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Exploring the burden of paediatric acute otitis media with discharge in the UK: a qualitative study

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Abstract

Background: Acute otitis media with discharge (AOMd) results from a tympanic membrane perforation secondary to a middle ear infection. Currently the impact of AOMd on children and young people (CYP) and their families is not well understood. There is also a need to explore the experience of healthcare professionals in treating AOMd. Interviews with CYP and their parents, and focus groups with medical professionals, were conducted to explore these objectives.

Methods: A total of 26 parents of CYP (age range: 7 months – 15 years) with a history of AOMd (within the last year) and 28 medical professionals, were recruited across the UK between August 2023 and March 2024. Healthcare professionals were from Primary Care (n=17), Ear, Nose and Throat (n=7), and Emergency Medicine (n=4) backgrounds. Thematic analysis was performed independently by three reviewers.

Results: The majority of CYP (n=25/26) (96.2%) had suffered with multiple episodes of AOMd. AOMd has a physical, psychological, educational, financial and social impact on CYP and their parents. Parents found accessing healthcare services and information difficult, which increased parental anxiety. Antibiotic overuse was also a concern amongst parents. The majority of GPs and emergency care staff described using oral amoxicillin, compared with ENT doctors who predominantly prescribed topical antibiotics.

Conclusions: AOMd has a significant impact on CYP and their parent's daily lives. Need for clear, easily accessible patient information was identified as a priority by the parents of CYP with AOMd. Evidence-based management guidelines should be developed once high-quality evidence is available.

Trial Registration: ISCTRN43760

- **What is already known on this topic**: Paediatric presentations of acute otitis media with discharge (AOMd) account for approximately 41,000 primary care appointments in the UK each year. Currently the impact of AOMd on children and young people (CYP) and their families is not understood.
- **What this study adds**: This study demonstrates the significant impact AOMd has on CYP and their parents' daily lives. It identifies that patient information material is required to help inform service users. Paediatric AOMd is primarily treated with antibiotics, the type and route are variable.
- **How this study might affect research, practice or policy**: This study has collected views from parents and medical professionals on how a future randomised controlled trial should be designed. Future work should aim to create patient information material and develop standardised management guidelines for paediatric AOMd.

Introduction

Acute otitis media with discharge (AOMd) results from a tympanic membrane perforation secondary to acute otitis media (AOM), which is one of the most common paediatric infections. Approximately 15% of children and young people (CYP) with AOM develop ear discharge[1]. CYP with AOMd have been shown to have more severe systemic illness and more disease-related complications, compared with CYP with AOM[1]. Patient and parental experience has been investigated within the context of AOM but not AOMd[2]. Approximately 41,000 primary care appointments are required each year to manage AOMd in the UK[3]. It is essential to explore the impact of AOMd on CYP and their parents to understand the burden of this disease.

The medical management of AOMd in primary and secondary care is heterogenous, with a mix of oral, topical, or no antibiotics being prescribed[3]. The National Institute for Health and Care Excellence (NICE) recommends CYP with AOMd are treated with oral amoxicillin[4]. This recommendation is based on evidence from a subgroup analysis of 116 CYP with AOMd treated with oral antibiotics against placebo, from a meta-analysis of six studies[5]. Topical antibiotics treat the source of the AOMd infection, but there is concern over the potential ototoxic effects which have been addressed by an ENT UK consensus report[6]. Understanding the principles governing management strategies from the perspective of different healthcare professionals is vital.

To help standardise medical management for AOMd, high-quality, randomised controlled trials (RCT) are required. Caldwell et. al. assessed parental attitudes to the participation of children in RCTs, highlighting risk-benefit decision making[7]. To ensure the design of a future RCT is relevant and impactful we must engage with the key stakeholders (CYP, parents and medical professionals) to hear their thoughts.

The primary aim was to explore the impact of AOMd on CYP and their parents' daily lives and to understand medical professionals' experiences and treatment strategies. The secondary aim was to assess parental and medical professional opinions on how to best design a RCT comparing antibiotic treatments for AOMd.

Methods

This study follows the consolidated criteria for reporting qualitative research (COREQ) checklist (supplementary material). The study protocol was registered (ISCTRN43760) and published online[8]. Ethical approval was received on 15th June 2023 (REC 23/NI0082). A Research Design Service (RDS) public involvement grant [RDSNW3687] allowed the involvement of patients and the public at an early stage to help determine the research questions and design. A public involvement group met at regular intervals during the study to help design participant information, refine the interview guide and interpret findings.

A direct to participant recruitment method was used by openly advertising the study in medical institutions, charitable organisations and on social media. Interested participants contacted the research team to take part.

Participants

Twenty-six semi-structured interviews were performed with parents. Three CYP, over the age of 5 years, joined their parent for the interview. Eligible CYP were under 17 years of age and had experienced at least one episode of AOMd within the 12months preceding the interview. Six focus groups were conducted with a total of 28 medical professionals who managed CYP with AOMd in daily practice.

Interview platform and topics

Interviews and focus groups were conducted by JL or EH from 8th August 2023 to 28th March 2024 on Microsoft Teams or telephone, depending on the preference of the participant. Remote consent was given by all parents and medical professionals, and assent from age-appropriate CYP. Interviews and focus groups lasted approximately 45 and 60 minutes respectively. The schedule of topics in the interviews and focus groups is provided in the supplementary material. Core topics used by Meherali et. al., who investigated parental experience of AOM, and Caldwell et. al., who investigated parental attitudes to participation in RCTs, were adapted for use in this study[2,7].

Analysis

Interviews and focus groups were transcribed verbatim onto Microsoft Excel. Transcripts were not returned to participants for comment. A deductive approach to thematic analysis was performed by three independent reviewers (EH, JL, JD). Themes from the prior two studies and additional themes that emerged from the interview and focus group data were used. Transcripts of interviews were coded in line with themes identified.

Parents of CYP were asked to rank order symptoms which was dealt with as quantitative data. Friedman K samples test was performed on the mean ranks of the ranked patient symptoms. Alpha significance value was set at <0.05.

Results

Overall, 26 parents of CYP, three CYP, and 28 medical professionals took part in this study. Demographics are outlined in table 1.

Parent, Children, and Young people

Frequency of AOMd

All parents except one (n=25/26) described that their child experienced multiple episodes of AOMd over a period of years. Several parents said their child's ear infections started before the age of one and continued for many years. Infections would occur frequently throughout the year (n=23/26). "*He's suffered from approximately six months old, he's five years old now and he's still suffering" (parent 8). "He had seven bouts of infections like seven lots of antibiotics throughout the year" (parent 24).*

Symptoms of AOMd

Parents ranked pain as the most prominent feature of AOMd (n=11/23). There was a significant difference between the ranked symptoms (p<0.01)(table 2). Sleep disturbance and impact on hearing was frequently discussed by parents.

