workload associated with offering the service.

In relation to appointment duration, the pilot service specification sets out an approximate length of time each appointment should normally take of between 15 and 30 minutes. Community pharmacy staff who were interviewed generally noted that they found the time required for appointments to be acceptable. However, a few mentioned that although it is currently manageable, any additional time required per consultation could pose a challenge.

> *"It's taking us between 20 minutes to half an hour…but it can take longer…and we've got a balance those appointments with our normal work…"*
>
> **Community pharmacy staff interviewee**

In the last quarter of the pilot, pharmacy staff were asked to compare their average approximate appointment duration at the start of the pilot to their approximate current appointment duration, with data gathered in July and September 2023 (months 10 and 12 of the pilot). Pharmacy staff reported some variability in the estimated time for completing patient treatment tasks and overall appointment durations. Some responded that earwax removal could take between 10 and 20 minutes, and others frequently indicated a 30-to-45-minute timeframe, which also accounted for patient treatment tasks and consultations.

Some respondents noted a marginal reduction in average consultation times for tier 1 and tier 2 appointments since the start of the pilot to both month 10 and month 12 of the pilot. This may show an increase in efficiency, but it is important to note that appointment duration increasing may also be appropriate for example where staff experience and familiarity with more complex cases increases, as well as where patients have additional requirements, meaning an ear examination or total appointment duration is longer.

Most respondents stated they delivered their appointments within the 15–30-minute timeframe, as outlined in the service specification. This suggests that the timeframes set out in the service specification are, in general, appropriate and the model is viable and deliverable. However, referral levels and appointment duration, should continue to be monitored, through both data analysis and qualitative feedback where possible to ensure the service model is sustainable for future rollouts.

There is a significant link between views on the amount of work required to deliver the service and time taken to complete tasks and views on the payment structure and level of remuneration received (and what this includes and excludes). This may impact on the sustainability of any future rollout and how far community pharmacies are prepared to engage with and undertake to provide the service.

Community pharmacy staff respondents noted concern around the total of 13% of booked patients not attending their appointments during the pilot. Some pharmacy staff reported the length of administrative time taken when patients DNA their booked appointments did present a challenge, especially when they had not cancelled; and as the payment structure did not renumerate pharmacies for patients who did not attend their appointment. SWL project team acknowledged this and responded by sending automatically generated text message to each patient to remind them of their appointment.

> *"the admin, in terms of booking appointments and chasing people up (DNA's), sometimes is the element that is taking a up a bit more time than maybe people have available."*
>
> **Community pharmacy staff interviewee**

When considering wider rollout of the service, both community pharmacy staff and general practice staff interviewed noted the importance of taking time to understand local capacity and ensure that it matches demand for the service in order to ensure that waiting times remain low and acceptable to patients. Managing variation in waiting times may be challenging in terms of supporting patient choice whilst also promoting effective utilisation across all pharmacy sites. The general practice staff also reported a potential challenge going forward with the popularity of the service and its impact on waiting times and overall care. In this regard, some community pharmacy staff stated that they would be happy to provide more than the 15 appointments per week maximum that has been commissioned during the pilot. It will be important therefore to ensure that capacity continues to meet demand otherwise there is a potential risk that patients will revert to general practices. Referrals and waiting times are discussed in more detail in Section 3: Acceptability.

7.3 Developing a Sustainable Workforce

All community pharmacy staff interviewed were keen to continue to offer the hearing health service beyond the period of the pilot, reiterating the types of benefits for patients, and stakeholders within the health service that have been discussed above. All general practice staff reported that they felt there was a need for this service and that they consider it a sustainable pathway. General practice staff noted that existing services are still overwhelmed, but putting in a simple referral process would alleviate the time taken to make referrals.

> *"Absolutely. I think I mentioned that it's one of the better received services... we're making a difference here … to patients, actual providers and we're working hand in hand with the GP surgeries, they're really, really happy. I'm sure it's reducing workloads everywhere. And we're quite happy to do it. And yes, I would like to carry on."*
>
> **Community pharmacy staff interviewee**

The opportunity to develop and upskill the community pharmacy workforce and develop interventions for pharmacies was discussed as a potential significant facilitator for primary care moving forward. General practices suggested it may change a patient's thought process when seeking health care and may impact how patients view pharmacies. A couple of general practice staff members felt a change in the culture is needed to normalise services being delivered by community pharmacies. Pharmacy staff generally appeared to agree with this perspective and appreciated the enhanced role involvement in the pilot had given them.

With this in mind, developing a workforce which can deliver such a service sustainably is important if such a service is to be rolled out further. In this regard, members of the SWL project team were asked in their focus groups about their views and perceptions of the workforce model for the service. One attendee commented that there is a danger of losing pharmacy staff who are very skilled in delivering this service and a mixed model needs to be considered to combat this. They stated that they felt other healthcare professionals could also deliver the service in a safe and effective way.

It was noted that the pharmacists who have been trained are not necessarily delivering much of the service because of their limited capacity and pharmacy technicians and pharmacy assistants are doing some of the procedures instead. There were a range of views on whether this was acceptable (see further develop the model to ensure effective clinical oversight and accountability is fully embedded in the Safety section). Some respondents suggested that following the pilot it may be necessary to develop the model to ensure effective clinical oversight and accountability is embedded for the clinical pharmacist, ensuring that staff at all levels are appropriately supervised. Others suggested that given the national shortage of pharmacists, it is important that the whole pharmacy workforce is utilised.

> *"It is really important that we utilise the whole pharmacy workforce and especially seeing as that's where NHS [workforce] strategy sits at the moment."*
>
> **SWL project team, focus group respondent**

Some pharmacists stated that in general practice a similar service is delivered by highly trained care coordinators and that this would support using pharmacy technicians and pharmacy assistants with appropriate training.

