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# **Parental perceptions and understanding of information provision, management options and factors influencing the decision-making process in the treatment of children with OME**

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## **Abstract**

**Objectives** Otitis media with effusion (OME) is a common cause of hearing loss and possible developmental delay in children, and there are a range of ‘preference sensitive’ treatment options. We aimed to evaluate the attitudes and beliefs of parents of affected children to treatment options including watchful-waiting, hearing aids, grommets, and, oral steroids with the intention of developing our understanding of decision-making and the factors influencing it, sources of parental information, and satisfaction with information provision.

**Design** We recruited a convenience sample of twelve parents of eleven children with OME at a single ENT department of a teaching hospital into a qualitative research study. The children of the parents interviewed had already been recruited into the Oral Steroids for the Resolution of Otitis Media with effusion In Children (OSTRICH) study. Semi structured interviews were audio recorded, transcribed and then coded using an inductive, thematic approach.

**Results** Parents were satisfied with the verbal provision of information during the treatment consultation, although many were keen to receive supplementary printed information. Discussion with family and friends helped the decision-making process, whereas insufficient information and a paternalistic approach were viewed as obstacles. Parents were particularly influenced by the following: the immediacy of the treatment option effect, perceived efficacy, perceived risks and adverse effects, social implications (especially with hearing aids) and past personal and informant experience.

**Conclusions** Parents appreciate clinicians tailoring information provision to parents' information needs and preferred format. Clinicians should also elicit parental attitudes towards the different management options for OME and the factors influencing their decisions, in order to optimise shared-decision making and ultimately provide a better standard of clinical care.

## **Introduction**

Otitis media with effusion (OME), also known as 'glue ear', is a condition resulting from fluid accumulation in the middle ear, in the absence of acute inflammation (Simpson, Lewis, van der Voort, & Butler, 2011). OME is a disease mainly of infancy and early childhood, with up to 80% of children being affected by the age of 4 years (Rovers et al., 2001). OME is the commonest cause of acquired hearing loss during childhood and has the potential to adversely affect IQ, language and behavioural development, as well as reading, extending into late teens (Bennett, Haggard, Silva, & Stewart, 2001; Lous, 1995). The overall prognosis is generally good with about 50% of cases resolving within three months and 95% within a year without treatment (Simpson et al., 2011).

The National Institute for Health and Care Excellence (NICE) recommends an active observation period of three months (watchful waiting) before surgery to insert ventilation tubes (grommets) is considered (NICE, 2013). Hearing aids are another option where surgery is not preferred or contraindicated (NICE, 2013). While oral steroids have been found to be beneficial in some small, randomised control trials (Simpson et al., 2011), effectiveness has not yet been evaluated in a rigorous, adequately powered trial of cost effectiveness. Previous research in parental decision-making in OME has not explored responses to all of the available treatment modalities simultaneously.

There has been a gradual shift away from paternalistic doctor-patient relationships with a move towards shared decision-making between patients and physicians (Gorodzinsky, Hong, & Chorney, 2015). Shared decision making has been found to lessen decisional conflict (Joosten et al., 2008). This is particularly pertinent when there are multiple treatment options (Lipstein, Brinkman, & Britto, 2012), such as in OME. In paediatrics, parents may not be involved in the decision-making process as much as they would wish to be (Aarthun & Akerjordet, 2014). In order to improve and facilitate the decision-making process in paediatric consultations, we need to better understand how parents decide when it comes to choosing treatments on behalf of their children (Lipstein et al., 2012) especially when there is considerable 'preference sensitive' variation in care (Wennberg, 2002), and which factors and sources of information influence their decisions.

The aim of this study was to explore parental experiences, understanding, and perceptions of the decision-making process regarding management options for children suffering from OME. This includes parental experiences and perceptions of information provision about treatment options, their views about the actual treatment options themselves (including oral steroids), and their views about the decision-making process.

## **Methods**

This was a qualitative study, involving semi-structured interviews with parents of children with OME who attended an Ear, Nose and Throat (ENT) outpatient clinic and had been recruited as part of the Oral STeroids for Resolution of otitis media with effusion In CHildren study (OSTRICH) Study. OSTRICH is a multi-centre, double-blinded, randomised control trial to investigate the efficacy, safety and cost-effectiveness of a short course of oral steroids in improving hearing loss in children with (Waldron et al., 2016).

