Managing Disease Risk in Hearing Healthcare Delivery

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The accessibility and affordability of hearing healthcare is driven by several factors, none the least of which is the need to identify and treat unrecognized ear diseases in adults with hearing loss. At the outset, it is important to recognize the obvious: identification and treatment are 2 distinct processes. Moreover, we can separate disease identification into 2 sub-processes: disease screening activities (for which we will use the term “disease detection”) and formal diagnosis. To understand why this is important, one simply needs to look at the population distributions underpinning the “silver tsunami” - the wave of baby Boomers who are beginning their matriculation into retirement years.
This is the population distribution from the 2000 Census...
... from the 2010 Census...
... And an estimate of the population distribution today
The vertical arrow highlights an estimated doubling in the number of individuals in their early 60s TODAY, relative to 2000 census data. One would reasonably expect that the number of individuals with age-related hearing loss would also increase following this trend.

During that same interval, there was not a doubling in the total number of hearing healthcare providers: otolaryngologists, audiologists, and hearing instrument specialists. As a result, we can anticipate that access to hearing healthcare will present a challenge in the very near future for individuals with age-related hearing loss.
Additionally, the nature of the disease identification problem changes with these shifting population demographics.

This slide shows an estimate of the number of individuals with hearing loss in 2010 terms, stratified by age.
Now let's add ear disease prevalence estimates for conditions that can cause hearing loss. These estimates were compiled from several sources and they are frail. There are few population based reports that stratify ear disease prevalence by age.
Not surprisingly, hearing loss prevalence increases with age. In contrast, the projected number of ear disease cases decreases with age – even using liberal disease prevalence estimates.
But in the context of disease identification and treatment, it is the increase in absolute numbers of individuals with age-related hearing loss that challenges our efforts to identify and treat ear disease.

In 2010, one could reasonably predict a 25% increase in the number of benign age-related hearing loss cases, relative to 2000.

This year, we would predict an increase of over 100%.

Why is this a challenge?
Disease surveillance is formalized in the hearing aid delivery system to combine disease identification and treatment into one process. Specifically, current FDA regulations require that all individuals with hearing loss see a physician, preferably a physician specializing in diseases of the ear, for a pre-hearing aid purchase medical evaluation. The “purpose of medical evaluation is (...and take note, you will hear this again...) to assure that all medically treatable conditions that may affect hearing are identified and treated before the hearing aid is purchased.” (21CFR801.420).

Now about 1/3 of the ear disease cases encountered in adults can evolve into potentially fatal conditions if not treated effectively. So rapid identification, diagnosis and treatment is clearly an important healthcare objective - and otolaryngologists are uniquely trained to do this.

Yet from a systems point of view, the medical evaluation presents a potential bottle neck for the majority of older adults who choose to pursue hearing aids.
To be accurate, current FDA regulations recognize two pathways for procuring hearing aids: We will call these “the FDA preferred method” and “the waiver method.”

In the FDA preferred method, the consumer sees an ear specialist, who performs a comprehensive otologic medical evaluation and then arranges for an audiological evaluation. The audiological evaluation, or at least a simple hearing test, is needed in every case. Specialists cannot reasonably exclude inner ear disease without audiological data. ...and then the
consumer returns to the physician.

Based on our fairly liberal disease prevalence estimates, at most 12% of individuals aged 50 years or older will have a condition that could potentially benefit from medical or surgical treatment. This means, in at least 88% of cases, the comprehensive evaluation will not identify any treatable condition.

Given the growing numbers of individuals with age related hearing loss, anticipated access challenges, and escalating Medicare expenditures, one might reasonably ask if the cost of the FDA preferred method is proportionate to disease risk?

The answer to that question is not so straightforward. It depends, at least in part, on the cost of missed disease - which may be significant. It will also depend on the performance of alternative disease surveillance approaches, and the risk we as a society find to be acceptable when a potential healthcare decision is left to the consumer and market place.
There is an alternative method. One that is strongly discouraged by the FDA. It entails a voluntary waiver of the pre-purchase medical evaluation. When the medical evaluation is waived, disease detection is left to the consumer, and the non-physician hearing healthcare provider—the audiologist or hearing instrument specialist.

Non-physician hearing healthcare providers remain obligated to refer consumers for medical evaluation if any FDA defined “red flag” sign or symptom of ear disease is recognized.
We don’t really know how well the red flag criteria work as a disease detection method. Nor do we know how many times the medical waiver is used. But anecdotally, the use of the medical waiver seems to be increasing rapidly.