Parents found it challenging to determine the main problem for children who are too young to express themselves. "*She experiences smelly fluid and difficulty hearing" (parent 6). "They can't communicate so you don't really know what's wrong" (parent 26). "I wasn't drinking, I wasn't eating, I couldn't sleep" (child 2).* Two parents highlighted additional challenges for their child with additional communication needs. "*He's also autistic as well so as in having leaky ears you get the aggressive behaviour" (parent 8).*

There was a theme that once the discharge started, parents would notice an improvement in pain and fever. "*It's like she gets a temperature and then once it bursts, the temperature goes after about 48 hours" (parent 19).*

Experiences and effect on quality of life

Parents explained that there was significant parental concern for their child's "suffering" during an episode of AOMd. Many felt helpless. *"As parents it is quite distressing for us seeing this because we are the parent, you are affected knowing that your child is suffering with this" (parent 12). "I'm watching him bang his head on the floor because he can't verbally tell me what hurts" (parent 1). "As parents its really difficult not being able to do a great deal to take that pain away" (parent 23).* Parents spent considerable time attending doctors' appointments and presenting to the Emergency Department, which in turn had an negative impact on their ability to work.

Parents noted hearing loss during and after infections. Many were concerned about long term implications. "*What damage is the infection going to be causing to his eardrums and the affect that that was having on his speech and language development" (parent 9)*. CYP were also stigmatised due to the discharge. "*It obviously embarrasses my daughter cause she's 11 and obviously she gets hearing loss with it as well" (parent 18).*

Parents' concerns and information needs

Many parents found it difficult to find clear or consistent information about the condition. Many researched treatment options online or were advised by family members with lived experience. "*I found it hard getting different information from different GPs and then kind of having to go away and do my own research. I think it would have been good if there was more like some uniform care" (parent 26).*

Dietary changes were frequently discussed by parents. Many were unsure what had caused the ear discharge. "*[I was] told by a doctor to come off dairy products and trial that for at least six weeks and see what happens. I thought he had caught [it] from somebody at nursery" (parent 5).* "*[I thought] it was something related to genetics" (parent 6).*

Antibiotic overuse was a concern amongst many parents. "*I'm definitely getting to the point now where I don't want him to be on antibiotics much more" (parent 7).*

Treatment access and expectations

Healthcare access, exposure to multiple treatment strategies and conflicting advice were key issues discussed. Some felt like their concerns were not taken seriously by medical professionals. It was common that CYP had tried multiple courses of antibiotics and received contradictory advice from medical professionals. "*We've had liquid, we've had sprays, we've had drops" (parent 8). "Obviously, seeing him unwell isn't nice, but it was a lot of going back and to the doctors and taking a while to get referred to the ENT specialists" (parent 9).*

Most parents expected the infection to improve within seven days of treatment. Parents frequently used the amount of ear discharge to determine treatment success*.* *"[Expected duration] probably within like three to five days, normally the course of the antibiotics it's gone" (participant 7)*.

Views on participation in a RCT

Parents were asked about barriers and motivators which would influence their involvement in a future trial investigating the best management of AOMd. Generally, parents wanted trial involvement to fit around work and their busy lives. "*They need to make it quite straight forward, not to complicate it" (parent 3).* There was no particular preference for oral or topical antibiotic. The majority of parents were against taking part in a trial involving a placebo. *"I feel comfortable with my daughter taking part in a* *clinical trial that really is effective to her condition and not be the dummy medication" (parent 6)*

Medical Professionals

Experiences of managing AOMd

There was acknowledgement that AOMd can be a challenging condition to manage and the impact it can have on the CYP was discussed in all focus groups. "*They would recurrently come back to me, which was very frustrating but what you also see is that impact on school, on hearing, on socialising, if it's a young child on development of speech, interaction" (medical professional 20).* "*It smells terrible, the kid's not happy, they're not doing well in school. So, then they can't go to swimming class" (medical professional 5).*

There was a strong feeling that parental concern was a key factor during consultations. "*They generally want to see a doctor as soon as possible, to get treatment as soon as possible and to see improvements in their children as soon as possible" (medical professional 11).*

Antibiotic management strategies

There were heterogenous management strategies dependant on work setting. The majority of GPs (General Practitioners) and emergency care staff used oral amoxicillin, compared with ENT (Ears, Nose and Throat) specialists who use predominantly topical ciprofloxacin. Oral amoxicillin was favoured most frequently for a treatment duration of 5 days. "*We always get confused about what to do, it's only been a few weeks back, I was looking at the guidance to see if you give them antibiotics" (medical professional 27).*

All GPs referred to NICE guidance to support their management decisions. "*There is the NICE guideline that you can, that you can kind of lean on" (medical professional 21).* Emergency care doctors used local antimicrobial guidelines. ENT doctors had no guidelines to support their management.

Non-antibiotic management strategies

All medical professionals agreed that water avoidance was required to prevent repeat infections. There was no consensus on the duration of avoidance required. One GP would see the patient back in 4-6 weeks to check tympanic membrane patency before advising normal activities. Some clinicians advised avoiding using cotton buds in the external auditory canal. Use of topical swabs was varied. Most secondary care professionals would take a swab if not yet taken in primary care.

Treatment expectations

Clinical improvement was expected from 5-14 days post treatment commencement. The majority of medical professionals defined treatment success as a reduction or complete cessation of discharge; Others used pain reduction as an indicator. "*I'll be aiming for total resolution. I think if there was still discharging after a week of antibiotics, I want to probably take a look at them again and reassess things" (medical professional 6).*

Future trial factors

All medical professionals described that they would not recruit CYP with AOMd into a trial with a placebo arm. "*I think you'd be hard pressed to justify a placebo in that situation" (medical professional 18).* They would also be against recruiting CYP who are systemically unwell to any trial. There was a strong opinion that a trial design should mirror current practice and clear patient information is important to help parents understand the trial.

Discussion

These findings show the physical, psychological, education, financial and social impact of AOMd on CYP and their parents and the heterogeneity of treatment provided in the UK. Our results demonstrate that the quality-of-life impact of AOMd on CYP and their parents is similar to those with recurrent AOM[2]. The findings differ considerably when comparing information needs and treatment experience. Parents of CYP with AOMd found it difficult to ascertain information about the condition while parents of CYP with AOM, based in the United States, found adequate information from healthcare providers or online[2]. In this study parents repeatedly commented on the variation and frequency of antibiotic treatment for AOMd which was not reported in the AOM group[2].