The trial protocol including for the qualitative interview study was reviewed and approved by Wales Research Ethics Committee (REC) 3 (approval number: 13/WA/0004). All hospital sites received Research and Development approval from the respective NHS Health Boards and Trusts in Wales and England.

### *Sample*

As part of the OSTRICH study, child participants were recruited through convenience sampling from ENT clinics across a number of UK hospitals. Participation in the OSTRICH study was subject to various inclusion/exclusion criteria (Table 1).

[Table 1 here]

For this present study, we decided to recruit the parents of children through convenience sampling at a single site, a hospital in South Wales, UK. Parents of children enrolled as part of the OSTRICH study were approached about participating in an optional semi-structured interview. No financial or other incentives were offered to the study participants, and eligible candidates were informed that participation was entirely voluntary and that the care of their child would not be affected by their decision.

### *Procedures*

The study involved semi-structured interviews, with the aim of investigating the parents' views about how they make decisions with regards to treatment options for OME. This included their views on the sources of information they used and satisfaction with information provision. We also sought to measure the parents' attitudes and beliefs towards conventional treatment modalities for OME (watchful waiting, grommets and hearing aids), as well as treatment with oral steroids (the intervention offered in the OSTRICH trial).

We developed a semi-structured interview schedule based on previous research findings, the aims of the study, and through discussion with members of the broader OSTRICH study team. The interview schedule (see Text, Supplemental Digital Content 1) consisted of 17 open questions and a number of follow-up prompts. A semi-structured approach was used because it allows collection of detailed information in a conversational style, whilst allowing for a profound exploration of different topics and better understanding of the answers provided (Harrell & Bradley, 2009). Taking into account the flexible nature of this qualitative approach, the interview schedule was revised throughout the study, to allow exploration of emerging topics from the participants' accounts. The interviews took place immediately after participant enrolment into the trial and were conducted in a private room by one member of the study team (VG). Prior to the interview, participants were briefed as to the nature and purpose of the study and a participant information leaflet was provided. In addition, written informed consent was obtained from all parents who agreed to participate.

Interviews were audio-recorded and then transcribed by VG. Any participant identifiable information was removed from the transcripts at this point.

Analysis was conducted using an inductive thematic approach (Bradley, Curry, & Devers, 2007) and began concordantly with data collection. VG and NF met regularly to discuss emerging themes and develop a coding framework, which was then also discussed at meetings of the broader OSTRICH Study Management Team. A coding framework document describing each theme in detail was developed in order to aid the consistency of coding. Line-by-line coding was conducted by VG and JK using the NVivo qualitative research software (QSR International Pty Ltd, 2012). Any disagreements were resolved through discussion and new themes were developed in consultation with the team.

## **Results**

11 child participants were recruited and interviews were conducted with 12 parents between June 2014 and January 2015. The interviews lasted between 5 and 15 minutes. Participant demographics are detailed on Table 2 below.

[Table 2 here]

The decision to stop interviews after 11 interviews (with 12 participants) was made due to time constraints. However, analysis of the data at this point had indicated data saturation: no novel themes emerged from the last two interviews.

From the study data, we were able to determine a number of key themes that influence parental decision-making, including the sources of information parents use and satisfaction with information provision. Moreover, we were able to identify factors that are important to parents when considering different treatment options for OME, such as immediacy of effect, perceived efficacy and risks of treatments, as well as past experience.

### ***1. How do parents make decisions?***

#### **1.1 Sources of information**

Parents reported getting most of their information about OME from the clinicians they had consulted with. This included General Practitioners (GPs), ENT doctors, nurses, audiologists and health visitors and was through a combination of discussion and provision of written information.

Most parents seemed to value having access to reading materials (e.g. leaflets, booklets), with some reporting that these were provided in ENT clinics. One parent was keen to have reading materials and complained that they were not available in the ENT clinic she attended. Another parent reported that she already had a good understanding of the information herself, but found the materials useful as an aid when explaining OME and treatment options to other family members. Not all parents seemed to want reading materials though and one parent reported that she valued personal contact with a clinician more. She felt that she would have more trust in the experience and qualifications of a clinician she had met than from reading materials:

*Researcher: "Did you feel that the information they provided you with from the beginning until now, was sufficient for you to make a choice?"*