It is important to note here that general practices are Care Quality Commission (CQC) regulated spaces whereas pharmacies are regulated by GPhC. Care needs to be taken in a sustainable workforce model as there is absence of a standard for this type of clinical service and pharmacy assistants are not GPhC registered staff. See the Workforce part of the Safety section for further discussion.

When rolling out such services more widely, ICBs will therefore need to take account of the fact that different opinions on suitable workforce models exist and take the time to engage widely with all key stakeholders to develop a workforce model that works for their area, ensuring that they assess the appropriateness of any local workforce model in the context of the maturity of local governance processes (as discussed in the Safety section).

Depending the the type of model used, it is important to ensure that staff at all levels are remunerated and trained appropriately in order to try and mitigate issues with staff turnover is important.

7.4 Delivering Environmental Sustainability

NICE guidance on hearing loss states, "Providing earwax removal closer to home, in primary care or community ear care services, will prevent the inappropriate use of specialist services". This evaluation has endeavoured to test whether this pilot has provided treatment closer to a patient's home through a community pharmacy location, compared to receiving treatment in a secondary care location. The carbon impacts of that change in journey distance were also calculated.

Data limitations referred to above have meant that a patient's registered general practice has formed a proxy for the patient's location, and this has been compared to the predicted secondary care referral location (following trends of patients receiving earwax removal in secondary care). Analysis was carried out to look at travel distance for patients and the associated emissions differences from the change in location of service delivery. It is important to note that this modelling does not accurately represent a patient's personal location, and the secondary care location is an assumption based on referral patterns which therefore may not predict or reflect the secondary care location that a patient would choose to attend.

On average, patients who were treated through the pilot in a community pharmacy travelled 2.76 miles less in comparison to receiving treatment in their assumed secondary care location. The largest difference was for 295 patients who saved 8 miles in their travel distance. 74 patients are suggested as having travelled further to access community pharmacy in comparison to their assumed secondary care location.

The average carbon emissions savings per patient treated within the pilot was 0.73 CO2 (kg). This represented a single journey, and therefore may be increased for patients who require multiple appointments. In total the pilot is estimated as having saved 3,626 CO2 (kg) through reducing the distance patients need to travel to receive treatment.

This suggested that the pilot had a positive impact on reducing travel times and associated CO2 emissions, however given the limitations noted with the data, it is recommended that NHS SWL ICB continue to monitor this in any future rollout and ensure that data is collected which allows accurate mapping of patient journey times from their place of residence to the community pharmacy and from place of residence to secondary care provider.

7.5 Commissioning and Contracting Sustainably

Contracting, finance and procurement processes were noted by focus group participants from the SWL project team as a challenge to set up initially, but a key factor in facilitating success. It is therefore important to ensure both initial set up processes and ongoing contractual arrangements are appropriate and sustainable to form an enabler to a sustainable model, not a barrier. In this regard, a participant in the SWL project team noted that the role of the LPC had worked well as an appropriate vehicle to support particularly the local contracting and payment processes, supported by strong local relationships and engagement with local stakeholders.

Learning from this pilot suggests that having a robust and effective governance framework in place, along with clear processes and a detailed service specification, is essential to ensuring effective and sustainable delivery of a service like this. Members from the SWL project team acknowledged that the pilot had seen some initial challenges in this regard due to the lack of central guidance and the fact that governance for community pharmacy was evolving; but one which they worked hard to develop between themselves, despite this taking considerable time and resource. The development of a clear governance framework with a project team was seen as a key outcome of this work.

> *"The service continues to succeed and be well received in the community. Fine tuning the governance process will help ensure the longevity of the service moving forward."*
>
> **SWL project team, Temperature Check survey respondent**

Although explored in more detail in section 6: Feasibility, it is important to note here that for such services to be developed and rolled out effectively, the development of governance processes needs to include due consideration for appropriate clinical governance arrangements.

7.6 Sustainability: Conclusions

Overall, the service has appeared to be seen positively by patients, community pharmacy staff and other stakeholders within the health and care system. It has been seen to provide a valuable service which can free up time for more specialist staff to focus on more complex cases and issues. If planned and utilised effectively, the pilot has appeared to generate potential savings when compared with carrying out comparable work in secondary care. However, to ensure that such a service can be rolled out sustainably in the future, it is important to ensure that the payment structure continues to be viable to support participation by community pharmacies and that utilisation is managed effectively, ensuring that capacity meets demand and that variation in waiting times are managed across the service to ensure that patients can access it in a timely manner.

There is the potential to generate further cost savings if available capacity is utilised effectively. Only a very small proportion of patients seen by the service required onward referral to specialist audiology or ENT services, suggesting that this these patients are in general more than suitable for treatment in a community setting. Both community pharmacy and general practice staff generally appeared to be very enthusiastic about the service and noted ongoing benefits both for local patients and for the health and care system. In particular, the opportunity to develop the community pharmacy workforce and change perceptions of community pharmacy is seen as a big positive of the pilot. The pilot has seen some impact in providing care closer to home by reducing travel distance for patients and therefore associated CO2 emissions by delivering care closer to home, though this should continue to be monitored given the data imitations, and to ensure that this remains the case.

Some concerns were raised amongst community pharmacy staff that the current payment structure does not necessarily make it sustainable to provide the service in the long run and may therefore make it difficult to attract new pharmacies to participate in such a scheme if this has not been addressed and rolled out further. Similarly, whilst patient choice is always likely to lead to a variation in waiting times, managing this variation effectively will be important to ensure that long waiting times do not build up at more popular pharmacies and that capacity continues to meet demand in any future rollout. However, the overall evidence has suggested that the service has been worthwhile and effective, which has supported local patients and appears to be benefiting the local health and care system; and is a service which can be rolled out sustainably moving forward.

