STANFORD
MUSSALLEM CENTER FOR
BIODESIGN

CASE: HE-3
DATE: SEPTEMBER 2024

# USING INCLUSIVE DESIGN TO RESHAPE STANDARD OF CARE

*"We've benefited greatly from deeply understanding the differing interests and requirements of the most relevant stakeholders and adopting empathy-based design principles."*
– Matt Oldakowski, Founder and Chief Technology Officer, EarFlo

## Background

Matthew Oldakowski, a PhD in bioengineering from Australia, and Jozef Bartunek, a cardiologist from Belgium, met when they joined Stanford Biodesign's global faculty training program. Both would return to their respective countries to launch or expand Biodesign-like programs at their home institutions. But first, they would learn and practice the principles of need-driven innovation by applying them to their own health technology innovation project. With a focus on otolaryngology, they gained access to Stanford's ear, nose, and throat (ENT) department to conduct needs finding. After weeks of observing and interviewing stakeholders in space, they became particularly interested in unmet needs related to a condition in children called otitis media with effusion (OME).

OME is particularly common in children under five and often occurs after a cold or ear infection. As Oldakowski explained, "It's caused by the poor function of the eustachian tube, which is the canal that links the middle ear to the nasal-sinus cavity. The eustachian tube helps balance pressure and drain fluid from the middle ear. Fluid can build up behind the eardrum when it's not working properly. When the eardrum can't move freely, hearing loss is caused. Some children experience this for a few weeks, then the condition resolves independently. Others have it for many months or years.[1] When OME is ongoing in young children, hearing loss can result in speech problems, difficulty with socialization, and developmental delays.

The standard of care for treating OME is surgery to place ear tubes that drain the fluid and help balance pressure in the ear. According to Oldakowski, the surgeons he and Bartunek spoke with felt that the current solution worked well. "They said, 'It's a very simple procedure to put in these pressure equalization tubes. It's very common and only takes 15 minutes under general anesthesia," Oldakowski recalled. However, when the team spoke with parents of affected children, they were much more concerned. They were highly concerned about the need for a general anesthetic and the potential risks associated with their children having surgery.

This misalignment between how the surgeons and the parents perceived the prevailing solution piqued Oldakowski and Bartunek's interest. Once they had a deep understanding of the unmet need, they decided to use what they had learned to devise a less invasive treatment option for OME. Together with ENT surgeon Peter Santa Maria and biomedical engineer Intan Oldakowska, they eventually founded a company called EarFlo to pursue the project. The team believed that the alternate approach would result in significant health, economic, and commercial value if surgery could be avoided.

## Finding an Actionable Insight

In their initial research, they found a paper from the 1950s that documented the work of a German physician who devised an approach to "milk out" the effusion. "He sat adult patients in a chair, angled their heads, and used a pneumatic otoscope to pressurize the eardrum and a Politzer bag to pressurize

This case study was prepared by Cyan Brown and Lyn Denend. Thank you to Matt Oldakowski and Intan Oldakowska for their contribution to this project. All quotations are from interviews conducted by the authors unless otherwise cited.

the nasal cavity," said Oldakowski. "He found that if he synchronized the three movements, he could clear 90% of effusions in adults. That helped convince us that the mechanism of action was sound."[2]

They investigated this approach further and learned that modern technologies, called auto-inflation devices, used a similar process for opening the eustachian tube and ventilating the middle ear. However, they were not widely adopted. Seeking to understand why, the team purchased several devices and tried using them themselves. That's when several problems became apparent. First, they were not child-friendly. "With one device, you have to hold it to your nose, put some water in your mouth, and then press a button while swallowing. Even adult patients have problems coordinating that sequence of activities. With another device, you have to blow up a balloon with your nose. Again, even for adults, it's complicated to inflate the balloon and maintain the appropriate pressure without air leaking. As a result, these devices really can't be used by kids under five years old," stated Oldakowski.[3] Second, current solutions on the market use pressure that's too high for children. As Oldakowska described, "It can be quite shocking for a young child when they're able to coordinate their movements and use a device properly to clear the pressure in the ear. Many of them don't want to use it again because the sensation is so unpleasant."[4] Third, while the clinical studies supporting the devices showed relatively good data, the average age of the patients in the studies was seven years old. "Around 90% of the problem is in kids under five," Oldakowski said. "So, we identified that there's this huge opportunity to leverage this mechanism of action, which has been proven to be effective. However, we would have to design something for a totally different user." They would focus exclusively on making something usable for children in the one to five age range.