*Participant 12: Yes, definitely.*

*Researcher: "How important was that to you and why"*

*Participant 12): "Very important...I think that you could have...you can be given a pile of leaflets about something and that's fine but I think for me...I trust what the consultants tell me. I would put my trust in a consultant, you know, they have done it before, they have experience, they've got all the necessary qualifications etc. so I think I prefer that "face to face"."*

Many parents reported using the Internet for information to clarify or add to the information given at consultations. Those that did reported both positive and negative experiences. They appreciated the access it provided them to accounts of different individuals with similar experiences. They also found it very useful when they perceived that they had been given inadequate information during their healthcare encounters, and for clarifying confusion regarding treatment options, such as the size of grommets. Some parents completely avoided using the Internet due to concerns about the quality and reliability of the information available online. These parents indicated that they thought that reading information on the Internet might lead to unnecessary worry or could potentially lead them to making the wrong decisions regarding the treatment of their child's OME. Additional reasons for not using the Internet included lack of time and a preference for personal contact with a clinician. The majority of parents that consulted the Internet did so critically and preferred websites from known sources such as the NHS or the National Deaf Children Society:

*Researcher: "On the internet, did you look at any particular websites or was it just generally googling?"*

*Participant 9: "NHS direct I looked on and that was good because anything I wasn't told, I was able to read on there and you know, NHS direct is good. I don't google things, problems, anything like that because it always ends up with god knows what. I'll only gone on the NHS one and I thought: "I'll be curious about it and have a nose" and that was nice."*

*Researcher: "Ok, you said previously you visited the Internet. When you went online, was it anything specific you looked for? What was your strategy in looking up information?"*

*Participant 4: "I didn't look a lot to be honest, not more than I normally do. I think I just went on the NHS website and had a look on what they said about it really. I don't trawl too far cause you read all sorts of rubbish (laughter)!"*

None of the interviewed parents used social media, such as Facebook or Twitter, to obtain information.

Some parents reported using their own experience and connections, including personal communication with friends and family, and occupational contacts and experiences. In particular, two parents reported that their scientific background allowed them to access and interpret scientific publications and this led them to being able to request more detailed information whilst in the clinic. One parent described exchanging views and obtaining information from another parent in a baby group.

## **1.2 Satisfaction with information provision**

Most (8/12) parents described feeling satisfied with the overall quantity and quality of information provided about treatment options for OME by different sources. One parent

mentioned that being aware of more than one treatment option was reassuring. Most parents did not indicate that any of these sources were better, however one parent reported receiving little information from her GP (who was uncertain of the diagnosis) and some parents reported not receiving adequate information from ENT clinics.

Nevertheless, a few parents expressed dissatisfaction with the information provided. Insufficient information, including only one treatment modality being discussed or complete lack of information regarding advantages and disadvantages of the different treatment options, were the main concerns articulated. One parent described feeling dissatisfied because despite a three-year period had elapsed, from her child's glue ear having been identified to ultimately having grommets inserted, she had never been informed about hearing aids as a possible management option. Another parent expressed frustration at what she perceived as a failure of the clinical staff to recognise the severity of her child's hearing loss (and its associated impact), the subsequent prolonged period of watchful waiting, and the relationship problems that this resulted in with her child, believing that her child blamed her for his hearing loss. Finally, one parent described herself as having high personal expectations and despite reporting that she was 'satisfied' with the information provided, she felt it was difficult to obtain all the necessary information in a consultation. Therefore, she felt it was necessary for her to independently look up information about OME and treatment options:

*Researcher: "So, were you satisfied with the whole process, in the sense that they gave you enough information to make informed decisions?"*

*Participant 10: "Ehm...not for me. But then that is not criticism of them, I just wanted to make sure that I wasn't missing anything. They did give me quite a lot of information, but then I'm also aware that when you are in an appointment you miss information as well...that someone has told you. So for my peace of mind and went on and researched it."*

### **1.3 Decision-making process**

Parents reported that a number of different factors influenced their decision-making around treatment options. Discussing treatment options with family and friends was a key strategy discussed. Parents indicated that this allowed them to compare their experiences, as well as the severity of symptoms, to those of others. Several parents mentioned that they had older children who had also suffered from OME and that this experience gave them additional knowledge and something to measure their child's symptoms against. Therefore, having this experience helped guide them in their current decisions about management.