8 CONCLUSIONS

The evidence compiled from the evaluaion has suggested that the pilot appears to be a worthwhile and effective service and has been very beneficial in addressing local patients hearing health needs. The patient demand has been high, with 70% of total referrals resulting in completed treatments, and the capacity to deliver this service within a community pharmacy setting has also shown to be suitable, providing that nominated staff are sufficiently trained. The feedback from the patients treated on the pathway has been very encouraging, with the majority of patients being happy with the staff professionalism and service received, the short waiting times, and recommending the service to others.

The advantages of delivering this service within a community setting have been widely accepted by most professional staff and stakeholder teams, acknowledging the benefits for patients with majority reporting they would recommend this service if commissioners were interested in implementing this elsewhere.

The evaluation also captured several opportunities for ongoing improvement of the pathway, noting that many of the issues raised and opportunities for improvement are likely to be reflective of a new service embedding. Recommendations for ongoing improvement include;

- Improving the clarity in the referral process and its application to avoid issues around inappropriate patients being referred.
- Ensuring governance and quality reporting processes continue to be robust and quality assured.
- Monitoring the workforce model and its impacts for safety and quality outcomes for patients, and to ensure effective and appropriate assurances and roles and responsibilities are in place.
- Considering ways in which capacity can better meet demand to ensure greater utilisation of capacity across community pharmacies to minimise waiting times, whilst continuing to enable and support patient choice of pharmacy location. This will support with minimising patient waiting times and enabling a more sustainable service.

Several key aims of the pilot were unable to be proven in the data at this point, and there are key recommendations set out for NHS SWL ICB to continue to monitor these areas including;

- Monitoring data to test if activity has reduced in general practice and in secondary care. Stakeholder insights have indicated that the has been diverted to community pharmacies. The data analysis should test if activity is in fact being diverted, and if a key aim of the pilot is being achieved in reducing primary and secondary care appointments and backlog.
- Patient demographics and outcomes data should also continue to be gathered and analysed data to test if the pilot is achieving one of its key aims of reducing health inequalities.
- Similarly, data should continue to be reviewed to understand the ongoing impact on care being delivered close to home, and whether the pilot is environmentally sustainable in terms of reducing journey times and associated CO2 emissions.

The pilot has appeared to be financially sustainable and has generated potential cost savings (non-cash releasing) when compared with delivering similar activity in secondary care. There is further potential to generate additional cost savings if available capacity is utilised effectively.

Overall, the pilot pathway has shown to benefit the local health and care system; and is a service which can be rolled out sustainably moving forward, with 94% of professional stakeholders responding to the temperature check surveys reported that they would recommend the service if it were to be implemented elsewhere.

There are a number of opportunities to take forward continuous improvements in this pilot pathway, summarised in a series of recommendations for consideration by NHS SWL ICB, and for NHS England, and by ICS commissioners considering implementing a pilot or at scale commissioning model of a hearing health pathway in community pharmacy recommendations (set out below).

9 RECOMMENDATIONS

A key part of this evaluation has been to capture learning from the pilot and its implementation, and to provide recommendations for considering implementing a pilot or at scale commissioning model of a hearing health pathway in community pharmacy.

Recommendations are set out below for NHS SWL ICB in considering any pilot extension or expansion, or operationalisation of the service;

NHS England in their national role; and for ICBs other commissioners considering implementing a pilot or service model of a hearing health pathway in community pharmacy.

9.1 Recommendations for NHS SWL ICB

Recommendations for ongoing improvement for consideration by NHS SWL ICB include;

1. **Gather and monitor data to test key aims of the pilot** including: to test if activity has reduced in practices and in secondary care; to test if health inequalities are being reduced; to test if care is being delivered closer to home.
2. Ensure the **training approach continues to be as equally rigorous** as during the pilot for refresher and revalidation training.
3. Improving the clarity in the **referral process** and consistency of its understanding and application, particularly of the inclusion and exclusion criteria to ensure red flags and inappropriate referrals to the service are minimised.
4. Continue to ensure **governance and quality reporting** processes and feedback continue to be robust and quality assured.
5. Continue to monitor the **workforce model** and safety and quality impacts for patients, and to ensure effective and appropriate assurances, and roles and responsibilities, are in place.
6. Ensuring key roles and responsibilities are **resourced in the future commissioning framework** to effectively deliver oversight if the pilot/service model scales up.
7. Consider if **support and monitoring mechanisms for pharmacy sites** are sustainable if the pilot/service model scales up.
8. Consider **digital clinical safety requirements** of deploying organisations (see detailed Digital Clinical Safety recommendations)
9. Consider ways in which **capacity can better meet demand** to ensure greater utilisation of capacity across community pharmacies, whilst continuing to enable and support patient choice of pharmacy location. This will support with minimising patient waiting times and enabling a more sustainable service.
10. Consider **ideas for improvements** to further increase patient choice and access through enabling visibility of waiting times or appointments slots at different pharmacies (see Usability section for more information)
11. Consider if the **model for reaching underserved populations** can be further enhanced e.g., in considering the influence of the location of participating pharmacies, and their ability to adapt their service to the needs of those with specific needs (e.g., offering longer appointment times and different reminder systems).
12. Consider how **interoperability between systems can be improved** to support local stakeholders not using the pilots IT systems to participate in future, and that the type of mobile devices which ensure best performance to reduce the risk of technical problems or need to replace devices.

9.2 Recommendations for NHS England

1. Recognise the **importance of local knowledge** to successfully implementing such services in other areas. Each area may have unique nuances and challenges that require local adaptation.
2. Consider **provision of commissioning guidance** to support and enable future hearing health pathway pilots.
3. Work with national stakeholders to ensure that national **governance processes support the successful implementation and delivery** of these services at a local level.