## Designing for Children

After undertaking an extensive concept generation and screening process, the EarFlo team came up with a preliminary solution that leverages the basic form factor of a sippy cup with a built-in electric air pump that pressurizes the nasal cavity when a child is naturally drinking to open the eustachian tubes and ventilate the middle ear. "We knew we needed a way to create a seal on the face, we knew we had to have a way to induce swallowing, and we knew we needed to coordinate those two things so they happened at the same time," Oldakowski explained. "To accomplish this, we decided to make it look exactly like a sippy cup and leverage the design language of a sippy cup that kids understand and are comfortable with."

The first design requirement was getting the pressure from the air pump right for children. After optimizing for this, they turned their attention to designing the device so that children would want to use it. Another critical design challenge was making sure the solution was usable by many different subgroups, as nose sizes vary by age and ethnicity. Additionally, children with cleft palates and Down syndrome are more prone to ear infections, and social determinants of health put specific subgroups at greater risk of OME.

With a strong commitment to inclusive design principles, they performed in-depth user research with parents and their kids. To help optimize the feedback process, Oldakowski looked into the literature for best practices in gathering design input from children who can't follow the same processes (like completing questionnaires) often used with adults. After getting ethics approval for the research, he and the team leveraged quality-of-life surveys for children with ear infections as a starting point for crafting discussion questions. They intentionally scheduled the meetings with parents and their children to take place outside of a clinical setting to promote an informal atmosphere where everyone was more relaxed and verbal and nonverbal feedback could be collected with greater ease.

The team was interested in understanding how comfortable children in the one to five age range would be when interacting with their prototypes, what they might be concerned about, whether they could drink by

themselves, and what they might struggle with to get the device working. By interacting with children directly, they learned a lot. For example, to effectively use the cup, the child has to press their nose into a “mask” on the lid to get their lips on the “sucker” and create a seal. An important takeaway was that the noise, vibration, and feeling of having the mask over the nose were crucial factors that scared some children away from using the device. They also saw how difficult it was to get the youngest children to follow even simple instructions without the involvement of parents or other caretakers.

This initial round of user input and the desire to have a product that worked with different facial anatomy led to a series of important design modifications. “We decided to start with two different masks,” said Oldakowski. “The first is for kids in the three to five-year-old group that have somewhat more mature features and the physical dexterity to use the device by themselves. The second mask is for younger children who need help from an adult to use the device. There are different constraints with this design. For example, the adult has to be able to help the child position the mask, so we made the mask transparent so it’s easier for them to achieve proper alignment. It also has to be softer and more flexible so that it’s comfortable when fitting around the young child's nose. Getting these two designs right has required a lot of testing and iteration."[5] Ultimately, three masks will be provided with the EarFlo device to maximize its usability, especially for children with diverse facial anatomy.

In addition to informing the practical design of the device, the user input guided EarFlo’s approach to user desirability and compliance. They knew they needed a solution that children would want to use in order for the device to deliver the necessary results. “As parents, we know that kids love screen time and games,” Oldakowski said. So, they set out to transform the solution from children perceiving it as a “medical device” to something that could be fun. “[We paired] the device … with a game that can be played on a smartphone,” he continued. “In the game, they have a rocket that moves upwards based on intranasal pressure. When they reach the right pressure, the rocket reaches a star. This helps them train themselves on how to use the device, and they get digital rewards each time they complete a session. Right now, each session requires them to get the desired effect five times. But we intend to study whether doing it more will cause children to get better even faster or whether five times is really necessary.”[6] Oldakowski added, “We've had some kids get the desired effect up to 60 times per day, and just hundreds and hundreds of uses, because they enjoy using it. And it's safe to do lots of times, so that's fine.”

In combination, these design modifications resulted in a solution that was authentically able to meet the needs of children. However, because it looked like a game-enabled sippy cup, parents associated it with a toy and expected it to cost the same as a common child’s cup. To address this challenge, the team made another round of design changes to appeal to both the user (child) and the purchaser (parent). “We shifted our design language to denote a premium product for the parents," Oldakowski said. The sleek, new design connoted a high-tech product (e.g., using LED lights to signal correct and incorrect usage). But we still wanted to make sure it was fun for the kids in other ways,” Oldakowski explained. “What we've done with the clinical trial is provide stickers, so the kids can put stickers on the device and feel like they own it. But this comes after we market the product to parents.”