Now I mentioned alternative approaches to the FDA preferred method. At the Mayo Clinic in Florida, adults complaining of hearing loss in isolation can be seen by audiologists without seeing physician providers. The audiologists obtain a history, physical examination, test hearing and then make recommendations concerning hearing aid candidacy, communication management options, and the need for further medical evaluation.
In 2010, we published a paper evaluating the effectiveness of our system in a cohort of over 1500 consecutive Medicare eligible adults. There was essentially no difference between Otolaryngologist and Audiologist decisions concerning who was or was not at risk for ear disease.

Importantly audiologists did not miss any ear disease that could cause hearing loss, or a single case of medically correctable hearing loss. I point this out because identifying ear disease and medically correctable hearing loss are the stated rational for the FDA pre-purchase medical evaluation.

So an audiologist based disease detection approach can work and is
appealingly practical. But does the Mayo experience generalized? I’m pretty sure it does. ... However, beyond our paper, I’m not aware of any published, systematically acquired data set that either supports or refutes our experience, or validates the need for the FDA preferred approach.
For some time our group has been thinking about ways to make disease detection more effective and efficient across the breadth of the evolving hearing healthcare delivery system.

We are developing two tools to evaluate the generalizability of the findings at the Mayo clinic with funding from the NIDCD. The first tool is called PEDRA, which stands for: “Professional Ear Disease Risk Analytics.” The aim of PEDRA is to standardize ear disease risk assessment across non-physician hearing healthcare providers.
PEDRA includes a structured interview, a standardized physical examination, standard audiological tests, and statistical methods that use collected data to provide a probabilistic estimate of ear disease risk. We will validate the generalizability of PEDRA in our multi-site study beginning this year.

But even if PEDRA disease detection works perfectly, we still face a growing population of citizens with age-related hearing loss that may soon overrun the capacity of physician and non-physician hearing healthcare providers alike.
At the same time, technological advances and growing market demand have incentivized the consumer electronics industry to offer hearing solutions. Consumer electronics can be sold directly to the consumer, potentially offering higher accessibility to hearing help at a lower cost. How do we detect ear disease when a consumer with hearing loss looks for help in advertisements at the back of a magazine, over the Internet, or from an electronics store?

We framed the issue this way: How well do consumers assess their own disease risk? ...And can we make a tool that would help them be more accurate in their decision making?
To this end, our second tool is consumer focused. It is called CEDRA: The Consumer Ear Disease Risk Assessment. CEDRA uses simple questions about health status and ear disease symptoms to quantify ear disease risk. Our aim is to produce a simple validated tool that can guide the consumer into making an informed decision about the need for further medical evaluation.
The interim performance of CEDRA is promising. Our current prototype has been cross validated in groups of hearing impaired adults between the ages of 40 and 80 years, both with and without ear disease. Even before any sophisticated analysis, CEDRA was able to accurately identify over 70% of those with benign age-related hearing loss relative to the gold standard of blinded neurotologist opinion.

If these results hold in our larger multi-site study, CEDRA by itself may be able to correctly identify the majority of hearing
aid seeking adults with age related hearing loss.

So what we envision is that individuals contemplating a hearing aid purchase would investigate alternatives over the internet for example, and be offered CEDRA as a service. If the received a passing score on CEDRA, they could have greater confidence in safely evaluating hearing solutions from any branch of the delivery system that was accessible and appropriate to their needs.

A smaller group of consumers will receive a “Refer” CEDRA score and would have reasonably high risk for ear disease - making disease detection using PEDRA, or a formal diagnostic otolaryngology evaluation more efficient and thus justifiable.
In summary, identifying and treating ear disease is an important healthcare objective.

But we have a bandwidth issue, driven by our aging population. The FDA preferred pre-purchase otolaryngology evaluation becomes more costly as evermore hearing impaired adults without ear disease are evaluated. Further, the evaluation becomes increasingly ineffective as consumers find alternative pathways to hearing help.
To us, it makes sense to at least consider separating disease detection, which can be accomplished by less expensive and more available non-physician providers, from the formal physician based diagnosis and treatment processes. PEDRA is designed to optimize and standardize non-physician based disease detection, and its performance will be well characterized by our multisite study. Given the Mayo Clinic experience with audiologist based disease detection, we are reasonably confident that this approach will work.

Yet, consumer behavior is already challenging the effectiveness of all provider based disease surveillance. Ear disease risk does not disappear when a consumer electronics product is purchased instead of a traditional hearing aid. We believe that tools like CEDRA may not only augment provider based disease detection, but also be the only way to provide disease surveillance in the direct-to-consumer market place.

Based on our early experience, we are optimistic that we will deliver effective disease detection tools that help manage
disease risk across the various arms of the hearing aid distribution system, and thereby improve the accessibility and affordability of hearing healthcare.

Speaking on behalf of myself, my colleagues, Sumit Dhar, Don Nielsen and our team, I want to express my gratitude to the Committee for inviting me to present today.
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