9.3 Recommendations for ICSs/At Scale Commissioning

Key considerations and recommendations for others for example, other ICSs to implement this pilot pathway or for this service to be commissioned at scale include;

Culture and relationships

1. Establish **effective relationships** in their local area across primary, community and secondary care, ensuring wide stakeholder engagement.
2. Foster a **culture of innovation** through dialogue among stakeholders, recognising the important of understanding local nuances and challenges in adapting services to meet local needs.
3. Establish **effective communication channels** with all stakeholders, including patients, to ensure they have a clear understanding of the service and its expectations.

Design of a local model

4. Design and **put in place suitable governance processes** to include clear delineation of roles and responsibilities early on, taking account of local organisational and system context.
5. Establish a **clear oversight group** such as a project team/task and finish group which can help to provide effective oversight, drive delivery and manage risks and issues as they emerge. Effective resourcing of key functions such as project management and communications and engagement resource should be considered.
6. **Work with local stakeholders to develop an operational model** which is sustainable for delivery beyond the life of any pilot and supports business as usual delivery.
7. Carefully **develop a localised pathway**, working with all stakeholders when planning such a service to which works in their area and which all parts of the system are signed up to and clear on.
8. **Carefully review local triage processes** to ensure their appropriateness is considered and assess the safety of the implementing the pathway within local organisational and system constraints.
9. **Consider the capacity of local stakeholders to attend and embed new training** for example, general practices on the referral and triage model, including the requirement for the training to be cyclical.
10. Ensure **feedback loops and ways to capture feedback** and ideas for improvement are considered at the outset for example, for when inappropriate referrals to the pathway are received

Information sharing and data

11. Ensure **expectations for effective quality clinical information sharing and processes** between professionals **are established at the outset,** for example, considering technology preferences, such as the use of video for diagnostic accuracy.

12. Consider the **interoperability requirements of local IT systems and the automation of patient information** flows from pharmacies to general practices where digital maturity allows.

13. **Consider mechanisms for enabling visibility of waiting times or appointment slots**, to better inform patient expectations and to support patients to select a pharmacy of their choice. For example, this could be visibility at general practice triage or for patients to self-book. Additionally, exploring the possibility of self-referral could be an option for expansion, noting that maintaining effective triage remains crucial to ensure patients are suitable for the service.

Safety, governance and workforce model

14. **Carefully assess and identify an appropriate workforce model for local implementation**, ensuring that this is considered within the context of the maturity of local governance processes.

15. Ensure **governance processes are robust and stress tested**, and local systems have assurance of this with appropriate support and assurance mechanisms in place, considering local system geography and other system conditions.

16. **Consider local digital maturity** the detailed recommendations set out below for deploying organisations.

Commissioning and contracting

17. Establish **clear and straightforward contractual and financial arrangements**, making sure funding processes are well-defined and understood by all stakeholders so that contracting can be an enabler rather than a barrier.

18. Ensure that a **reasonable level of service delivery/utilisation is established**. This should be balanced with enabling and facilitating patient choice of pharmacy location, whilst keeping waiting times to a minimum.

19. Agree a **local payment structure** that is realistic and viable to ensure sustainable future delivery, and to avoid overburdening pharmacy staff.

20. Consider **workforce resilience** to balance numbers trained for operational resilience, with budget available.

Set up of a pilot / service model

21. Prepare thorough **mobilisation and implementation plans**, including testing IT systems and data entry and outputs, clarifying the training pathway, and agreeing on the provision of consumables to each site.
22. Ensure **system processes capture responsibilities at different steps of the pathway**, for example, responsibilities for clinical oversight at different parts of the pathway.
23. **Ensure data gathering and management approaches** are considered early in the design process to ensure that the pilot/service can effectively measure its impact.
24. Put in place **assurance mechanisms for data quality and the quality of data entry.** In particular, timely data entry and training about where personal identifiable data is appropriate or not are important, and accuracy of recording for example, dropped/rejected reasons.
25. Ensure **mechanisms are in place to collect patient feedback and experience data** and this captures demographic data to assist with testing impacts on health inequalities. Depending on the needs of the local area and population, survey distribution, language and formats need consideration.

Implementation

26. **Continue to ensure strong collaboration** and regular communication and engagement among all professional stakeholders, including community pharmacies, general practice, and others involved in the service.
27. **Utilise communication channels and mechanisms** clearly and regularly in order to establish with all stakeholders, including patients, a clear understanding of the service and its expectations.
28. **Establish clear mechanisms to report issues** and resolve operational issues effectively, or to suggest improvement ideas as the pilot evolves and embeds.
29. **Implement regular training** and updates including peer support meetings, particularly for those triaging and delivering the service, to help maintain consistency, and address and resolve operational issues promptly.
30. **Monitor patient outcomes** and dropped/rejected/DNA data to track outcomes and patient stories for those not completing the pathway to understand the reasons for this, and to endeavour to enhance access to and successful completion of the service.
31. **Monitor variation in referrals and waiting times** across different community pharmacies to ensure that long waiting times do not build up at more popular providers. It will be important to ensure that capacity continues to meet demand is to provide an efficient and effective alternative to other pathways or services.

