12-2022

Incorporating Over-the-Counter Hearing Aids into Private Audiology Practice

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INCORPORATING OVER-THE-COUNTER HEARING AIDS INTO PRIVATE AUDIOLOGY PRACTICE

A Scholarly Project Submitted in Partial Fulfillment
of the Requirements for the Degree of
Doctor of Audiology

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Department of Communication Sciences and Disorders
Audiology

November 2023

This Scholarly Project by: Ryan K. Anderson

Entitled: *Incorporating Over-the-Counter Hearing Aids into Private Audiology Practice*

Has been approved as meeting the requirement for the Degree of Doctor of Audiology in College of Natural and Health Sciences in the Department of Communication Sciences and Disorders, Program of Audiology.

Accepted by the Scholarly Project Research Committee

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ABSTRACT

Anderson, Ryan K. *Incorporating Over-the-Counter Hearing Aids into Private Audiology Practice*. Unpublished Doctor of Audiology Scholarly project, University of Northern Colorado, 2024.

Over-the-counter (OTC) hearing aids are a new category of hearing aid devices designed to help adults with mild to moderate sensorineural hearing loss. This new category of devices was created with the aim to provide increased access to hearing aids for millions of Americans. Their advent has created significant change for hearing healthcare within the United States as they can be purchased without consulting an audiologist or medical professional.

As a result of these changes, private audiology practice owners must choose how they will react. Moving forward they must decide if they will integrate OTC hearing aids into their practices, and if they do, how that integration would work for both the practice owner/audiologist and the consumer/patient. The advantages and disadvantages of incorporating OTC hearing aids into private audiology practice are discussed along with three different models of integration that could be utilized. The hybrid model is proposed as the most advantageous option.

Little to no scholarly research on OTC hearing aids currently exists. As such, directions for future research and other needs are considered to better understand the impact that these devices will certainly have.

ACKNOWLEDGMENTS

This project could not have been completed without the guidance, insight, and help of my Doctoral Scholarly Project Committee. I am deeply grateful for all of the time and effort each of them sacrificed to make this possible. To Dr. Deanna Meinke, thank you for the constant support you provided to me throughout this project. Your direction, insight, and encouragement were invaluable. To Dr. Erinn Jimmerson, I sincerely appreciate all the time given and moral support you provided to me as I worked to complete this project. To Dr. Jennifer Weber, I express my gratitude for the valuable instruction and feedback you provided.

I would also like to thank my amazing wife, Susan Anderson, for her unwavering support through the many days and hours I spent away from her as I worked through this project. She is my biggest fan, and I could not have done this without her by my side.

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LIST OF ABBREVIATIONS

AAA	American Academy of Audiology
ALD	Assistive Listening Devices
ANSI	American National Standards Institute
ASA	Acoustical Society of America
ASHA	American Speech-Language-Hearing Association
BTE	Behind-the-Ear
CCC-A	Certificate of Clinical Competence in Audiology
CDC	Centers for Disease Control and Prevention
CIC	Completely-in-the-Canal
CMS	Centers for Medicare and Medicaid
DHHS	Department of Health and Human Services
FDA	Food and Drug Administration
GBD	Global Burden of Disease
HATS	Hearing Assistance Technology Systems
HIA	Hearing Industries Association
HIS	Hearing Instrument Specialist
ITC	In-the-Canal
ITE	In-the-Ear
LTASS	Long-Term Average Speech Spectrum
mBTE	Mini Behind-the-Ear

NASEM	National Academies of Science, Engineering, and Medicine
NBC-HIS	National Board for Certification in Hearing Instrument Sciences
NHANES	National Health and Nutrition Examination Survey
NIDCD	National Institute on Deafness and Other Communication Disorders
NIH	National Institutes of Health
OTC	Over-the-counter
PSAP	Personal Sound Amplification Product
QOL	Quality of Life
RIC	Receiver-in-the-Canal
RITA	Receiver-in-the-Aid
WHO	World Health Organization

CHAPTER 1

Introduction and Review of Literature

In March 2017, the Over-the-Counter Hearing Aid Act (S. 670) was passed by both the U.S. Senate and House of Representatives during the first session of the 115th congress. This legislation established a new category of hearing devices called over-the-counter (OTC) hearing aids (Warren, 2017). The bill defines an OTC hearing device as one that:

> (A) uses the same fundamental scientific technology as air conduction hearing aids (as defined in section 874.3300 of title 21, Code of Federal Regulations) (or any successor regulation) or wireless air conduction hearing aids (as defined in section 874.3305 of title 21, Code of Federal Regulations) (or any successor regulation);
>
> (B) is intended to be used by adults over the age of 18 to compensate for perceived mild to moderate hearing impairment;
>
> (C) through tools, tests, or software, allows the user to control the over-the-counter hearing aid and customize it to the user's hearing needs;
>
> (D) may use wireless technology; or include tests for self-assessment of hearing loss; and
>
> (E) is available over-the-counter, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online. (Sec. 2)

The bill ordered the U.S. Food and Drug Administration (FDA) to create and publish regulations and rules surrounding OTC hearing devices within three years of the law being enacted. The FDA failed to meet the deadline amidst the global Covid-19 pandemic of 2020. On July 9, 2021,

President Joe Biden issued an executive order directing the FDA to issue the proposed rules and regulations within 120 days (United States Government, 2021). The proposed rules were released on October 21, 2021, and the final ruling was released on August 17, 2022 (United States Food and Drug Administration, 2022)