Concerns about development and acquisition of new skills also acted as a driving force in encouraging parental involvement with the decision-making process. One parent mentioned that being able to bypass the NHS waiting list for grommets and have their child have the operation privately was a positive factor in making a decision. A desire to avoid unnecessary procedures and treatments, as well as increased trust in physicians' decisions were also viewed as expediting factors in making a decision.

Our data showed that children's views weighed heavily in the decision-making process, particularly regarding decisions about the use of hearing aids. The child's acceptance and often excitement over hearing aids acted as a catalyst for choosing the particular treatment option:

*Participant 3: "...when he got used to them it was great...he accepted them. I think they recommended that we'd use them couple of hours a day...and we did initially, but he liked it so much, he just wore them all the time and it was fantastic."*

*Participant 4: "...I mentioned hearing aids to [child's name]. She got very excited about the idea..."*

The size and overall appearance also played an important role in the decision about choosing hearing aids or not.

Overall, despite the fact that most parents felt adequately involved in the decision-making process, a few parents described factors that hindered their decision-making. A number of parents indicated that poor provision of high quality information in the clinical setting, and difficulty accessing information from other sources, impeded reaching a decision. One parent described feeling pressurised by their ENT consultant to not choose grommet surgery and found this paternalistic approach as an obstacle to her decision-making:

*Researcher: "And did you feel they involved you in the whole decision-making process?"*

*Participant 12: "I think it was more of a case they were trying to talk me out of it (grommets), it was almost as if: "You're really sure you wanna have grommets? You're really sure? This is a really last resort"..."*

Another parent described her child's ambivalence about hearing aids as a barrier to making a decision.

## ***2. What factors are important to parents when considering different management options?***

### ***2.1 Immediacy of effect***

Parents talked about the desire to achieve rapid improvement in hearing, and identified hearing aids and grommets as being likely to produce immediate benefits, something that was discussed as a positive factor in favour of these two treatment modalities. Parents did not have an understanding of how quickly steroids might work, but appeared to be willing to try them because of the short duration of the treatment course.

### ***2.2 Perceived efficacy***

#### *Watchful waiting*

A number of parents (4/12) described watchful waiting as unacceptable, due to concerns about the impact of OME, including short and long term school performance and wider impacts on their child's education. Moreover, watchful waiting was largely seen as unacceptable when OME had been longstanding or the symptoms were perceived as worsening. One parent described her child having a developmental delay and was therefore keen to use hearing aids rather than just watchful waiting. However, other parents indicated that watchful waiting was acceptable if the symptoms of the child were mild, caused minor interruptions at school and speech and development were normal.

#### *Hearing aids*



The main factors that led to parents considering use of hearing aids were long duration of symptoms and significant impact of the hearing loss on their child's confidence. One parent indicated that hearing aids had a substantial beneficial impact on the family and school life of their child:

*Participant 3: "...in nursery when he had the hearing aids, the transformation was so...was so quick...you know it was like a day and he was like a different child. I think it came as a shock to the teachers that he was actually like...you know he wasn't...he would not sit, he wouldn't listen to stories before and as soon as he had the hearing aid, he would listen the stories and the rest of it...so, there was a huge difference to what he was like before..."*

There were differing perceptions around the indications for choosing hearing aids over grommet insertion. One parent reported that hearing aids were perceived as a treatment option for severe cases of OME. However, another parent, who had not experienced use of hearing aids, did not perceive them as particularly effective and thought of them as providing a compensation rather than a solution to the problem. One parent whose child had been treated with grommets first and was currently using hearing aids, experienced decision-regret. The parent perceived her child's surgery as traumatic for herself and the effect offered by the grommets was short-lived, thus she regretted not choosing hearing aids as a treatment option first.

#### *Grommets*

Most parents perceived grommet surgery as being highly effective, and one parent described being reassured by the technological and surgical advances of modern clinical practice. Parents reported being willing for their child to undergo surgery if their symptoms were severe and placed a significant burden on daily living, social functioning and school progress. Failure of symptom improvement with other treatment modalities, such as hearing aids, was also mentioned as a factor that prompted parents to consider grommet surgery. Nevertheless, some parents voiced concerns about the possibility of the surgery failing or uncertainty about the grommets only having a short-lived effect. One parent described a past experience in which they had the expectation that grommets would provide a long-lasting effect, but were disappointed thereafter by how quickly the problem recurred. Another parent described how previous failure of grommet surgery had led them to consider trying hearing aids, a treatment option that they had been previously apprehensive about. Lastly, the fluctuating nature of OME with temporary symptoms was discussed as a reason why grommet surgery may not be the best option.