9.4 Digital clinical safety recommendations for NHS SWL ICB and other deploying organisations

Consider their requirements in terms of digital clinical safety as a deploying organisation in terms for wider post-pilot deployment of the TympaHealth system to meet the DCB0160 standard, including;

- Local systems should consider their digital maturity and ensure a Clinical Safety Officer is able to complete a review of the DCB0129 deliverables by the supplier, and complete the DCB0160 assurance for the deploying organisation. DCB0129 and DCB0160 are applicable for the entire lifecycle of the system and as such are fundamental considerations for a business as usual service.
- For a wider, post-pilot deployment of the TympaHealth system, a deploying organisation will task their Clinical Safety Officer(s) with assurance of the system to meet the DCB0160 standard. As part of that assurance work, the Clinical Safety Officer will examine the DCB0129 documentation and reject any which do not appear complete or comprehensive. As such is it recommended that the TympaHealth DCB0129 deliverables are reviewed against the observations noted in order to develop and improve the documentation.
- A deploying organisation will need to examine those controls which are handed over by TympaHealth in their DCB0129 and ensure that they are considered during implementation and incorporated where applicable into the DCB0160 Hazard Log and Clinical Safety Case Report. They must also determine the specific use-case of the system as it applies their local implementation and ensure hazards pertinent to their environment, community, and processes are considered.
- A deploying organisation should also ensure they have in place mechanisms and procedures to ensure effective incident reporting within the organisation, to the system manufacturer (TympaHealth), and to the NHS Clinical Safety Team (where appropriate) are in place.

10 APPENDICES

Appendix A: Evaluation Specification

NHS SWL ICB TympaHealth service pilot - Evaluation specification

The purpose of the evaluation is to understand and measure the impact and realised benefits of the pilot, with an aim of capturing the learning to inform the development of the future locally commissioned service and contract negotiations.

Theme/ Strategy / Policy	Objective	Pre-pilot state and demonstration of objective achievement (post-pilot) through KPIs	Questions	Evaluation Stage
NHS SWL ICB OP Transformation Programme Key Objectives	Increase the number of patients accessing faster non-admitted planned care treatment within primary and secondary care	• Reduce steps in the (ENT) hearing loss pathway • Increase the number of earwax removal treatments • Increase in number of practitioners • Increase in treatment sites available in SWL • Enabling faster treatment i.e., PTL size/growth rate decrease • Reduction in acute centre visits • Enabling more complex patients seen quicker in an acute setting • Reduction in number of earwax-related attendance codes in primary care and secondary care, compared with pre-pilot	**1.** How many steps (min & max) pre-pilot and post-pilot in (ENT) hearing loss pathway? **2.** How many earwax removal treatments performed in Primary Care (PC) and how many referred from general practice and performed in Secondary Care (SC) within pilot geography during same period last year? **3.** How many referrals made to participating pharmacies during the pilot and what impact it made on general practice (with and without earwax removal service) workload and what reduction in workload on Secondary Care? **a.** How many patients did not attend? Why? **b.** How many patients were offered earwax removal? **c.** How many required microsuction from one ear and how many from both? **d.** How many patients required a follow up appointment for earwax removal? **e.** How many patients were offered hearing check And how many received (valid and invalid)? **f.** How many procedures / tests were successful? **g.** How many procedures/ tests were unsuccessful/ invalid? How many patients were referred to general practice as a result? **h.** How many follow up appointments were offered? **i.** How many patients attended the follow up appointment? How many patients did not attend the follow up appointment? Why DNA? **j.** Time taken for administrative referral process to pharmacy from PC?	S1, S10 S1 S2, S6 S3 S4 S4 S4 S4 S4 S4, S5 S4 S4 S2

Theme/ Strategy / Policy	Objective	Pre-pilot state and demonstration of objective achievement (post-pilot) through KPIs	Questions	Evaluation Stage
			4. Waiting list/time until patient seen in pharmacy	S3
			5. How long were the consultations with pharmacist (mean, max., min.)? and is there a learning curve? – time in 5 minute blocks (<10 mins, 10 to 15 minutes etc)	S3, S4
			6. How many practitioners available prior to the pilot inc primary and secondary care to perform hearing assessment, digital otoscopy, and earwax removal? How many additional practitioners trained through the pilot?	S1 S13
			7. How many sites available for hearing assessment, digital otoscopy, and earwax removal (inc secondary care) prior to the pilot in SWL? How many sites added due to the pilot?	S1 S10
			8. How many days from referral to treatment prior to pilot during same period last year, and the change in situation post-pilot including any follow-up sessions at pharmacy, general practice, or SC?	S1 S6
			9. How much reduction in secondary care visits?	

Theme/ Strategy / Policy	Objective	Pre-pilot state and demonstration of objective achievement (post-pilot) through KPIs	Questions	Evaluation Stage
NHS SWL ICB Strategic Objectives	Health and Wellbeing: Reduce inequalities and improve healthier living	NHS earwax removal services are not available in all general practices. Patients may be advised to seek private treatment (£80) or expect extremely long waiting times. • Provide better access to free ear health for more patients in SWL reducing inequality. • Reduction in days from referral to treatment • Improvement in patient satisfaction	**10.** Patient demographics - age group, gender, ethnicity, postcode (to get IMD) **11.** Referral details – which general practice, which pharmacy, patient postcode **12.** What patient have been referred with (hearing problems, earwax – in which ear) **13.** How many days reduced in referral to treatment? (linked to Q8) **14.** Patient survey on: Speed of resolution of issue, increase in knowledge of hearing health, self-management and reduction in associated problems e.g., social isolation due to deafness.	S3 S2 S2 S1, S3, S4 S7
	Care and Quality: Improve health and care outcomes	• Hearing loss affects patients of all ages, often caused by wax build up or modern audio devices. In younger people it can affect their education and social life; in older people, it can lead to social isolation, falls, and a higher risk of developing dementia. • Faster and more accessible treatment provided in this pilot will support health outcomes by reducing hearing loss issues, social exclusion and exacerbation of associated conditions.	**15.** How many referrals made to Secondary Care after Tier 1/ Tier 2 consultation(s)? **16.** What feedback from general practice and Secondary Care professionals on: a. Quality of data received from pharmacies b. Use of available digital data/video files c. Assessment of practitioners at pharmacies and any training improvement requirements **17.** How many referrals made back to general practices after Tier 1 and/or Tier 2 consultations? **18.** How many unintended harm cases occurred as a result of the microsuction procedure? How to capture these when not all known yet? **19.** Are the intended population treated as per specification? **20.** Safety netting and self-care correctly provided (which process available, qualitative)	S5 S11, S12 S5 S? S3, S4, S10 S?, S7, S12