AOM causes otalgia by stretching of the tympanic membrane and irritation of cranial nerves passing through the temporal bone[9]. Once the tympanic membrane perforates and pressure is released, the assumption is that otalgia and fever reduce. Smith et. al.

demonstrated that otalgia was more frequently associated with AOM (56%) compared with AOMd (11%)[1]. However, participants in this study rated otalgia as the worst feature. This could be due to overlapping symptoms experienced from AOM to AOMd or ongoing noxious effects of the infection such as the development of otitis externa secondary to discharge. Other highly ranked symptoms such as difficulty sleeping and crying may well be associated with pain levels.

Our results demonstrate there is a significant financial and psychological impact on parents. Numerous healthcare appointments require parents to take time off work in addition to the travel expense. The psychological burden on parents has been shown when caring for chronic childhood illness but there is little evidence in recurrent acute disease such as AOMd[10]. Another key problem identified in this disease context is lack of patient information which contributes to parental anxiety. Limited medical information for AOMd likely prevents medical professionals from providing adequate counselling to parents. There is a need for patient, parent and professional level information for AOMd.

Antimicrobial resistance is a growing global problem[11]. The majority (72-92%) of CYP with AOMd receive antibiotics despite there being minimal evidence for their effectiveness[1,3]. Current NICE guidance within the UK recommends treatment with oral amoxicillin for CYP with AOMd[4]. However, a recent study has showed that topical antibiotic treatment is more effective than oral antibiotics for tympanostomy tube otorrhoea[12]. Clinicians from both primary care and emergency departments favour oral antibiotics. ENT doctors prefer topical antibiotics. Despite working in secondary care, ENT doctors also manage acute presentations of AOMd in follow-up and rapid access clinics, emergency departments and provide advice to other specialities. The difference in prescribing practice is likely multifactorial, reasons may include their familiarity and access to topical antibiotic drops. Treatment variation and antibiotic overuse was a key concern of parents, with CYP frequently receiving multiple courses of various types of antibiotics. Parental concern regarding antibiotic overuse in middle ear infections has also been reported in North America[13]. High-quality evidence is required to identify the most effective antibiotic treatment for AOMd.

The use of appropriate outcome measures in healthcare research is essential to derive meaningful results. Both parents and medical professionals most commonly use cessation of discharge as an indicator for treatment success. However, the expected time frame for cessation is variable from 5-14 days. Parental attitudes to participation in a future RCT were comparable to the findings of Caldwell et. al. in that the benefits of taking part should outweigh the risks[7]. Parents and medical professionals are cautious of participation in trials involving placebos as they find it difficult to justify when treating a paediatric infection.

The strength of this study is the large sample of participants from across the UK with the combination of perspectives from both CYP, parents and medical professionals. Data saturation was met in both groups. The main limitation of this study is a recruitment bias in that parents self-identified themselves to be recruited. It is likely that those CYP who suffer frequently would be more likely to be volunteered by their parents to participate, skewing the cohort to those more severely affected by AOMd. This research did not address the role of socioeconomic disparities in this disease context. This is requirement for further research.

This research highlights that AOMd has a significant physical, psychological, educational, financial and social impact on CYP and their parents. There is an urgent need for tailored patient information materials in this disease context. Treatments for AOMd vary dependant on clinician setting. To standardise management high-quality evidence is required to support treatment guidelines for paediatric AOMd. Based on the results presented here, such a trial should be patient-centred to work around families' busy lives and be co-designed by service users.

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Declaration of interests

No completing interests declared.

Data availability statement

Data are available upon reasonable request.

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Tables

Table 1. Patient and medical professional demographics

Demographic	
Children and Young People (n=26)	
Female: Male	n=10 (38.5%): n=16 (61.5%)
Age	5.3 years (range: 7 months – 15 years)
Medical Professional (n=28)	
General Practitioner (Consultant)	n=15
General Practitioner (Registrar)	n=2
Ear, Nose and Throat (Consultant)	n=2
Ear, Nose and Throat (Registrar)	n=5
Ear, Nose and Throat (Advanced Nurse Practitioner)	n=2
Emergency Department (Nurse Consultant)	n=2
Emergency Department (Registrar)	n=2

Table 2. Frequency of most important symptom*

Symptom	Mean ranking score	Standard Deviation	Range of ranking scores
Pain	2.96	2.81	1-4
Difficulty Sleeping	4.00	2.74	1-8
Crying	4.96	2.74	2-7

Reduced Hearing	5.00	2.81	1-7
Smelly Fluid	5.38	2.95	1-8
Colour of Fluid	5.54	2.75	1-8
Fever	6.00	2.71	1-8
Appetite	6.62	2.29	2-8

* A symptom ranking of 1 is the worst symptom (range 1-8).

Supplementary Material 1. Interview Schedule

Families and Carers and Children / Young People with Acute Otitis Media with Discharge

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Welcome and introduction - Seek verbal consent to continue, reminder of audio-recording of interview (/video recording if on Teams), re-cap of project and plan for interview. Perform member check after each question or where necessary.

The study is aiming to understand what it is like for children and young people to live with an ear infection which causes a leaky ear. The interviews will explore your views and we are interested in your experience. It will help us to understand more about children and families' experiences of leaky ears. We also wanted to talk to you about how we might conduct research in the future on leaky ears, and if you think it is acceptable way of doing things. With this information we hope to help change how we treat children and young people with leaky ears.

If you do not feel you are able to comment on any area, please say so and we can stop at any time. Do you have any questions before we start?

1. Can you tell me when you had leaky ears and for how long?

2. Can you tell me about the impact of having leaky ears has had on you / your child's everyday life?
    - Prompt: What we mean is has it stopped you from doing things that you were doing before or changed the way you feel about things. If it has, can you tell me more about it.
    - Prompt: Please tell me about any other things that also had an impact. Impact on school, sport, social, mental wellbeing

3. Which aspect about the leaky ears affected you the most?
    - Prompt: What we mean is things like the smelly fluid from the ear, pain in the ear, fever, crying, the need to visit the doctors, or problems with sleeping?

4. Can you put these in order, symptom that most affected to least affected you:
    - Smelly fluid, colour of fluid, pain, fever, crying, difficulty sleeping, reduced hearing and appetite

5. Can you tell me about your experience of being treated for leaky ears from when it first started up until now?
    - Prompt: Can you tell me about what happened when you first noticed leaky ears and asked for help. Then what happened after this?

6. Can you tell me about any treatments you were given for the leaky ears?
    - Prompt: Can you tell me about any liquid/tablet antibiotics or ear drops you were given to use by the doctor and was there a reason ever to stop early
    - What was your experience giving the treatment and which was preferred?
    - Did you try/use any other ways to treat your leaky ears? Where did you obtain this information/advice?