#### *Steroids*

Most parents had no views on the likely efficacy of oral steroids, though one parent reported that use of steroids for another medical condition they themselves had in the past and its successful resolution, led them to believe that steroids might be effective for their child's OME:

*Researcher: "Ok, ... what do you think about using steroids to treat glue ear?"*

*Participant 4: "...I have them for my asthma and they work straight away so...if they work for glue ear, brilliant."*

In addition, another parent mentioned that steroids had been effective in treating ear infections previously.

## 2.3 Perceived risks/adverse effects

### *Watchful waiting*

Although most parents described not being very keen on watchful waiting as a treatment strategy, one parent talked about its value. She described being pleased to have the option of giving OME time to resolve by itself, thereby sparing the child of unnecessary surgery, and potentially harmful, interventions.

### *Hearing aids*

The apprehension that was most widely discussed in relation to hearing aids was the risk of bullying. One parent mentioned having to discontinue use of hearing aids because their child was being bullied, despite being satisfied with their effectiveness:

*Participant 9: "She's got a hearing aid. At first, I loved it, because it's instant and she was just upset before and then she was like: "I can hear myself from here, I can hear you" and when I talked to her she said: "I love hearing your voice" so I was like: "Oh my god", but now she's being bullied for it...*

*...now she won't wear it...and now "we" don't want it...I wouldn't want her to wear it now anyway, cause you know...kids are cruel. Especially when you are young, kids are cruel...it's ok if it's a meantime thing, but she's only five and they are picking on her. So I don't like that."*

Parents expressed a fear of bullying, with one mentioning that they themselves had experienced bullying as a child about using hearing aids. Another parent reported that they were already worried about bullying because their child had to wear plastic caps over their teeth, which impaired articulation, and they were anxious about further stigmatisation and bullying at school if their child wore hearing aids as well. Finally, one parent expressed concerns that hearing aids might result in permanent hearing loss.

### *Grommets*

Grommet surgery was seen as invasive and risky by some parents and this led to them expressing a preference for watchful waiting, hearing aids, and/or oral steroids over surgery. A particular perceived concern was the risk of ear drum scarring and the potential for life-long hearing loss. The other main perceived risk of grommets was the need for anaesthesia. One parent described that watching their child become anaesthetised prior to grommet insertion surgery was very traumatic and one of the most negative aspects of grommets as a treatment option:

*Participant 12: "The only thing I must tell you, was that it was traumatic for myself to watch him being anaesthetised, it is very worrying and stressful..."*

### *Steroids*

Most parents expressed few concerns about the use of steroids for treating OME. Some parents indicated that the steroid treatment involved a small dose and short duration, and this made them feel less apprehensive about side effects. One parent indicated that they would feel happy because their child (who was five years old) was 'older', but they would not be as happy if their child was younger. Another parent indicated that they felt happy with using steroids, due to the fact that it is a 'well-established and approved' medication and not 'new' or 'unknown':

*Researcher: “Do you have any concerns”*

*Participant 10: “No. It’s to try and test the steroid, isn’t it? It’s not brand new medicine, you know? If it’s brand new medicine, I wouldn’t try it, it wouldn’t be safe. They are trying to test the medicine, so if it works, it works”*

On the other hand, one parent voiced concerns regarding weight gain as a potential side effect, whereas another parent talked about being anxious about the dose strength and potential side effects of steroids, although they did not have a clear idea of what such side effects might be.

## **2.4 Past experience**

Two parents described being in favour of grommet surgery for their children because of their own positive experiences with grommets as a child. On the contrary, one parent described her own experience of grommets that had failed to fall out and required further surgery to be removed, and this negative experience made her wary of considering grommet surgery for her child. Another parent mentioned that their own fear of not recovering from anaesthesia when they had surgery was projected onto their child, resulting in negative feelings about a surgical treatment option:

*Researcher: “And what about the operation is it that puts you off?”*

*Participant 9: “I don’t know...anaesthetic I think...I don’t like the idea of...I’ve had an operation myself and I was afraid that if I got knocked out, I wouldn’t wake up and I think that’s what frightens me. It wasn’t related (to grommets) but that’s what panics me. With me I thought I wasn’t gonna wake up and I think that’s why...(I wouldn’t want my child to go through surgery)”*

One parent reported that their child had undergone anaesthesia for a different surgical procedure, and as they had not suffered any adverse effects from it, the parent was reassured about the prospect of grommet surgery.