Theme/ Strategy / Policy	Objective	Pre-pilot state and demonstration of objective achievement (post-pilot) through KPIs	Questions	Evaluation Stage
NHS SWL ICB Strategic Objectives	Achieve financial sustainability	One OP appointment costs on average £120-140 suggesting an annual cost of £46-40 million. True figure may be closer to £60 million ex cost of general practice time. This pilot may create cost saving • Compared with the £120 OP appointment it could be as low as ~£20 per appt.	**21.** What is the cost of service per patient? **22.** What are the costs per patient of other hearing health services (general practice appointment, Urgent Care appointment)? **23.** What are overall financial savings? **24.** What is the cost of implementing this service (capital, project management, operational) in an ICS?	S10 S10 S10 S?
	Optimise our capability (processes, people, partnerships and assets)	If patients suffering from hearing related issues were seen in a community setting by a trained non-specialist healthcare professional (e.g. HCA, pharmacist) instead of OP appointment this would: • Enable senior clinicians to work at the top of their licence, reduce waiting times, save money, reduce burden on PC & SC	**25.** How are secondary care managing the additional data provided by tympa with a referral? What impact is it having on triage etc, has this increased workload for secondary care **26.** How was the referral process to pharmacy from general practice's point of view? **27.** How easy is to provide feedback/communicate among general practices, Pharmacies, technology provider and project management team on regular basis to solve operational issues and for improvement? **28.** Ease of information back to primary care where required **29.** Time and ease of using the Tympa link and appending it to eRS for patient referral	S11 S12 S9, S12-14 S3, S4, S8, S9
NHS Long Term Plan	Doing things differently	• A novel care pathway, providing a more efficient & innovative way of delivering care. • Good patient uptake (number of available slots filled) and improvement of patient satisfaction	**30.** Is the pilot service specification working as intended in pharmacy setting i.e. is it an appropriate pathway and if not what needs to change? **31.** What are the barriers and enablers to implementation? **32.** Is the support and communication in changing service user perceptions of where and how care can be delivered sufficient and efficient?	S8, S9 S7-14 S7

Theme/ Strategy / Policy	Objective	Pre-pilot state and demonstration of objective achievement (post-pilot) through KPIs	Questions	Evaluation Stage
NHS Long Term Plan	Preventing illness and tackling health inequalities	Enabling more patients to access timely ear health care supports reduction of inequalities, helps avoid health complications, reduced SC need and medicine/ABX use.	**33.** How many patients had "red flags" identified? **34.** How many and what ear infections were identified? **35.** How many patients required an onward referral to general practice or Urgent Care?	S3 S3, S4 S5
	Backing our workforce	• Upskilling workforce to deliver ear health care assessment and treatment • Protect senior ENT clinicians' time for most appropriate cases	**36.** Evaluation of training and how ready pharmacists felt in delivering the service. Feedback from pharmacy practitioners and management in increase in learning and capabilities and impact on staff retention. **37.** Feedback from Secondary Care professionals on workload and change in activity load and type at post-pilot stage	S8, S9 S11
	Making better use of data and digital technology	The device provides digital otoscopy – a video of the ear can be taken and saved for review by consultants, providing a more efficient pathway for senior review. • Better data quality for more effective triaging, improved access to senior clinical knowledge to support clinicians	**38.** What is the feedback from general practice, pharmacy practitioner, and Secondary Care professionals on: Data quality, time consumption, ease of data entry and access, safety & data protection, any improved effectiveness in triage, improvement in access to senior clinicians' knowledge & experience. **39.** Patient feedback on use of digital technology by practitioners, and availability of recorded video to their general practice and Secondary Care team for future reference	S8, S9, S11, S12 S7
	Getting the most of the taxpayers' investment in the NHS	This pilot provides a more efficient pathway that can provide: • care delivered away from secondary care • reducing outpatient spend • providing better quality care at a lower cost.	**40.** How long did the Tier 1 consultation take? **41.** How long did the Tier 2 consultation take? **42.** How long did the follow up consultation take? **43.** How many Secondary Care visits saved? **44.** How many general practice visits saved? **45.** Cost savings by reducing number and duration of visits to Secondary Care?	S3 S4 S4, S6 S2, S5 S2 S6

Theme/ Strategy / Policy	Objective	Pre-pilot state and demonstration of objective achievement (post-pilot) through KPIs	Questions	Evaluation Stage
NICE (2018) guidance on hearing loss in adults	"Providing earwax removal closer to home, in primary care or community ear care services, will prevent the inappropriate use of specialist services"	• This pilot supports SWL to follow NICE guidelines. • Share learning with other ICSs to help implement this service widely (subject to success) and to reduce national PTL	**46.** What is the average distance travelled by patients to referred pharmacy compared to distance they had to travel to a Secondary Care facility?	S2
			47. What is the estimated carbon emission reduction? (via NHS Futures environmental impact calculator)	S10?
			48. Feedback from patients on provided/available pharmacy service vs Secondary Care service should they had to visit Secondary Care. Patient experience should include primary care (right from point of contact to primary care), pharmacy and secondary care experience.	S7
			49. Does stakeholders support to develop new service model for national rollout supported by NHSX with potential to be used as exemplar?	S7-14

Evaluation stages/steps:

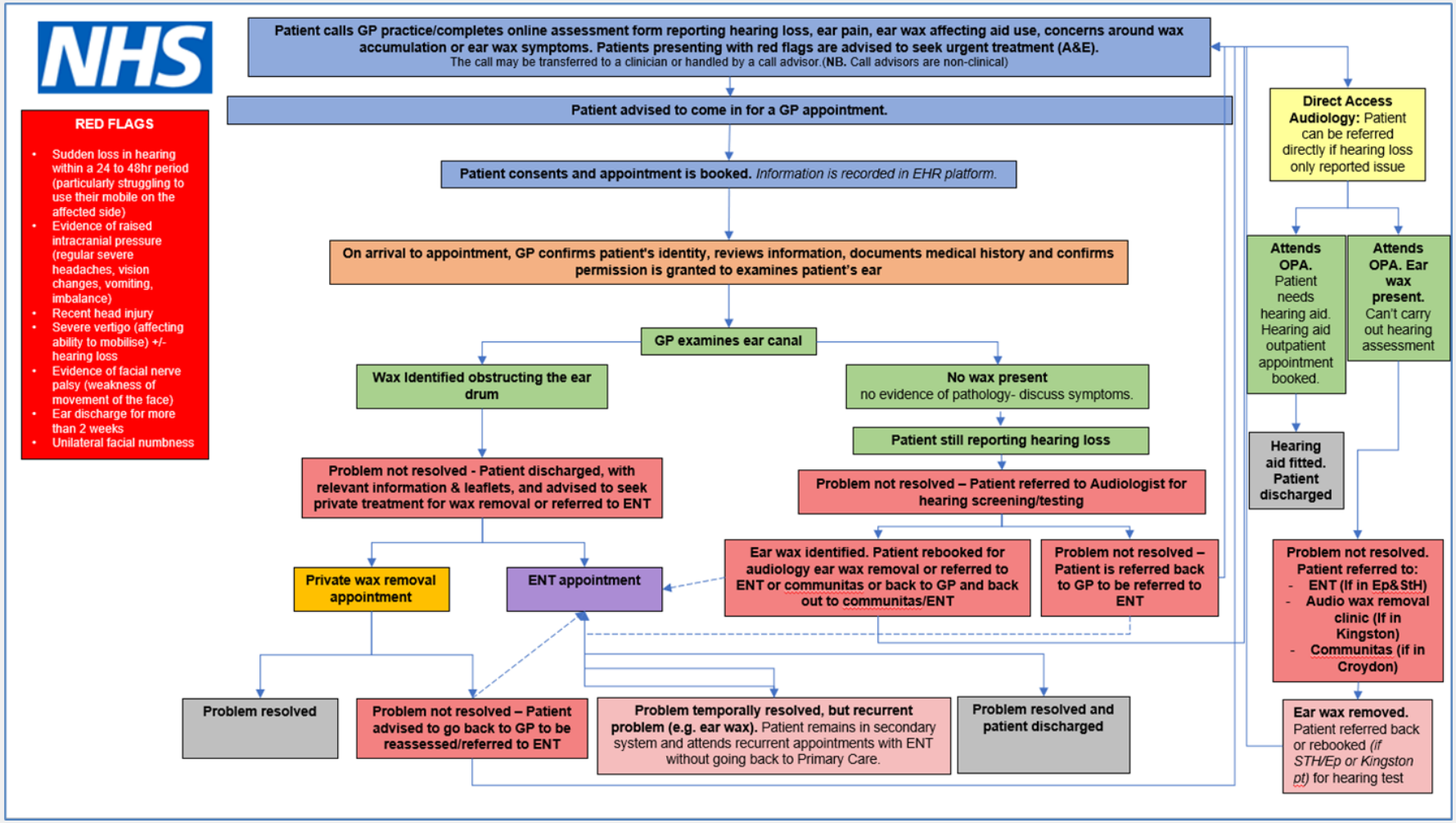
Stage 1 (S1): Capture from existing data
Stage 2 (S2): General practice to Pharmacy referral
Stage 3 (S3): Pharmacy assessment and otoscopy - Tier 1 consultation
Stage 4(S4): Earwax removal and/or hearing check - Tier 2 consultation
Stage 5 (S5): Pharmacy to general practice or Secondary Care or Urgent Care referral
Stage 6 (S6): Secondary Care treatment
Stage 7 (S7): Patient and/or carer, patient representative group(s) feedback – online survey or 1:1 telephonic interview
Stage 8 (S8): Practitioner feedback
Stage 9 (S9): Pharmacy management feedback
Stage 10 (S10): Project management feedback
Stage 11 (S11): Feedback from Secondary Care (e.g., availability of digital data inc videos)
Stage 12 (S12): Feedback from general practice
Stage 13 (S13): Feedback from the technology provider (TympaHealth)
Stage 14 (S14) Feedback from IT provider

Types of measure:

M1: Patient outcome
M2: Benefit to staff
M3: Cost/ Service delivery / Benefits to the NHS & Taxpayer
M4: Green NHS/ Benefit to environment