7. What do you think could be done better or differently to improve the way patients with leaky ears are treated in the future?

8. How long after treatment was started would you expect the symptoms to improve?

9. How long would you be happy to give your child an antibiotic medicine to treat the leaky ear?

10. What would be the most important sign that the infection is improving?

11. How much improvement in the ‘most important sign’ would show the treatment was successful?

12. How long would you expect the treatment to take to improve the most important sign?

13. If we offered you 2 different treatment options what difference in time to the ‘most important sign’ resolution would make you make you pick one over the other?

I would like to ask you a few more questions about taking part in research in the future. This is not an invitation to take part in another study now but more general questions about taking part in research studies.

Randomised Controlled Trials

14. What do you know about research studies that try to decide which treatment is the best called randomized controlled trials?
    - Prompt: (An explanation of randomized controlled trial is given by facilitator): “*A randomised controlled trial is a special study which can find out what is the best treatment, when it is not clear which treatment is best. When a randomised controlled trial is conducted, nobody, not even the doctors or scientists, know which is the better treatment.*
      There are usually two treatments being compared, and the treatment each child receives is decided by chance. It is necessary to decide the treatment by chance to make sure that at the beginning of the study, both groups of children are very similar. Therefore, we know that any differences at the end of the study will be due to the treatment alone.”

15. What questions might you have if your child with a leaky ear was invited to participate in a trial where their treatment was randomly selected?

16. If the options were to have a liquid antibiotic orally or antibiotic drops to the ear, how would you feel about the child's treatment being chosen by chance to one medicine or another?
    - Prompt: Do you have any feelings about giving oral liquid antibiotics or antibiotics in drop form to the ears

17. How do you feel about the child's treatment being allocated by chance which could be a placebo (which is a dummy medicine)?
    - Prompt: Sometimes, randomised controlled trials involve the use of a placebo, which is a nonactive medication. It is used when testing whether using a particular treatment is better than not using anything.

Motivators and Barriers

18. What would make you more likely to get involved with an RCT?
    - Examples - improve treatment for children/ get better care for their child (better treatment compared to available or access to specialist doctors quicker)

19. What would put you off joining an RCT?
    - Examples - extra visits, safety of medications

20. How would you feel if you went to your GP and were offered to sign up to a study on the same day? Would you want time to think about it?

21. If we gave you a diary to fill in for a week every day, would you prefer a paper diary or one online?

22. What do you think are some of the things that researchers need to think of when they design research for leaky ears?

Anything not covered?

Is there anything that we haven't covered in the interview that you think we should know or think about?

Closing and thanks - Thank for their time and contribution.

Clinicians (nurses, audiologists, allied medical professionals, GPs, Emergency Department and Otolaryngology doctors).

Welcome and introduction - Seek verbal consent to continue, and check that all members must interact with patients aged 16 and below with paediatric otorrhoea in daily practice to be eligible to take part. Provide a reminder of the video-recording of focus group (Teams) will be saved, re-cap of project and plan for focus group discussion. Perform member check after each question or where necessary.

The study is aiming to understand how and why children and young people (CYP) with acute otitis media with discharge are treated in primary and secondary care and to understand what treatments are acceptable to medical professionals. We are interested in your perceptions, based on your knowledge and experience. If you do not feel you are able to comment on any area, please say so. Do you have any questions before we start?

1. Could everyone please firstly introduce themselves, provide their job role and say roughly how regularly they see children with otorrhoea.
    - Prompt: On average, how many children with otorrhoea would you see in a month?

2. What are your experiences of managing CYP with otorrhoea?
    - Impact on patient, their QoL/communication
    - Number of healthcare attendances
    - Recurrent condition or not
    - Straightforward/challenging to manage
    - Complications of condition

3. Please describe how otorrhoea in a 3, 6 and 14 year old patient is normally treated and what are the reasons behind management decisions.
    - When do you treat them? first presentation / future presentation / significant symptoms / delayed antibiotic course?

- How do you treat children? Oral / topical antibiotics, analgesia, advice given other treatments like removal of otorrhoea
- What is a typical treatment duration?
- What is your second line treatment if there’s no or limited improvement? Longer course or change in treatment
- When would you refer the patient onwards (if working in primary care)
- Why do they treat in this way? Experience / normal practice / current guidelines
- Why do you decide to treat – pain, fever, otorrhoea, hearing loss, prevent complications, age, co-morbidities, vaccination status
- Do you swab the discharge? Wait for results to help treatment?

4. Do you give any lifestyle advice? (examples: Swimming avoidance, water precautions, Time off daycare, exposure to passive smoking/pets)

5. Do you feel supported with clear guidelines or evidence how to manage this condition?

6. Routinely how long would you prescribe antibiotics for in one course?

7. From your perspective, how would you feel recruiting patients to an RCT with a placebo alone option, placebo with an active treatment? Are there some patients you wouldn’t want to give a placebo?

8. How long after treatment was started would you expect the symptoms to improve?

9. What would be the most important sign that the infection is improving?

10. What is the least you would expect from the treatment to indicate its working in terms of the most important sign? - What is the minimum improvement in the 'most important sign' you would regard as showing the treatment was successful?

11. If you prescribed two treatments what is the minimum difference in the 'most important sign' that showed one was better than the other? What would make you pick one treatment over another treatment.

12. If you prescribed two treatments what is the maximum difference in the 'most important sign' you would regard as showing one was equivalent to the other?

I would like to ask you a few more questions about taking part in research in the future.

13. What would improve participation in such a study in Primary Care?

14. What factors would be a barrier to participation?

15. For people working in primary care: how do you feel about patients being identified in primary care then referred to a central research team for randomisation and treatment?

16. From your perspective, how would you feel about your patients receiving either oral or topical antibiotic treatment in an RCT?

17. If a RCT showed that a different antibiotic type or route was more effective than your current preference would you change practice?

Anything not covered?

Is there anything that we haven’t covered in the focus group that you think we should know or think about?

Closing and thanks - Thank for their time and contribution.

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Exploring the burden of paediatric acute otitis media with discharge in the UK: a qualitative study

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Exploring the burden of paediatric acute otitis media with discharge in the UK: a qualitative study

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Abstract

Background: Acute otitis media with discharge (AOMd) results from a tympanic membrane perforation secondary to a middle ear infection. Currently the impact of AOMd on children and young people (CYP) and their families is not well understood. There is also a need to explore the experience of healthcare professionals in treating AOMd. Interviews with CYP and their parents, and focus groups with medical professionals, were conducted to explore these objectives.