Since being developed, OTC hearing aids joined a variety of other types of hearing devices available to consumers. These include prescriptive hearing aids, personal sound amplification products (PSAP), assistive listening devices (ALD), and hearables. The Center for Devices and Radiological Health under the FDA (2018) define hearing aids as Class I or Class II medical devices that are designed to aid people with or compensate for impaired hearing. They define PSAP's as wearable electronic devices that can provide modest amplification of environmental sounds. PSAP's are not regulated by the FDA and cannot be marketed as being able to help people with hearing loss. Hearables are similar to PSAP's and are considered any device at ear-level that is intended to enrich or complement a listening experience. ALD's are a large class of hearing devices that help individuals with hearing loss manage environments that are not adequately handled with other hearing devices (American Academy of Audiology [AAA], 2018).

OTC hearing aids are distinctly different from prescriptive hearing aids in that they give consumers the ability to customize and control the settings. OTC devices are available for purchase without a prescription from a licensed professional. Unlike PSAP's, which are not recommended for any level of hearing loss, OTC hearing aids are specifically directed toward adults with a mild to moderate sensorineural hearing loss. As such, this literature review will focus on adults with hearing loss rather than children. OTC hearing aids are regulated by the

FDA which requires manufacturers to strictly follow labeling requirements for the proper use of the devices.

There are many driving factors that led to the development of the OTC hearing aid legislation. The National Academies of Science, Engineering, and Medicine (NASEM) organized a committee tasked with evaluating and providing a report on the condition of hearing care in the United States. In their report, Blazer et al. (2016) indicated that the high cost of hearing aids, a lack of insurance coverage, limited understanding of available options, and stigma are common impediments to accessing hearing health care. They proposed that more affordable hearing technology, such as OTC hearing aids, could properly aid consumers with a mild to moderate hearing loss, potentially expanding access to hearing health care for millions of Americans who suffer with hearing loss.

Epidemiology of Hearing Loss

Hearing loss is a global health issue that negatively affects millions of people worldwide (Haile et al., 2021). Hearing sensitivity is measured using formal audiometric testing that should be completed in a controlled environment that meets criteria set forth by the American National Standards Institute/Acoustical Society of America (ANSI/ASA). This private, non-profit organization maintains consensus standards for systems, services, processes, and products in the United States (Acoustical Society of America [ASA], 2010, 2018, 2019). The American Speech-Language-Hearing Association (ASHA) (2015) explains that audiometric testing measures hearing sensitivity through the presentation of pure tones to identify an individual's threshold of hearing at different frequencies. An audiogram plots the hearing thresholds on a scale of decibel (dB) hearing level (HL) and frequency.

Hearing loss is generally described using three aspects: degree, type, and configuration. The degree of hearing loss indicates the severity of loss, and ranges from normal to profound. Table 1 provides a detailed view of the degrees of hearing loss and their associated range of dB HL. The type of hearing loss is used for categorization of hearing loss. There are three basic types of hearing loss: sensorineural, conductive, and mixed. Configuration refers to the pattern of hearing loss across the frequencies as shown on an audiogram. The most common configurations of hearing loss are normal, flat, sloping, rising, trough, peaked, and other (Margolis & Saly, 2007). Other descriptors of hearing loss include bilateral versus unilateral, symmetrical versus asymmetrical, progressive versus sudden onset, and fluctuating versus stable over time.

Table 1

Degrees of Hearing Loss

Degree of hearing loss	**Hearing loss range (dB HL)**
Normal	-10 to 15
Slight	15 to 25
Mild	26 to 40
Moderate	41 to 55
Moderately severe	56 to 70
Severe	71 to 90
Profound	91+

Note. Reprinted with permission from Clark, J. G. (1981). Uses and abuses of hearing loss classification. ASHA (Rockville, Md.), 23(7), 493-500.

The World Health Organization (WHO) (1991) categorizes hearing loss into four grades of hearing impairment. Table 2 provides a detailed explanation of each grade of impairment with its corresponding decibel range, the expected performance of someone with that grade of impairment, and recommendations. According to WHO's classification, only adults 15 years and

older with hearing loss above 40 dB HL, and children with hearing loss greater than 30 dB HL are regarded as having a “disabling hearing impairment”. Olusanya et al. (2019) indicated that WHO’s system of classification is lacking in three major ways. First, people with any level of unilateral hearing loss and those with a mild bilateral hearing loss are not considered to have a disabling hearing impairment. Second, the 25 dB HL threshold for normal hearing does not agree with literature indicating that 20 dB HL should be the threshold for normal hearing. Third, the uneven steps between grades of impairment have no rational or scientific basis.

Stevens et al. (2013), on behalf of the Global Burden of Disease (GBD) Hearing Loss Expert group, proposed a revised classification of hearing impairment after reviewing the WHO classification and other data inputs. Their proposed classification in Table 3 addresses all three of the concerns outlined by Olusanya et al. (2019). The limit for normal hearing was changed from 25 to 20 dB HL, unilateral hearing loss was given its own category, and the categories for each degree of hearing loss were separated consistently by steps of 15 dB HL.