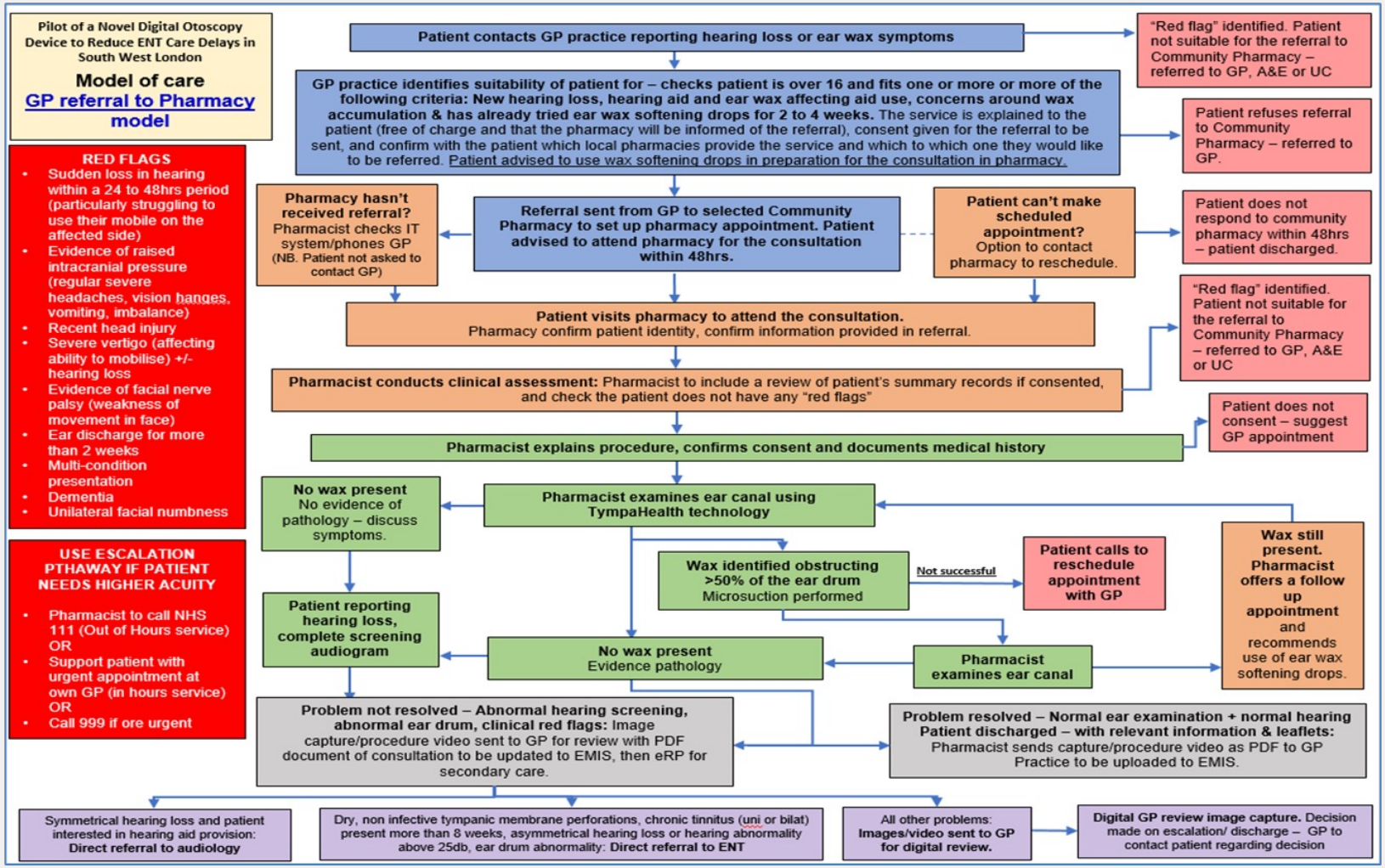
Appendix B: Pathway Models

Pre-pilot pathway:



Appendix B: Pathway Models

Pilot pathway:



Appendix B: Pathway Models

NHS SWL ICB have referred to the expertise of ENT clinical network, service models that have already been set up using the selected device and NICE guidance: www.nice.org.uk/guidance/ng98/chapter/Recommendations#assessment-and-referral

Inclusion Criteria: Below is a table that identifies patients that would be suitable for community pharmacy pathway.

SWL Pilot TympaHealth (hearing health) Pathway (THHP) Inclusion/Exclusion Criteria

Criteria	Inclusion Criteria	Exclusion Criteria*
*If a patient meets any of the exclusion criteria, DO NOT REFER to the TympaHealth Hearing Health Service, refer to General Practice		
Patient demographics		
Age	18 years and over	Below 18 years of age
Housebound	No	Yes
Patient health		
General health	Feeling well	Acutely unwell
COVID-19 symptoms *-New onset cough* *-New onset temperature over 38C* *-New onset loss of taste/smell*	No COVID-19 symptoms present	COVID-19 symptoms present
Mental health	No mental health concerns	Acute mental health crisis
	Capacity to consent referral	No capacity to consent to referral (e.g. significant dementia)
Presenting complaint		
Hearing loss	New gradual onset	Sudden onset (within 1 week)
Ear wax	Concerns around wax accumulation	No previous use of ear wax softening drops for 10 to 14 days
	Use of ear wax softening drops for 10 to 14 days	
	Hearing aid user and ear wax is affecting aid use	
Ear pain	No ear pain present	Acute ear pain
		Acute pain secondary to ear trauma
Other	No signs of infection present	Severe vertigo/dizziness
		Ear discharge for more than 2 weeks
Patient consent		
Referral to community pharmacy	Patient happy to be referred to a community pharmacy	Patient not happy to be referred to a community pharmacy
CLINICAL RED FLAGS - PATIENT REQUIRES MEDICAL ASSESSMENT (DO NOT REFER TO COMMUNITY PHARMACY)		
•Evidence of raised intracranial pressure (regular severe headaches, acute vision changes, vomiting, imbalance)		**Signpost patient to A&E**
•Sudden onset of unilateral or bilateral hearing loss *(loss of sensation or a sudden change in hearing over 24 to 48 hours resulting in hearing difficulties not previously experienced, for example reduced ability to use mobile phone on affected ear)*		**Patient to be escalated to duty doctor for urgent same day review**
•Evidence of facial nerve palsy (drooping on one side of the face) •Recent head injury •Patient with known mastoid cavity •Unilateral facial numbness		**Patient to be referred back to GP**

Developed by the TympaHealth Hearing Health Pathway (THHP) Task and Finish group
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SCW

NHS
South West London

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Health Innovation Wessex