Methods: A total of 26 parents of CYP (age range: 7 months – 15 years) with a history of AOMd (within the last year) and 28 medical professionals, were recruited across the UK between August 2023 and March 2024. Healthcare professionals were from Primary Care (n=17), Ear, Nose and Throat (n=7), and Emergency Medicine (n=4) backgrounds. Thematic analysis was performed independently by three reviewers.

Results: The majority of CYP (n=25/26) (96.2%) had suffered with multiple episodes of AOMd. AOMd has a physical, psychological, educational, financial and social impact on CYP and their parents. Parents found accessing healthcare services and information difficult, which increased parental anxiety. Antibiotic overuse was also a concern amongst parents. The majority of GPs and emergency care staff described using oral amoxicillin, compared with ENT doctors who predominantly prescribed topical antibiotics.

Conclusions: AOMd has a significant impact on CYP and their parent’s daily lives. Need for clear, easily accessible patient information was identified as a priority by the parents of CYP with AOMd. Evidence-based management guidelines should be developed once high-quality evidence is available.

Trial Registration: ISCTRN43760

- **What is already known on this topic**: Paediatric presentations of acute otitis media with discharge (AOMd) account for approximately 41,000 primary care appointments in the UK each year. Currently the impact of AOMd on children and young people (CYP) and their families is not understood.
- **What this study adds**: This study demonstrates the significant impact AOMd has on CYP and their parents' daily lives. It identifies that patient information material is required to help inform service users. Paediatric AOMd is primarily treated with antibiotics, the type and route are variable.
- **How this study might affect research, practice or policy**: This study has collected views from parents and medical professionals on how a future randomised controlled trial should be designed. Future work should aim to create patient information material and develop standardised management guidelines for paediatric AOMd.

Introduction

Acute otitis media with discharge (AOMd) results from a tympanic membrane perforation secondary to acute otitis media (AOM), which is one of the most common paediatric infections. Approximately 15% of children and young people (CYP) with AOM develop ear discharge[1]. CYP with AOMd have been shown to have more severe systemic illness and more disease-related complications, compared with CYP with AOM[1]. Patient and parental experience has been investigated within the context of AOM but not AOMd[2]. Approximately 41,000 primary care appointments are required each year to manage AOMd in the UK[3]. It is essential to explore the impact of AOMd on CYP and their parents to understand the burden of this disease.

The medical management of AOMd in primary and secondary care is heterogenous, with a mix of oral, topical, or no antibiotics being prescribed[3]. The National Institute for Health and Care Excellence (NICE) recommends CYP with AOMd are treated with oral amoxicillin[4]. This recommendation is based on evidence from a subgroup analysis of 116 CYP with AOMd treated with oral antibiotics against placebo, from a meta-analysis of six studies[5]. Topical antibiotics treat the source of the AOMd infection, but there is concern over the potential ototoxic effects which have been addressed by an ENT UK consensus report[6]. Understanding the principles governing management strategies from the perspective of different healthcare professionals is vital.

To help standardise medical management for AOMd, high-quality, randomised controlled trials (RCT) are required. Caldwell et. al. assessed parental attitudes to the participation of children in RCTs, highlighting risk-benefit decision making[7]. To ensure the design of a future RCT is relevant and impactful we must engage with the key stakeholders (CYP, parents and medical professionals) to hear their thoughts.

The primary aim was to explore the impact of AOMd on CYP and their parents' daily lives and to understand medical professionals' experiences and treatment strategies. The secondary aim was to assess parental and medical professional opinions on how to best design a RCT comparing antibiotic treatments for AOMd.

Methods

This study follows the consolidated criteria for reporting qualitative research (COREQ) checklist (supplementary material). The study protocol was registered (ISCTRN43760) and published online[8]. Ethical approval was received on 15th June 2023 (REC 23/NI0082). A Research Design Service (RDS) public involvement grant [RDSNW3687] allowed the involvement of patients and the public at an early stage to help determine the research questions and design. A public involvement group met at regular intervals during the study to help design participant information, refine the interview guide and interpret findings.

A direct to participant recruitment method was used by openly advertising the study in medical institutions, charitable organisations and on social media. Interested participants contacted the research team to take part.

Participants

Twenty-six semi-structured interviews were performed with parents. Three CYP, over the age of 5 years, joined their parent for the interview. Eligible CYP were under 17 years of age and had experienced at least one episode of AOMd within the 12months preceding the interview. Six focus groups were conducted with a total of 28 medical professionals who managed CYP with AOMd in daily practice.

Interview platform and topics

Interviews and focus groups were conducted by JL or EH from 8th August 2023 to 28th March 2024 on Microsoft Teams or telephone, depending on the preference of the participant. Remote consent was given by all parents and medical professionals, and assent from age-appropriate CYP. Interviews and focus groups lasted approximately 45 and 60 minutes respectively. The schedule of topics in the interviews and focus groups is provided in the supplementary material. Core topics used by Meherali et. al., who investigated parental experience of AOM, and Caldwell et. al., who investigated parental attitudes to participation in RCTs, were adapted for use in this study[2,7].

Analysis

Interviews and focus groups were transcribed verbatim onto Microsoft Excel. Transcripts were not returned to participants for comment. A deductive approach to thematic analysis was performed by three independent reviewers (EH, JL, JD). Themes from the prior two studies and additional themes that emerged from the interview and focus group data were used. Transcripts of interviews were coded in line with themes identified.

Parents of CYP were asked to rank order symptoms which was dealt with as quantitative data. Friedman K samples test was performed on the mean ranks of the ranked patient symptoms. Alpha significance value was set at <0.05.

Patient and Public Involvement

A patient and public involvement (PPI) group, with lived experience, was created to help determine the most important research priorities. The PPI group met monthly prior to, during and after this study. The PPI group helped to shape the structure and content of the semi structured interviews and patient information material. The PPI group designed material to advertise the study to service users. The results have been interpreted with input from the PPI group. Members of the PPI group have been sent a lay summary and an infographic outlining the results of this research.

Results

Overall, 26 parents of CYP, three CYP, and 28 medical professionals took part in this study. Demographics are outlined in table 1. Of the 17 General Practitioners (GPs) 14 worked in different practices. All Ears, Nose and Throat (ENT) doctors worked at different hospitals; one consultant worked in a tertiary paediatric unit. Both

Emergency Department nurse consultants worked in the same hospital, the registrars worked in different units.