Table 2

WHO's Grades of Hearing Impairment

Grade of Impairment	Corresponding audiometric ISO value[a,b]	Performance	Recommendations	Comments added to the previous classification
0: no impairment	25 dB or better	No or very slight hearing problems. Able to hear whispers	None	20 dB also recommended. People with 15-20 dB levels may experience hearing problems. People with unilateral hearing losses may experience hearing problems even if better ear is normal
1: slight impairment	26 – 40 dB	Able to hear and repeat words spoken in normal voice at 1m	Counseling. Hearing aids may be needed	Some difficulty in hearing but can usually hear normal level of conversation
2: moderate impairment	41 – 60 dB	Able to hear and repeat words using raised voice at 1m	Hearing aids usually recommended	None
3: severe impairment	61 – 80 dB	Able to hear some words when shouted into better ear	Hearing aids needed. If no hearing aids available, lip-reading should be taught	Discrepancies between pure-tone thresholds and speech discrimination score should be noted
4: profound impairment including deafness	81 dB or greater	Unable to hear and understand even a shouted voice	Hearing aids may help in understanding words. Additional rehabilitation is needed. Lip-reading and sometimes signing essential	Spoken speech distorted, the degree depending on the age at which hearing was lost

Note: Disabling hearing loss refers to hearing loss greater than 40 dB in the better hearing ear in adults and greater than 30 dB in the better hearing ear in children. Reprinted with permission from Olusanya et al. (2019). Hearing loss grades and the international classification of functioning, disability, and health. World Health Organization. Bulletin of the World Health Organization, 97(10), 725-728. http://dx.doi.org/10.2471/BLT.19.230367

[a] In the better ear. [b] Average of 500, 1000, 2000, and 4000 Hz.

Table 3

Global Burden of Disease Updated Grades of Hearing Impairment

Category	Pure-tone audiometry [a,b]	Hearing experience in a quiet environment	Hearing experience in a noisy environment
Normal hearing	-10 to 4.9 dB hearing level 5.0 to 19.9 dB hearing level	Excellent hearing Good hearing	Good hearing Rarely have difficulty in following/taking part in conversation
Mild hearing loss	20.0 to 34.9 dB hearing level	Does not have problems hearing what is said	May have real difficulty following/taking part in a conversation
Moderate hearing loss	35.0 to 49.9 dB hearing level	May have difficulty hearing a normal voice	Has difficulty hearing and taking part in conversation
Moderately severe hearing loss	50.0 to 64.9 dB hearing level	Can hear loud speech	Has great difficulty hearing and taking part in conversation
Severe hearing loss	65.0 to 79.9 dB hearing level	Can hear loud speech directly in one's ear	Has very great difficulty hearing and taking part in conversation
Profound hearing loss	80.0 to 94.9 dB hearing level	Has great difficulty hearing	Cannot hear any speech
Complete or total hearing loss	95.0 dB hearing level or greater	Proundly deaf, hears no speech or loud sounds	Cannot hear any speech or sound
Unilateral	< 20.0 dB hearing level in the better ear, 35.0 dB hearing level or greater in the worse ear	Does not have problems unless sound is near poorer hearing ear	May have real difficulty following/taking part in a conversation

Note: Reprinted with permission from Olusanya et al. (2019). Hearing loss grades and the international classification of functioning, disability, and health. World Health Organization. Bulletin of the World Health Organization, 97(10), 725-728. http://dx.doi.org/10.2471/BLT.19.230367

[a] In the better ear. [b] Average of 500, 1000, 2000, and 4000 Hz.

These classification systems for hearing loss used by WHO and GBD studies provide the foundation for understanding how hearing loss is measured, categorized, and reported in the context of epidemiological studies that strive to report the number of people with hearing loss in a given population. The most recent estimates of the global prevalence of hearing impairment released by WHO (2018) indicate that nearly 466 million (6.1%) of the world's population are

affected by disabling hearing loss. The GBD, Injuries, and Risk Factors study of 2017 approximated the global prevalence of hearing impairment at 1.4 billion or 18.7% of the world's population from 1990 to 2017 (James et al., 2018). The discrepancy between the prevalence of hearing loss reported in each of these cases can be attributed to the system of classification used by each organization as explained above. The prevalence reported by the GBD study is much larger because it incorporates a broader inclusion criterion due to the inclusion of mild and unilateral hearing losses.

The prevalence of hearing loss in U.S. adults has also been reported by epidemiological studies and surveys. In the early 1960's, the Centers for Disease Control and Prevention (CDC) began the National Health and Nutrition Examination Survey (NHANES). This program was designed to assess the nutritional status and health of United States citizens. Within the last decade, three studies have examined data on hearing loss obtained through different NHANES survey periods in order to provide estimates of the prevalence of hearing loss for adults in the United States. Lin et al. (2011) evaluated NHANES data from 2001 through 2008. From their analysis they estimated that 30 million (12.7%) of Americans 12 years or older had a bilateral hearing loss, and that 48.1 million (20.3%) had at least a unilateral hearing loss. Goman and Lin (2016) examined NHANES data from 2001 through 2010. They estimated the prevalence of bilateral hearing loss in Americans aged 12 years and older to be 38.2 million (14.3%), and 60.7 million (22.7%) with at least a unilateral hearing loss. Most recently, Hoffman et al. (2017) compared the 2011-2012 and the 1999-2004 NHANES prevalence rates of adults ages 20 to 69 with bilateral hearing impairment. They found there was a statistically significant decline in the prevalence rate, with 28 million (15.9%) in the 1994-2004 cycles compared with 27.7 million

(14.1%) in the 2011-2012 cycle. The prevalence estimates from these studies indicate that hearing loss is a major health issue in the United States.