Parents appeared to be positively predisposed towards steroids, based not only on their children’s, but also on their own previous experiences. Some parents reported that steroids had been effective in treating previous ear infections, with minor or no side effects. Others talked about the beneficial role that steroids played in the management of other conditions, such as skin infections and asthma. Overall, these past experiences tended to result in parents having a positive attitude towards the use of oral steroids for the resolution of OME.

## **Discussion**

The aims of this study were to explore parental perceptions of information provision, treatment options, and decision-making for children with otitis media with effusion (OME). We identified that parents rely primarily on verbal information from healthcare professionals, searching the Internet and talking to friends and family for information about OME and treatment options. This has been confirmed by previous research (Gorodzinsky et al., 2015), however it has also been demonstrated that clinicians should check parental understanding surrounding their children’s condition and also exercise caution when it comes to basing their understanding on the experiences of others which may not always be applicable in the case of

their child (Gorodzinsky et al., 2015). Most parents were satisfied with the amount and quality of information provided, but some expressed frustration at what they perceived to be inadequate information provision and lack of printed materials, and some expressed unease about identifying high quality information on the Internet.

The decision-making process was facilitated through discussion with family and friends and children themselves, particularly in the case of hearing aids, and influenced by parents' past experiences. The impact of OME on the child's learning, development and social life and the likely speed of onset of treatment options, were important factors in deciding on treatment. Concerns about anaesthetic effects (for grommet surgery) and social stigma (for hearing aids) also played a big role. Generally, a short course of oral steroids was considered a safe and acceptable experimental treatment option. One parent was concerned however about potential side effects, although they were not certain of what such side effects might be. It is worth mentioning that parents had been provided with written and verbal information about the trial, including list of side effects, immediately prior to the interview.

A review about parental decision making for children with cancer reported that most parents had a preference for a collaborative approach to treatment decision making, however this varied depending on a number of illness factors, person factors and relationship factors (Stewart, Pyke-Grimm, & Kelly, 2005). Paternalistic interactions often involve physicians making assumptions about the patient's values and beliefs and therefore making a decision on their behalf which is not in line with their expectations (Emanuel & Emanuel, 1992). We found that in the case of one parent, the use of a paternalistic approach by the clinician she consulted was viewed as an obstacle to making an informed decision.

It has been consistently documented that surgery can place a significant emotional burden on children and parents (Simpson et al., 2007). Moreover, anaesthesia has been postulated to be one of the most stressful elements for parents whose children undergo surgery (Franck & Spencer, 2005). Both of these findings were confirmed in our study. As far as hearing aids were concerned, we identified that bullying was a significant issue surrounding their choice as a treatment option. However, one qualitative study found that children who were using hearing aids for OME were not as adversely affected by bullying or low self-esteem as their parents thought they might be (Qureishi, Garas, Mallick, & Parker, 2014).

#### *Limitations and strengths*

We were only able to recruit a small sample of parents to participate in this study, mainly due to time constraints, but also due to the small number of children enrolling in the larger OSTRICH study at the time. Parents had already consented to participate in a trial of oral steroids, therefore the sample did not include parents who may be concerned about the use of steroids and therefore declined to take part in the trial. In addition, the participants were all recruited from a single centre located in South East Wales, and as such, it is difficult to gauge the generalisability of our study findings. Nonetheless, the factors playing a key role in decision-making are in line with previous findings from literature and therefore, we have confidence in their validity. Recent studies have acknowledged the role of nasal insufflation in the management of OME (Perera, Glasziou, Heneghan, McLellan, & Williamson, 2013) but this was not a treatment option that we explored in our study. Hence, it would be useful for future studies to consider parental perceptions of this management option. Another interesting factor which could be explored with regards to parental decision-making in OME and not

included in our analysis, are different sociodemographic variables, such as socioeconomic status, age and gender, as well as marital status, as these have been found to influence the way parents behave and make decisions (Hollen & Brickle, 1998). Nonetheless, in the case of some parents, it was reported that their educational background and health literacy facilitated the decision-making process. Lastly, since the majority of the interviews were with the mother who was interviewed alone, apart from one interview, it would be worth exploring whether the other parent had been consulted, if there was any conflict and how that affected the decision-making process.