Parent, Children, and Young people

Frequency of AOMd

All parents except one (n=25/26) described that their child experienced multiple episodes of AOMd over a period of years. Several parents said their child's ear infections started before the age of one and continued for many years. Infections would occur frequently throughout the year (n=23/26). "*He's suffered from approximately six months old, he's five years old now and he's still suffering" (parent 8). "*He *had seven bouts of infections like seven lots of antibiotics throughout the year" (parent 24).*

Symptoms of AOMd

Parents ranked pain as the most prominent feature of AOMd (n=11/23). There was a significant difference between the ranked symptoms (p<0.01)(table 2). Sleep disturbance and impact on hearing was frequently discussed by parents.

Parents found it challenging to determine the main problem for children who are too young to express themselves. "*She experiences smelly fluid and difficulty hearing" (parent 6). "They can't communicate so you don't really know what's wrong" (parent 26). "I wasn't drinking, I wasn't eating, I couldn't sleep" (child 2).* Two parents highlighted additional challenges for their child with additional communication needs. “*He’s also autistic as well so as in having leaky ears you get the aggressive behaviour” (parent 8).*

There was a theme that once the discharge started, parents would notice an improvement in pain and fever. “*It's like she gets a temperature and then once it bursts, the temperature goes after about 48 hours” (parent 19).*

Experiences and effect on quality of life

Parents explained that there was significant parental concern for their child’s “suffering” during an episode of AOMd. Many felt helpless. *“As parents it is quite distressing for us seeing this because we are the parent, you are affected knowing that your child is suffering with this” (parent 12). “I'm watching him bang his head on the floor because he can't verbally tell me what hurts” (parent 1). “As parents its really difficult not being able to do a great deal to take that pain away” (parent 23).* Parents spent considerable time attending doctors’ appointments and presenting to the Emergency Department, which in turn had an negative impact on their ability to work.

Parents noted hearing loss during and after infections. Many were concerned about long term implications. “*What damage is the infection going to be causing to his eardrums and the affect that that was having on his speech and language development” (parent 9)*. CYP were also stigmatised due to the discharge. “*It* *obviously embarrasses my daughter cause she's 11 and obviously she gets hearing loss with it as well" (parent 18).*

Parents' concerns and information needs

Many parents found it difficult to find clear or consistent information about the condition. Many researched treatment options online or were advised by family members with lived experience. "*I found it hard getting different information from different GPs and then kind of having to go away and do my own research. I think it would have been good if there was more like some uniform care" (parent 26).*

Dietary changes were frequently discussed by parents. Many were unsure what had caused the ear discharge. "*[I was] told by a doctor to come off dairy products and trial that for at least six weeks and see what happens. I thought he had caught [it] from somebody at nursery" (parent 5). "[I thought] it was something related to genetics" (parent 6).*

Antibiotic overuse was a concern amongst many parents. "*I'm definitely getting to the point now where I don't want him to be on antibiotics much more" (parent 7).*

Treatment access and expectations

Healthcare access, exposure to multiple treatment strategies and conflicting advice were key issues discussed. Some felt like their concerns were not taken seriously by medical professionals. It was common that CYP had tried multiple courses of antibiotics and received contradictory advice from medical professionals. “*We’ve had liquid, we’ve had sprays, we’ve had drops” (parent 8). “Obviously, seeing him unwell isn’t nice, but it was a lot of going back and to the doctors and taking a while to get referred to the ENT specialists” (parent 9).*

Most parents expected the infection to improve within seven days of treatment. Parents frequently used the amount of ear discharge to determine treatment success*. “[Expected duration] probably within like three to five days, normally the course of the antibiotics it’s gone” (participant 7)*.

Views on participation in a RCT

Parents were asked about barriers and motivators which would influence their involvement in a future trial investigating the best management of AOMd. Generally, parents wanted trial involvement to fit around work and their busy lives. “*They need to make it quite straight forward, not to complicate it” (parent 3).* There was no particular preference for oral or topical antibiotic. The majority of parents were against taking part in a trial involving a placebo. *“I feel comfortable with my daughter taking part in a clinical trial that really is effective to her condition and not be the dummy medication” (parent 6)*

Medical Professionals

Experiences of managing AOMd

There was acknowledgement that AOMd can be a challenging condition to manage and the impact it can have on the CYP was discussed in all focus groups. "*They would recurrently come back to me, which was very frustrating but what you also see is that impact on school, on hearing, on socialising, if it's a young child on development of speech, interaction" (medical professional 20).* "*It smells terrible, the kid's not happy, they're not doing well in school. So, then they can't go to swimming class" (medical professional 5).*

There was a strong feeling that parental concern was a key factor during consultations. "*They generally want to see a doctor as soon as possible, to get treatment as soon as possible and to see improvements in their children as soon as possible" (medical professional 11).*

Antibiotic management strategies

There were heterogenous management strategies dependant on work setting. The majority of GPs and emergency care staff used oral amoxicillin, compared with ENT specialists who use predominantly topical ciprofloxacin. Oral amoxicillin was favoured most frequently for a treatment duration of 5 days. "*We always get confused about what to do, it's only been a few weeks back, I was looking at the guidance to see if you give them antibiotics" (medical professional 27).*

All GPs referred to NICE guidance to support their management decisions. "*There is the NICE guideline that you can, that you can kind of lean on" (medical professional*

21). Emergency care doctors used local antimicrobial guidelines. ENT doctors had no guidelines to support their management.

Non-antibiotic management strategies

All medical professionals agreed that water avoidance was required to prevent repeat infections. There was no consensus on the duration of avoidance required. One GP would see the patient back in 4-6 weeks to check tympanic membrane patency before advising normal activities. Some clinicians advised avoiding using cotton buds in the external auditory canal. Use of topical swabs was varied. Most secondary care professionals would take a swab if not yet taken in primary care.

Treatment expectations

Clinical improvement was expected from 5-14 days post treatment commencement. The majority of medical professionals defined treatment success as a reduction or complete cessation of discharge; Others used pain reduction as an indicator. "*I'll be aiming for total resolution. I think if there was still discharging after a week of antibiotics, I want to probably take a look at them again and reassess things" (medical professional 6).*

Future trial factors

All medical professionals described that they would not recruit CYP with AOMd into a trial with a placebo arm. "*I think you'd be hard pressed to justify a placebo in that* *situation" (medical professional 18).* They would also be against recruiting CYP who are systemically unwell to any trial. There was a strong opinion that a trial design should mirror current practice and clear patient information is important to help parents understand the trial.

Discussion

These findings show the physical, psychological, education, financial and social impact of AOMd on CYP and their parents and the heterogeneity of treatment provided in the UK. Our results demonstrate that the quality-of-life impact of AOMd on CYP and their parents is similar to those with recurrent AOM[2]. The findings differ considerably when comparing information needs and treatment experience. Parents of CYP with AOMd found it difficult to ascertain information about the condition while parents of CYP with AOM, based in the United States, found adequate information from healthcare providers or online[2]. In this study parents repeatedly commented on the variation and frequency of antibiotic treatment for AOMd which was not reported in the AOM group[2].