OTC hearing aids will specifically be designed for adults 18 years and older with a mild to moderate sensorineural hearing loss. The study by Goman and Lin (2016) also reported the prevalence of hearing loss in the United States categorized by degree of hearing loss. Their analysis estimates that of the 60.7 million Americans with at least a unilateral hearing loss, 53.5 million (88%) have a hearing loss within the mild or moderate range. It should be noted that this number includes people with either a sensorineural or conductive hearing loss. As such, the actual number of people with a mild to moderate sensorineural hearing loss that could be aided by OTC hearing aids would only be a portion of this group.

The Impact of Hearing Loss

Hearing loss is a health issue that impacts individuals, families, and society as a whole. Individuals with hearing loss face challenges on a daily basis that impact their quality of life (QOL). Difficulty with communicating and communication breakdowns are major challenges that come as a result of hearing loss (Erber & Scherer, 1999; Giolas & Wark, 1967; Heine & Browning, 2004). Dalton et al. (2003) found that 52% (n=2,688- of participants in their study reported having difficulties with communication (i.e., talking on the phone, speaking with family members, and interacting at social events.) Participants with mild hearing loss were three times more likely to report communication difficulties than those without hearing loss. They further reported that participants with a moderate to severe hearing loss were nearly eight times more likely to report communication difficulties than those without a hearing loss. It has also been shown that more cognitive effort is required from individuals with hearing loss as they communicate (Lin et al., 2011; Zekveld et al., 2011).

Increased difficulty with communication leads to other impacts on QOL such as loneliness and decreased self-esteem (Chen, 1994; Sung et al., 2016), depression, anxiety, and stress (Jayakody et al., 2018; Lawrence et al., 2020; Mener et al., 2013), social isolation (Mick et al., 2014; Shukla et al., 2020), and increased fall risk (Agmon et al., 2017). Emmett and Francis (2015) found that compared to normal hearing individuals, people with hearing loss are 3.21 times more likely to reach a lower educational level, 1.58 times more likely to have a low income, and 1.98 times more likely to be either underemployed or unemployed.

Studies by Lin and Ferrucci (2012) and Lin et al. (2013) provide population-based evidence for an association between hearing loss and faster physical and cognitive aging. Albers et al. (2015) reported that hearing loss is associated with dementia and falls. Lin et al. (2011) also found hearing loss to be independently associated with lower test scores of executive function and memory.

Hearing loss also has a major impact on the lives of those closest to individuals with hearing loss. These include family members, spouses, friends, partners, and coworkers. A systematic review completed by Kamil and Lin (2015) evaluated 24 articles relating to the experiences of communication partners of individuals with hearing loss. They found that communication partners experienced lower relationship satisfaction, restricted social lives, an increased burden of communication, and overall poorer quality of life.

The societal cost of hearing loss is evident when one considers the economic impact it has in the United States. Huddle et al. (2017) indicate that there are direct and indirect economic costs of hearing loss. Direct costs include the medical expense of treating hearing loss, which includes the cost of purchasing hearing aids. Indirect costs come in the form of lost work productivity and income. Mohr et al. (2000) estimated the lifetime medical cost for individuals

with hearing loss by age group. Adults with onset of hearing loss between the ages of 18-44 years had lifetime excess medical expenditures of $79,343, compared to $56,752 for adults 45-64 years old, and $33,794 for adults 65 years or older. Foley et al. (2014) estimated the annual excess medical cost of hearing loss for adults 65 years and older to be $420 per person. This equates to a nationwide cost of $3.3 billion annually. Jung and Bhattacharyya (2012) estimated the one-year net loss in annual wages to be $8,878 for adults with hearing loss. They asserted that adults with hearing loss earn significantly less income and are more likely to be unemployed compared to adults without hearing loss. Estimates of lost productivity range from $1.8 billion to $194 billion in the United States (Kochkin, 2010; Stucky et al., 2010). While hearing loss exerts a significant economic impact on society as a whole, it is an issue that cannot be ignored or disregarded as unimportant. Individuals with hearing loss require specialized treatment that comes in many forms.

Treatment for Hearing Loss

There are a variety of treatments for hearing loss. The appropriate treatment depends on the underlying disease or trauma and the type, degree, and configuration of the hearing loss being treated. Types of hearing loss are categorized as conductive, sensorineural, and mixed. The type of hearing loss depends on the part of the ear that is damaged or affected. Conductive hearing loss relates to the outer and middle ear whereas, sensorineural hearing loss occurs when there is damage or a problem with the inner ear and/or auditory neural pathways. Mixed hearing loss has both conductive and sensorineural components that contribute to the overall etiology.

Conductive hearing losses are caused by an obstruction or impairment of the middle or outer ear. Examples include cerumen impaction, otitis externa, otitis media, perforations of the tympanic membrane, otosclerosis, and cholesteatomas. The majority of pathologies causing a

conductive hearing loss, or the conductive component of a mixed hearing loss can be treated with medical, pharmacological, or surgical means by a qualified medical professional. Surgical treatments for conductive pathologies are normally performed by an otolaryngologist, otologist, or neurotologist. Surgical treatments for conductive hearing loss may include tympanoplasty (repair/replacement of a tympanic membrane), middle ear reconstructions, myringotomy with tubes or implant bone-anchored hearing devices. A bone-anchored implant is a surgically implanted hearing device often used in the treatment of conductive, mixed, and unilateral sensorineural hearing losses. This type of device transmits a signal to the cochlea by mechanical vibrations therefore bypassing the conductive components of the ear that are impaired (Kramer & Brown, 2019). Treatment of a conductive hearing loss often, but not always, leads to the near-normal restoration of an individual's hearing sensitivity.