This study is novel in that it attempted to address various issues surrounding parental perceptions and decision-making, taking into account not only all of the finely balanced available treatment options for OME, but also oral steroids. This information will be of great value should oral steroids be shown to be an effective treatment for children with OME and form part of the medical management of OME in the future.

Our findings suggest that although many parents are happy with verbal information, some rely on poor quality information and others are keen to have access to printed information. Information about the risks and benefits of various treatment options is particularly valued, and information targeted at older children should also be made available. These data should help clinicians and healthcare managers to ensure that parents are provided with the information they require, and in the format that suits them, to meet their needs. Consequently, this will help clinicians pre-empt the likely questions about OME treatment options that parents are likely to have, and proactively correct common areas of parental misunderstanding, hence leading to shared decision-making, improved parental satisfaction and clinical outcomes.

## References

- Aarthun, A., & Akerjordet, K. (2014). Parent participation in decision-making in health-care services for children: an integrative review. *J Nurs Manag*, *22*(2), 177-191. doi: 10.1111/j.1365-2834.2012.01457.x
- Bennett, K. E., Haggard, M. P., Silva, P. A., & Stewart, I. A. (2001). Behaviour and developmental effects of otitis media with effusion into the teens. *Archives of Disease in Childhood*, *85*(2), 91-95. doi: 10.1136/adc.85.2.91
- Bradley, E. H., Curry, L. A., & Devers, K. J. (2007). Qualitative data analysis for health services research: developing taxonomy, themes, and theory. *Health Serv Res*, *42*(4), 1758-1772. doi: 10.1111/j.1475-6773.2006.00684.x
- Emanuel, E. J., & Emanuel, L. L. (1992). Four models of the physician-patient relationship. *Jama*, *267*(16), 2221-2226.
- Franck, L. S., & Spencer, C. (2005). Informing parents about anaesthesia for children's surgery: a critical literature review. *Patient Educ Couns*, *59*(2), 117-125. doi: 10.1016/j.pec.2004.11.002
- Gorodzinsky, A. Y., Hong, P., & Chorney, J. M. (2015). Parental knowledge in pediatric otolaryngology surgical consultations: A qualitative content analysis. *International journal of pediatric otorhinolaryngology*, *79*(7), 1135-1139. doi: 10.1016/j.ijporl.2015.05.013
- Harrell, M., & Bradley, M. (2009). Data Collection Methods: Semi-Structured Interviews and Focus Groups., from [http://www.rand.org/pubs/technical\\_reports/TR718.html](http://www.rand.org/pubs/technical_reports/TR718.html)