AOM causes otalgia by stretching of the tympanic membrane and irritation of cranial nerves passing through the temporal bone[9]. Once the tympanic membrane perforates and pressure is released, the assumption is that otalgia and fever reduce. Smith et. al. demonstrated that otalgia was more frequently associated with AOM (56%) compared with AOMd (11%)[1]. However, participants in this study rated otalgia as the worst feature. This could be due to overlapping symptoms experienced from AOM to AOMd or ongoing noxious effects of the infection such as the development of otitis externa secondary to discharge. Other highly ranked symptoms such as difficulty sleeping and crying may well be associated with pain levels.

Our results demonstrate there is a significant financial and psychological impact on parents. Numerous healthcare appointments require parents to take time off work in addition to the travel expense. The psychological burden on parents has been shown when caring for chronic childhood illness but there is little evidence in recurrent acute disease such as AOMd[10]. Another key problem identified in this disease context is lack of patient information which contributes to parental anxiety. Limited medical information for AOMd likely prevents medical professionals from providing adequate counselling to parents. There is a need for patient, parent and professional level information for AOMd.

Antimicrobial resistance is a growing global problem[11]. The majority (72-92%) of CYP with AOMd receive antibiotics despite there being minimal evidence for their effectiveness[1,3]. Current NICE guidance within the UK recommends treatment with oral amoxicillin for CYP with AOMd[4]. However, a recent study has showed that topical antibiotic treatment is more effective than oral antibiotics for tympanostomy tube otorrhoea[12]. Clinicians from both primary care and emergency departments favour oral antibiotics. ENT doctors prefer topical antibiotics. Despite working in secondary care, ENT doctors also manage acute presentations of AOMd in follow-up and rapid access clinics, emergency departments and provide advice to other specialities. The difference in prescribing practice is likely multifactorial, reasons may include their familiarity and access to topical antibiotic drops. Treatment variation and antibiotic overuse was a key concern of parents, with CYP frequently receiving multiple courses of various types of antibiotics. Parental concern regarding antibiotic overuse in middle ear infections has also been reported in North America[13]. High-quality evidence is required to identify the most effective antibiotic treatment for AOMd.

The use of appropriate outcome measures in healthcare research is essential to derive meaningful results. Both parents and medical professionals most commonly use cessation of discharge as an indicator for treatment success. However, the expected time frame for cessation is variable from 5-14 days. Parental attitudes to participation in a future RCT were comparable to the findings of Caldwell et. al. in that the benefits of taking part should outweigh the risks[7]. Parents and medical professionals are cautious of participation in trials involving placebos as they find it difficult to justify when treating a paediatric infection.

The strength of this study is the large sample of participants from across the UK with the combination of perspectives from both CYP, parents and medical professionals. The majority of medical professionals were based at different departments which provides an overview of UK practice. Data saturation was met in both groups. The main limitation of this study is a recruitment bias in that parents self-identified themselves to be recruited. It is likely that those CYP who suffer frequently would be more likely to be volunteered by their parents to participate, skewing the cohort to those more severely affected by AOMd. This research did not address the role of socioeconomic disparities in this disease context. This is requirement for further research.

This research highlights that AOMd has a significant physical, psychological, educational, financial and social impact on CYP and their parents. There is an urgent need for tailored patient information materials in this disease context. Treatments for AOMd vary dependant on clinician setting. To standardise management high-quality evidence is required to support treatment guidelines for paediatric AOMd. Based on the results presented here, such a trial should be patient-centred to work around families' busy lives and be co-designed by service users.

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Declaration of interests

No completing interests declared.

Data availability statement

Data are available upon reasonable request.

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Contributorship Statement

EH, JL, JM, RI, DMA, ADH, JRN and IAB conceived and designed the study. EH and JL performed the interviews and focus groups. EH, JL and JB performed the thematic analysis. All authors edited the final manuscript. EH is the guarantor.

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Tables

Table 1. Patient and medical professional demographics

Demographic	
Children and Young People (n=26)	
Female: Male	n=10 (38.5%): n=16 (61.5%)
Age	5.3 years (range: 7 months – 15 years)
Medical Professional (n=28)	
General Practitioner (Consultant)	n=15
General Practitioner (Registrar)	n=2
Ear, Nose and Throat (Consultant)	n=2
Ear, Nose and Throat (Registrar)	n=5
Ear, Nose and Throat (Advanced Nurse Practitioner)	n=2
Emergency Department (Nurse Consultant)	n=2
Emergency Department (Registrar)	n=2

Table 2. Frequency of most important symptom*

Symptom	Mean ranking score	Standard Deviation	Range of ranking scores
Pain	2.96	2.81	1-4
Difficulty Sleeping	4.00	2.74	1-8
Crying	4.96	2.74	2-7
Reduced Hearing	5.00	2.81	1-7

Smelly Fluid	5.38	2.95	1-8
Colour of Fluid	5.54	2.75	1-8
Fever	6.00	2.71	1-8
Appetite	6.62	2.29	2-8

* A symptom ranking of 1 is the worst symptom (range 1-8).

Supplementary Material 1. Interview Schedule

Families and Carers and Children / Young People with Acute Otitis Media with Discharge

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Welcome and introduction - Seek verbal consent to continue, reminder of audio-recording of interview (/video recording if on Teams), re-cap of project and plan for interview. Perform member check after each question or where necessary.

The study is aiming to understand what it is like for children and young people to live with an ear infection which causes a leaky ear. The interviews will explore your views and we are interested in your experience. It will help us to understand more about children and families' experiences of leaky ears. We also wanted to talk to you about how we might conduct research in the future on leaky ears, and if you think it is acceptable way of doing things. With this information we hope to help change how we treat children and young people with leaky ears.

If you do not feel you are able to comment on any area, please say so and we can stop at any time. Do you have any questions before we start?

1. Can you tell me when you had leaky ears and for how long?

2. Can you tell me about the impact of having leaky ears has had on you / your child's everyday life?
    - Prompt: What we mean is has it stopped you from doing things that you were doing before or changed the way you feel about things. If it has, can you tell me more about it.
    - Prompt: Please tell me about any other things that also had an impact. Impact on school, sport, social, mental wellbeing

3. Which aspect about the leaky ears affected you the most?
    - Prompt: What we mean is things like the smelly fluid from the ear, pain in the ear, fever, crying, the need to visit the doctors, or problems with sleeping?