Sensorineural hearing losses are caused by disorders of the cochlea or neural structures involved in auditory sensory perception. Some otologic diseases and disorders require immediate medical attention (e.g. sudden sensorineural hearing loss) or they may be life-threatening if left untreated (e.g. mass lesions). These types of serious otologic diseases are somewhat rare and surgical treatment is not a common intervention. Persons with sensorineural hearing loss are fit with hearing aids when no (further) medical treatment is indicated. Severe to profound sensorineural hearing losses that cannot be helped by hearing aids can be treated surgically through the use of an implanted device called a "cochlear implant". A cochlear implant bypasses the outer and middle ear and provides direct electrical stimulation to the neurons of the 8th cranial nerve (Kramer & Brown, 2019). Auditory brainstem implants are another surgically implanted device used to treat profound sensorineural hearing losses. They completely bypass the peripheral auditory system as they are implanted in the brainstem and provide direct

electrical stimulation to the cochlear nucleus (Deep et al., 2019). Yet another surgically implantable device available for the treatment of sensorineural hearing loss is the middle ear implant. These devices provide amplification of sound as they are coupled to the bones of the middle ear and generate mechanical energy that is transferred to the cochlea. They are designed for sensorineural hearing losses in the moderate to severe range (Haynes et al., 2009). Surgical implantation of any of these devices requires the expertise of an otolaryngologist, otologist, or neurotologist.

Rehabilitative interventions are also used to treat all types of hearing loss. Aural rehabilitation is an "intervention aimed at minimizing and alleviating the communication difficulties associated with hearing loss" (Tye-Murray, 2008, p. 3). Services provided through aural rehabilitation treatment include auditory training, communication strategies training, personal adjustment counseling, speech-language therapy, frequent communication partner training, speechreading training, use of hearing assistance technology systems (HATS), ALD's, and listening devices such as hearing aids (Tye-Murray, 2008).

Hearing Aids

The FDA defines a hearing aid as "any wearable instrument or device designed for, offered for the purpose of, or represented as aiding persons with or compensating for, impaired hearing" (United States Food and Drug Administration, 2008). Hearing aids deliver amplified sound to a listener's ear by detecting physical sound with a "microphone". The physical sound is then converted to an electrical signal which is sent to an "amplifier" which increases the electrical power. The amplified electrical signal is then converted to a physical sound wave and presented to the ear canal by a "receiver" (National Institute on Deafness and other Communication Disorders, 2018). There are a wide variety of different types and styles of

hearing aids. Ricketts et al. (2019) provide a thorough overview of hearing aids in their book, *Essentials of Modern Hearing Aids*. Before the mid 1990's, analog hearing aids were the main type of hearing aid offered and worn by most individuals with hearing loss. Digital hearing aids now dominate the global hearing aid market as they provide multiple advantages over analog aids. These advantages include but are not limited to the use of digital signal processing, ease of programming, greater control over programming the parameters of sound, and power efficiency.

Hearing Aid Styles

An assortment of different styles of modern hearing aids include the following: traditional behind-the-ear (BTE), mini behind-the-ear (mBTE), and traditional custom hearing aids. Each style encloses the electrical components of the aid in a plastic case. As the name implies, traditional and mini BTE's are worn behind the ear. Traditional BTE's route the sound to the ear through an earhook, plastic tubing, and a custom-made earmold. Mini BTE's can be subdivided into two categories, receiver-in-the-aid (RITA), or receiver-in-the-canal (RIC). This distinction simply refers to the location of the speaker or receiver. RITA's route the sound to the ear through a slim tube whereas RIC's use a thin wire that is attached to the receiver positioned in the ear canal. Both RITA's and RIC's can be coupled to the ear using either a custom earmold or stock eartip. Traditional custom hearing aids are made from an impression of an individual's ears and are therefore designed to fit only their ears. They can range in size from a full shell, in the ear (ITE) style that completely fills the concha, half-shell ITE's that only fill a portion of the concha, in the canal (ITC) style that fits in the canal and only shows the faceplate of the aid, or a completely in the canal (CIC) style that cannot be seen without looking directly into the opening of the ear canal.

Hearing Aid Candidacy

While hearing aids can be used to help with all different types of hearing loss, they are most commonly recommended for individuals with sensorineural hearing loss who are not candidates for surgical or medical treatment. Individuals with hearing losses ranging in degree from mild to profound can receive benefit from hearing aids and are therefore considered candidates. Hearing losses between the range of 55-80 dB are thought to obtain the most benefit from hearing aids. This means that individuals with mild, moderate, or profound hearing losses can receive benefit from hearing aids, but the perceived benefit will vary and largely be dependent on individual circumstances and needs (Dereby & Luxford, 2010).