In terms of results to date, Oldakowski summarized, "We completed a single-use pilot study, using an early prototype, with good results. Thirty-one children, with an average age of about three years old, used the device once in a controlled environment, and approximately 65% experienced a clinical improvement. [Next, we] started a pilot daily-use study with an injection-molded prototype that families took home for four weeks. They used the device daily, and we found that, at four weeks, the vast majority of kids had significantly improved hearing. This is really exciting data that we are currently publishing in the journal of the American Academy of Otolaryngology-Head and Neck Surgery."[7]

One grateful parent described his daughter's experience as follows: "She really liked to use it, and it was simple for her to use. She wanted to do it more, actually! It's been a year since we noticed her hearing loss, but her hearing is perfect now."

## An Explicit Focus on Health Equity and Access

As the EarFlo team continued to advance its clinical activities, they also started thinking about how to ensure the solution would be accessible to all children who need it, beginning with those in their initial market in Australia. The Indigenous community of Australia, the Australian Aboriginal children, have among the highest reported rates of OME and associated hearing loss in the world.[8] To serve the needs of these children, they dedicated themselves to engaging with partners in the Aboriginal community to further inform their work, with particular attention paid to the ethics and cultural sensitivities of working with this group of people. For example, through additional user research, they learned about this population's focus on communal ownership instead of personal ownership. Accordingly, in planning an additional trial in collaboration with the Pilbara Aboriginal Health Alliance, the team and its partners decided that schools in the region would be provided with 10 devices rather than having each family of a child with OME get their own household device. While this introduced new design requirements around ease of cleaning and sterilization, the decision was better aligned with the values of the community.

In an Indigenous population study, the EarFlo team found that the vast majority of patients had immediate clinical improvement after using the device. The mother of one of the Indigenous patients described the effect of treatment on her daughter this way: "My daughter has problems listening to us, even when we are sitting right next to her. And just now, after using the device, I whispered to her, and she heard me. She's never been able to hear me whisper to her before!"

Oldakowski and his team attribute their ability to invest so much time in optimizing the product's usability features, in part, to the fact that they did not have to commercialize the device immediately. "We intentionally sought nondilutive grant funding, which has allowed us to do things the way we think is best for the patients and the business," he said. "Our goal is for this to become standard of care globally, so it's worth spending a bit of time making sure that we're not going to trip over something silly." He also noted that being intentional about inclusive design from the start of an innovation project is fundamental to practicing good design. While encouraged that FDA guidance documents now help innovators think about the diverse communities they may be designing for, Oldakowski hopes that inclusive design becomes a mission for more health technology companies rather than merely a checklist for solution development.

## Key Take-Aways

- EarFlo gained insights by realizing that the solutions on the market could be more user-friendly, particularly for children since they are the primary intended beneficiaries.
- The team spent time with children and their parents in nonclinical settings to gather data on what was off-putting about their early designs and how to improve.
- They took variations of facial and nasal anatomy into account early on and considered designing for specific subpopulations, such as children with cleft palates.
- The team struck a balance when making design choices to appeal to children (users), as well as parents (buyers).
- EarFlo intentionally decided to trial their device in Indigenous communities to understand what extra design features may be needed for it to work well in multiple settings (e.g., being easy to clean and sterilize for community use).

*The progression of product designs (courtesy of the EarFlo team).*

*A child learning to use the device (courtesy of the EarFlo team).*

[1] "Preventing Hearing Loss in Children: An Interview with Intan Oldakowska and Matt Oldakowski of EarFlo," Stanford Biodesign, https://biodesign.stanford.edu/our-impact/technologies/Earflo.html (August 25, 2024).

[2] Ibid.

[3] Ibid.

[4] Ibid.

[5] Ibid.

[6] Ibid.

[7] Ibid.

[8] Annette Kaspara and Amanda Jane Leacha. "Hearing Loss Among Australian Aboriginal Infants and Toddlers: A Systematic Review," Public Health Pract (Oxf), October 12, 2020, https://pubmed.ncbi.nlm.nih.gov/36101696/ (September 25, 2024).