- Hollen, P. J., & Brickle, B. B. (1998). Quality parental decision making and distress. *J Pediatr Nurs*, 13(3), 140-150. doi: 10.1016/s0882-5963(98)80072-9
- Joosten, E. A., DeFuentes-Merillas, L., de Weert, G. H., Sensky, T., van der Staak, C. P., & de Jong, C. A. (2008). Systematic review of the effects of shared decision-making on patient satisfaction, treatment adherence and health status. *Psychother Psychosom*, 77(4), 219-226. doi: 10.1159/000126073
- Lipstein, E. A., Brinkman, W. B., & Britto, M. T. (2012). What is known about parents' treatment decisions? A narrative review of pediatric decision making. *Med Decis Making*, 32(2), 246-258. doi: 10.1177/0272989x11421528
- Lous, J. (1995). Otitis media and reading achievement: a review. *International journal of pediatric otorhinolaryngology*, 32(2), 105-121.
- NICE. (2013). Assessment and treatment for children with otitis media with effusion (without Down's syndrome or cleft palate). Retrieved 2nd December 2015, from <http://pathways.nice.org.uk/pathways/surgical-management-of-otitis-media-with-effusion-in-children>
- Perera, R., Glasziou, P. P., Heneghan, C. J., McLellan, J., & Williamson, I. (2013). Autoinflation for hearing loss associated with otitis media with effusion. *Cochrane Database Syst Rev*, 5, Cd006285. doi: 10.1002/14651858.CD006285.pub2
- QSR International Pty Ltd. (2012). NVivo qualitative data analysis Software (Version 10).
- Qureshi, A., Garas, G., Mallick, A., & Parker, D. (2014). The psychosocial impact of hearing aids in children with otitis media with effusion. *J Laryngol Otol*, 128(11), 972-975. doi: 10.1017/s0022215114002163
- Rovers, M. M., Straatman, H., Ingels, K., van der Wilt, G. J., van den Broek, P., & Zielhuis, G. A. (2001). Generalizability of trial results based on randomized versus nonrandomized allocation of OME infants to ventilation tubes or watchful waiting. *J Clin Epidemiol*, 54(8), 789-794.
- Simpson, S. A., Lewis, R., van der Voort, J., & Butler, C. C. (2011). Oral or topical nasal steroids for hearing loss associated with otitis media with effusion in children. *Cochrane Database Syst Rev*(5), Cd001935. doi: 10.1002/14651858.CD001935.pub3
- Simpson, S. A., Thomas, C. L., van der Linden, M. K., Macmillan, H., van der Wouden, J. C., & Butler, C. (2007). Identification of children in the first four years of life for early treatment for otitis media with effusion. *Cochrane Database Syst Rev*(1), Cd004163. doi: 10.1002/14651858.CD004163.pub2
- Stewart, J. L., Pyke-Grimm, K. A., & Kelly, K. P. (2005). Parental Treatment Decision Making in Pediatric Oncology. *Seminars in Oncology Nursing*, 21(2), 89-97. doi: 10.1016/j.soncn.2004.12.003
- Waldron, C. A., Thomas-Jones, E., Cannings-John, R., Hood, K., Powell, C., Roberts, A., . . . Francis, N. (2016). Oral steroids for the resolution of otitis media with effusion (OME) in children (OSTRICH): study protocol for a randomised controlled trial. *Trials*, 17. doi: 10.1186/s13063-016-1236-1
- Wennberg, J. E. (2002). Unwarranted variations in healthcare delivery: implications for academic medical centres. *Bmj*, 325(7370), 961-964.

**Table 1: Inclusion and exclusion criteria of the OSTRICH study**

Inclusion Criteria	Exclusion Criteria
Between two and nine years of age	Was participating (or had participated during the preceding 4 months) in another clinical trial of an investigational medicinal product
Had symptoms of hearing loss attributable to OME for at least three months (or audiometry proving hearing loss for at least three months)	Had systemic infection or ear infection at time of recruitment
Had a diagnosis of bilateral OME made in an ENT clinic on the day of recruitment or during the preceding week	Had cleft palate, Down Syndrome, diabetes mellitus, Kartagener's or Primary Ciliary Dyskinesia
Had audiometry confirming hearing loss on the day of recruitment or within the preceding 14 days	Had renal failure, hypertension or congestive heart failure
Was child's first time in the OSTRICH study	Had confirmed, major developmental difficulties, tube fed, chromosomal abnormalities
Parent/carer was able to understand & give informed consent	Had taken oral steroids in the preceding four weeks
	Had had a live vaccine in the preceding four weeks if aged under 3 years old
	Had a condition that increased their risk of adverse effects from oral steroids
	Had been in close contact with someone known or suspected to have Varicella or active Zoster during the three weeks prior to recruitment and had no prior history of Varicella infection or immunisation
	Had existing known sensory hearing loss
	Child already had grommets (ventilation tubes)
	Was on a waiting list for grommet surgery and anticipated having surgery within 5 weeks and would have been unwilling to delay it

**Table 2: Participant demographics**

Participant Number	Age of Child (years)	Gender of Child	Interviewee(s) Relationship to Child	Duration of OME Symptoms (months)	First Episode of OME?	Previously Affected Sibling?
1	4	Male	Mother	> 12	Yes	No
2	6	Male	Mother	> 12	Yes	No
3	6	Male	Mother	> 12	Yes	No
4	5	Female	Mother	6 – 9	Yes	No
5	5	Male	Mother	> 12	Yes	No
6	5	Male	Mother	> 12	Yes	N/A*
7	4	Female	Mother	> 12	Yes	No
8	5	Female	Mother	> 12	Yes	No
9**	3	Female	Mother	> 12	Yes	Yes
10**	3	Female	Father	> 12	Yes	Yes
11	6	Female	Mother	< 6	No	Yes
12	7	Male	Mother	6 – 9	No	No

\*This child did not have a blood-related sibling.

\*\*Participants 9 and 10 were a couple and were jointly interviewed