Hearing Aid Regulation, Dispensing, and Fitting

Hearing aids are regulated and controlled by the FDA. The FDA categorizes hearing aids as Class II medical devices that are exempt from premarket approval and notification. Hearing aids must meet specific labeling requirements outlined by the FDA in the Code of Federal Regulations, Title 21, Volume 8 (United States Food and Drug Administration, 2008). They state,

> (b) Label requirements for hearing aids. Hearing aids shall be clearly and permanently marked with:
>
> (1) The name of the manufacturer or distributor, the model name or number, the serial number, and the year of manufacture.
>
> (2) A " + " symbol to indicate the positive connection for battery insertion, unless it is physically impossible to insert the battery in the reversed position.
>
> (c) Labeling requirements for hearing aids - (1) General. All labeling information required by this paragraph shall be included in a User Instructional Brochure that shall be

developed by the manufacturer or distributor, shall accompany the hearing aid, and shall be provided to the prospective user by the dispenser of the hearing aid in accordance with § 801.421(c). The User Instructional Brochure accompanying each hearing aid shall contain the following information and instructions for use, to the extent applicable to the particular requirements and characteristics of the hearing aid:

(i) An illustration(s) of the hearing aid, indicating operating controls, user adjustments, and battery compartment.

(ii) Information on the function of all controls intended for user adjustment.

(iii) A description of any accessory that may accompany the hearing aid, e.g., accessories for use with a television or telephone.

(iv) Specific instructions for:

(a) Use of the hearing aid.

(b) Maintenance and care of the hearing aid, including the procedure to follow in washing the earmold, when replacing tubing on those hearing aids that use tubing, and in storing the hearing aid when it will not be used for an extended period of time.

(c) Replacing or recharging the batteries, including a generic designation of replacement batteries.

(v) Information on how and where to obtain repair service, including at least one specific address where the user can go, or send the hearing aid to, to obtain such repair service.

(vi) A description of commonly occurring avoidable conditions that could adversely affect or damage the hearing aid, such as dropping, immersing, or exposing the hearing aid to excessive heat.

(vii) Identification of any known side effects associated with the use of a hearing aid that may warrant consultation with a physician, e.g., skin irritation and accelerated accumulation of cerumen (ear wax).

(viii) A statement that a hearing aid will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions.

(ix) A statement that in most cases infrequent use of a hearing aid does not permit a user to attain full benefit from it.

(x) A statement that the use of a hearing aid is only part of hearing habilitation and may need to be supplemented by auditory training and instruction in lipreading.

The labeling must also contain a warning to hearing aid dispensers that prospective hearing aid users should be advised to consult with a licensed medical professional if they encounter any condition that should be treated by a medical professional. Hearing aid dispensers should also ensure that hearing aids are not fit to exceed sound pressure levels of 132 decibels. The labeling must also contain a notice for prospective hearing aid users that states it is a requirement for individuals with hearing loss to obtain a medical evaluation by a licensed physician before purchasing a hearing aid, but that an informed adult may sign a waiver declining the medical evaluation. As of 2016 the FDA announced that this requirement would no longer be enforced (Ricketts et al., 2019).

Hearing aid dispensing is also regulated on the state level in the U.S., typically through professional licensure laws (hearing aid specialists and audiologists) and/or consumer protection acts (e.g. https://www.asha.org/advocacy/state/). Each state establishes their own requirements for the dispensing (sale) of hearing aids for both adults and children. These regulations are in addition to the FDA requirements.

Dispensing Hearing Aids

Hearing aids can be dispensed and fit by a select group of professionals and other licensed individuals. Dispensing refers to the sale or distribution of hearing aids. Fitting refers to the process and procedures followed in order to obtain an optimal selection and fit (acoustically and physically) of hearing aids. Ear specialists such as otolaryngologists, otologists, and otorhinolaryngologists are licensed physicians who specialize in diseases of the ear. They are medically trained and qualified to diagnose and treat hearing loss in context of a person's total health. Audiologists are licensed professionals, qualified by training and experience, who help prevent, diagnose, and treat hearing and balance disorders. Most states require audiologists to obtain either their Certificate of Clinical Competence in Audiology (CCC-A) through the American Speech-Language-Hearing Association, or be board certified through the American Board of Audiology in order to obtain state licensure. Audiology technicians or assistants are individuals who are trained to assist audiologists and perform delegated tasks under their supervision but are not licensed to fit hearing aids. Each state has different laws and regulations for audiology technicians, with some requiring licensure. Hearing instrument specialists are individuals who have completed a training program through the National Board for Certification in Hearing Instrument Sciences (NBC-HIS) and subsequently may become eligible for a state

license to dispense hearing aids. The licensure requirements for hearing instrument specialists also vary by state.

Hearing aids have most traditionally been dispensed at the clinical practices of medical ear specialists, and audiologists, or dispensing storefronts of hearing instrument specialists (HIS). Within the last two decades, big box retailers such as Costco and Sam's Club have also begun to dispense hearing aids and employ both audiologists and HISs. A simple google search also reveals the availability for consumers to obtain hearing aids through a streamlined mail-order delivery process without the need to consult any kind of hearing specialist. Mail-order or internet-sale hearing aids may also be regulated in some states as well. As of 2012, nine states had restrictions on mail-order and internet-sale of hearing aids (AAA, 2011).

Fitting Procedures and Best Practices

In 2003, the American Academy of Audiology (AAA) assembled a task force and charged them with the responsibility of developing an updated guideline for the audiologic management of adult patients. The guideline was published by Valente (2006) and provides evidence-based practice standards for audiologists managing the hearing care of adult patients. The standards and best practices for hearing aid selection, fitting, and verification are explained in detail in the guideline and will be outlined here.