4. Can you put these in order, symptom that most affected to least affected you:
    - Smelly fluid, colour of fluid, pain, fever, crying, difficulty sleeping, reduced hearing and appetite

5. Can you tell me about your experience of being treated for leaky ears from when it first started up until now?
    - Prompt: Can you tell me about what happened when you first noticed leaky ears and asked for help. Then what happened after this?

6. Can you tell me about any treatments you were given for the leaky ears?
    - Prompt: Can you tell me about any liquid/tablet antibiotics or ear drops you were given to use by the doctor and was there a reason ever to stop early
    - What was your experience giving the treatment and which was preferred?
    - Did you try/use any other ways to treat your leaky ears? Where did you obtain this information/advice?

7. What do you think could be done better or differently to improve the way patients with leaky ears are treated in the future?

8. How long after treatment was started would you expect the symptoms to improve?

9. How long would you be happy to give your child an antibiotic medicine to treat the leaky ear?

10. What would be the most important sign that the infection is improving?

11. How much improvement in the ‘most important sign’ would show the treatment was successful?

12. How long would you expect the treatment to take to improve the most important sign?

13. If we offered you 2 different treatment options what difference in time to the ‘most important sign’ resolution would make you make you pick one over the other?

I would like to ask you a few more questions about taking part in research in the future. This is not an invitation to take part in another study now but more general questions about taking part in research studies.

Randomised Controlled Trials

14. What do you know about research studies that try to decide which treatment is the best called randomized controlled trials?
    - Prompt: (An explanation of randomized controlled trial is given by facilitator): “*A randomised controlled trial is a special study which can find out what is the best treatment, when it is not clear which treatment is best. When a randomised controlled trial is conducted, nobody, not even the doctors or scientists, know which is the better treatment.*
      There are usually two treatments being compared, and the treatment each child receives is decided by chance. It is necessary to decide the treatment by chance to make sure that at the beginning of the study, both groups of children are very similar. Therefore, we know that any differences at the end of the study will be due to the treatment alone.”

15. What questions might you have if your child with a leaky ear was invited to participate in a trial where their treatment was randomly selected?

16. If the options were to have a liquid antibiotic orally or antibiotic drops to the ear, how would you feel about the child's treatment being chosen by chance to one medicine or another?
    - Prompt: Do you have any feelings about giving oral liquid antibiotics or antibiotics in drop form to the ears

17. How do you feel about the child's treatment being allocated by chance which could be a placebo (which is a dummy medicine)?
    - Prompt: Sometimes, randomised controlled trials involve the use of a placebo, which is a nonactive medication. It is used when testing whether using a particular treatment is better than not using anything.

Motivators and Barriers

18. What would make you more likely to get involved with an RCT?
    - Examples - improve treatment for children/ get better care for their child (better treatment compared to available or access to specialist doctors quicker)

19. What would put you off joining an RCT?
    - Examples - extra visits, safety of medications

20. How would you feel if you went to your GP and were offered to sign up to a study on the same day? Would you want time to think about it?

21. If we gave you a diary to fill in for a week every day, would you prefer a paper diary or one online?

22. What do you think are some of the things that researchers need to think of when they design research for leaky ears?

Anything not covered?

Is there anything that we haven't covered in the interview that you think we should know or think about?

Closing and thanks - Thank for their time and contribution.

Clinicians (nurses, audiologists, allied medical professionals, GPs, Emergency Department and Otolaryngology doctors).

Welcome and introduction - Seek verbal consent to continue, and check that all members must interact with patients aged 16 and below with paediatric otorrhoea in daily practice to be eligible to take part. Provide a reminder of the video-recording of focus group (Teams) will be saved, re-cap of project and plan for focus group discussion. Perform member check after each question or where necessary.

The study is aiming to understand how and why children and young people (CYP) with acute otitis media with discharge are treated in primary and secondary care and to understand what treatments are acceptable to medical professionals. We are interested in your perceptions, based on your knowledge and experience. If you do not feel you are able to comment on any area, please say so. Do you have any questions before we start?

1. Could everyone please firstly introduce themselves, provide their job role and say roughly how regularly they see children with otorrhoea.
    - Prompt: On average, how many children with otorrhoea would you see in a month?

2. What are your experiences of managing CYP with otorrhoea?
    - Impact on patient, their QoL/communication
    - Number of healthcare attendances
    - Recurrent condition or not
    - Straightforward/challenging to manage
    - Complications of condition

3. Please describe how otorrhoea in a 3, 6 and 14 year old patient is normally treated and what are the reasons behind management decisions.
    - When do you treat them? first presentation / future presentation / significant symptoms / delayed antibiotic course?

- How do you treat children? Oral / topical antibiotics, analgesia, advice given other treatments like removal of otorrhoea
- What is a typical treatment duration?
- What is your second line treatment if there's no or limited improvement? Longer course or change in treatment
- When would you refer the patient onwards (if working in primary care)
- Why do they treat in this way? Experience / normal practice / current guidelines
- Why do you decide to treat – pain, fever, otorrhoea, hearing loss, prevent complications, age, co-morbidities, vaccination status
- Do you swab the discharge? Wait for results to help treatment?

4. Do you give any lifestyle advice? (examples: Swimming avoidance, water precautions, Time off daycare, exposure to passive smoking/pets)

5. Do you feel supported with clear guidelines or evidence how to manage this condition?

6. Routinely how long would you prescribe antibiotics for in one course?

7. From your perspective, how would you feel recruiting patients to an RCT with a placebo alone option, placebo with an active treatment? Are there some patients you wouldn't want to give a placebo?

8. How long after treatment was started would you expect the symptoms to improve?

9. What would be the most important sign that the infection is improving?

10. What is the least you would expect from the treatment to indicate its working in terms of the most important sign? - What is the minimum improvement in the 'most important sign' you would regard as showing the treatment was successful?

11. If you prescribed two treatments what is the minimum difference in the 'most important sign' that showed one was better than the other? What would make you pick one treatment over another treatment.

12. If you prescribed two treatments what is the maximum difference in the 'most important sign' you would regard as showing one was equivalent to the other?

I would like to ask you a few more questions about taking part in research in the future.

13. What would improve participation in such a study in Primary Care?

14. What factors would be a barrier to participation?

15. For people working in primary care: how do you feel about patients being identified in primary care then referred to a central research team for randomisation and treatment?

16. From your perspective, how would you feel about your patients receiving either oral or topical antibiotic treatment in an RCT?

17. If a RCT showed that a different antibiotic type or route was more effective than your current preference would you change practice?

Anything not covered?

Is there anything that we haven’t covered in the focus group that you think we should know or think about?

Closing and thanks - Thank for their time and contribution.