Many factors need to be considered in the selection of appropriate hearing aids. The decision for each factor should be based on the individual needs of the patient. Factors that need to be considered include: the style of the hearing aid, occlusion, feedback, dexterity of the patient, monaural vs. binaural, telecoil circuitry, gain processing, frequency shaping, maximum output levels, multiple programs, digital noise reduction, digital feedback

suppression/cancelation, directional and omnidirectional microphones, and other advanced technologies.

The best practices for fitting and verification of hearing aids are designed to obtain an optimal fit that is comfortable for the patient and includes all the features they desire. First, the physical fit of the hearing aids should be verified to ensure the patient can easily insert and remove the hearing aids, is satisfied with the appearance and comfort of the aids, and that audible feedback is not present. Next, absence of occlusion should be verified to ensure the patients' own voice is comfortable and not problematic. The verification of prescribed gain for validated prescriptive methods should be done next (Valente, 2006). This is done using "probe microphone" or "real ear" measures to ensure the prescribed amount of gain for each patient's hearing loss is being provided in the ear canal. This procedure is performed by placing a probe microphone in the ear canal within 5 mm of the eardrum. The hearing aid is then placed in the ear as it will be worn by the patient. Next, a calibrated speech signal is presented through a loudspeaker and the actual gain presented by the hearing aid at the eardrum is recorded. This recording is represented graphically as a Long-Term Average Speech Spectrum (LTASS) and is used to confirm that the prescribed targets of gain are obtained (Ricketts et al., 2019). Next, the maximum output of the hearing aids should be verified to ensure they do not exceed the patient's threshold of discomfort. Lastly, the special features and other technologies such as directional microphones and telecoil circuitry should be verified to ensure they are functioning properly and providing the patient with all the potential benefits.

Consumer Issues Related to Hearing Aid Purchase and Use

Despite the high number of U.S. citizens with hearing impairment who could benefit from hearing aid use, and the many impacts hearing loss has on psychosocial interaction and

everyday communication, hearing aid adoption and use is relatively low. Since 1989 national surveys have been conducted every three to four years by the Hearing Industries Association (HIA). These surveys, coined as “MarkeTrak” reports, provide valuable information on the hearing status and interaction with hearing aids of U.S. citizens with hearing loss. According to the most recent report, MarkeTrak10, among adults with hearing impairment, only 41.6% of those 65 years and older, and 22.9% of those 35 to 64 years old, currently have a hearing aid (Jorgensen & Novak, 2020). The MarkeTrak surveys and other studies have also shown that those who could benefit from hearing aid use often delay hearing aid adoption. Simpson et al., (2019) reported that the average delay in hearing aid adoption following hearing aid candidacy was 8.9 years. Using data collected in MarkeTrak8, Kochkin (2012) reported that those with hearing impairment who had not adopted hearing aids had been aware of their hearing loss for an average of 12.4 years. Delaying hearing aid adoption is detrimental to the individual with hearing loss and those they associate with as they deal with the impacts of hearing loss discussed earlier. While there is no conclusive evidence of such, some speculate that delayed hearing aid adoption could decrease future benefits obtained from hearing aid use due to potential cognitive decline with age. Research by Sarant et al. (2020) suggests that treating hearing loss with hearing aids may delay cognitive decline. This is an area of need for further exploration in future research.

There are many factors that influence hearing aid uptake and help to explain the low rates of adoption discussed previously. Kochkin (2012) also reported the top six reasons found for not pursuing hearing aids in the MarkeTrak8 report. Listed in descending order beginning with the most influential reason, they include the following:

- patients believing their type of hearing loss does not warrant hearing aid use
- affordability

- patients minimizing their need for hearing aids
- a negative attitude toward hearing aids
- a lack of knowledge or understanding
- stigma associated with hearing aid use

While each of these factors could be discussed in greater detail, the affordability of hearing aids is most relevant to the creation of OTC hearing aids. Perhaps the strongest argument for the need to develop the OTC category of hearing aids is a lack of affordability in the current hearing aid market, and the scarcity of insurance coverage available in the United States to help cover or offset the high cost of hearing aids with advanced technology.

Cost of Hearing Aids

Bailey (2021) reported that the average price paid for a pair of hearing aids in 2020 was $4,672. Average price also varies based on the technology level of the hearing aids purchased. A pair of low-end technology hearing aids cost an average of $3,208 while a pair of high-end technology hearing aids cost an average of $5,302. Hearing aids sold in audiology settings are typically sold in a bundled package that includes the cost of the hearing aids, professional services for fitting/programming the hearing aid(s), and any professional services required for the maintenance, repair, cleaning, and upkeep of the hearing aid(s) for a certain duration of time (e.g., three-to-five-year warranty period) or the life of the hearing aid. Some practice locations utilize an unbundled model of dispensing. Under this model the patient purchases only the hearing aids upfront. The patient is then billed separately for each professional service that is rendered. The upfront cost of hearing aids is naturally much lower with an unbundled model of dispensing, but the lifetime expense can end up being similar to the price charged in a bundled model in many cases.

The type of dispensing model (bundled vs. unbundled) used does not negate the reality that purchasing hearing aids represents a substantial expense for the average American. Donahue et al. (2010) indicate that the lifetime cost of purchasing multiple sets of hearing aids is one of the highest expenses for adults, comparable to the purchase of a car or home. A 2016 report from the National Academies of Sciences, Engineering, and Medicine (NASEM, 2016) explained that the high cost of hearing aids creates a barrier to accessing treatment for sensorineural hearing loss. Data collected from the MarkeTrak10 report indicates that for non-hearing aid owners who have had a hearing care provider recommend hearing aids, the top two reasons for not adopting hearing aids were that the devices are too expensive and that they could not afford them (Carr, 2020). When asked about different factors that might expedite hearing aid purchase, respondents of the MarkeTrak8 survey indicated the cost of hearing aids being $500 or less as the fourth most important factor that would motivate them to adopt the use of hearing aids. Having 100 percent insurance coverage, having a money back guarantee, and increased reliability were ranked number one, two and three respectively (Kochkin, 2012).

While the high cost of hearing aids is surely a major deterring factor in the uptake of hearing aids, other data reiterates that it is not the primary barrier. Valente and Amlani (2017) point out that there is only a 9.5% difference between the hearing aid adoption rate of the United States at 33%, and Norway who has the highest adoption rate of any country at 42.5%. The high adoption rate in Norway makes sense as hearing aids are fully subsidized by the government and made available at no cost to all who need them. This data indicates that even if the United States were to completely subsidize the cost of hearing aids, the market penetration would likely only increase by about ten percent.

Insurance Coverage

In the US, coverage by insurance for the full price, or even a portion of the cost of hearing aids is limited. In 1965, an amendment to the Social Security Act was passed and the federal programs of Medicare and Medicaid were created (Cohen, 1957). These programs were originally designed to provide basic coverage of particular medical expenses relating to outpatient physician services and inpatient hospital visits for low-income individuals (i.e., Medicaid) and seniors 65 and older (i.e., Medicare) (Anderson, 2019). At the time of the amendments passing, eyeglasses, hearing aids, and other medical devices were considered low-cost and of routine nature (McNeal, 2016). As such, the amendment statutorily excluded them from coverage under Section 1862(a)(1)(A) (United States Social Security Administration, 2019).

Medicaid is a joint federal-state program that is administered by each state. Half the funding is provided by the federal government and the other half is provided by the states. Each state establishes their minimum standards for eligibility (Centers for Medicare & Medicaid Services [CMS], 2015). Medicaid is designed to provide healthcare for individuals who are low-income, and most states offer full coverage of hearing aid costs for qualifying children up to 18 years of age, but coverage does vary. Medicaid coverage of hearing aids for adults, in general, is much more limited and can vary widely from state to state (CMS, 2019a). For instance, in Colorado, Medicaid does not fund hearing aids for adults age 22 and older, while Alaska does provide assistance to adults needing hearing aids (Hearing Loss Association of America, n.d.).

Medicare is a federal program designed to provide certain healthcare benefits to seniors 65 and older, people with End-Stage Renal Disease, and people with certain disabilities under age 65. There are four parts of Medicare: Parts A, B, C, and D. Parts A and B are considered

original Medicare and are administered by the federal government, whereas parts C and D are administered contractually through private companies. Medicare Part A is also called hospital insurance and covers inpatient care provided in hospitals. Part B is also called medical insurance and covers outpatient care provided in doctors' offices as well as some services and durable medical equipment that are considered medically necessary. Cochlear implants are an example of a medically necessary medical device covered by Part B. No changes have been made to the status of hearing aids as non-medically necessary medical devices that are supplemental and not covered by Part B. Medicare Part D provides outpatient prescription drug coverage (CMS, 2019b)

Medicare Part C is offered through private health insurance companies and is completely optional. Most Part C health plans are purchased for a monthly premium. They usually provide the same coverage offered through Medicare Parts A, B, and sometimes Part D. Part C plans typically offer supplemental benefits or services not covered by original Medicare such as dental, vision, and sometimes hearing aids. When coverage for hearing aids is offered through Part C plans, it varies widely as each private company establishes their own limitations and requirements which may change year-to-year. Most often, stipulations set forth by the private insurance companies dictate that the hearing aid benefit is limited to use with certain nationwide third-party providers (i.e., Hear USA) who are contractually aligned to provide limited hearing health services at a negotiated rate, and only provide certain preapproved hearing aids. Even when a hearing aid benefit is offered through Part C plans, the coverage is often limited to one use every three or five years, and only covers a portion of the cost (i.e., $500 per aid).

Like Medicaid, private health insurance coverage of hearing aids varies from state to state. Nineteen states require all health insurance plans to cover the cost of hearing aids for

children. Five other states require hearing aid coverage for both children and adults (American Speech-Language-Hearing Association, 2016). This information indicates that for the vast majority of U.S. adults, private health insurance provides no benefits to help cover the cost of hearing aids.

The limited nature of insurance coverage for the cost of hearing aids is a secondary factor contributing to the overall out-of-pocket cost required of individuals with hearing loss seeking rehabilitation. Data from both MarkeTrak8 and 9 indicate that hearing aid uptake is influenced by the lack of insurance benefits to cover all or even a portion of the cost (Abrams, 2015). As mentioned previously, Kochkin (2012) showed that having insurance cover 100% of the cost of hearing aids was the number one most important factor that would motivate hearing aid adoption among those surveyed.

OTC hearing aids will certainly provide more affordable and low-cost rehabilitative amplification options for those with mild to moderate sensorineural hearing loss and by so doing help to address these barriers to hearing aid adoption. While this will indubitably galvanize a larger portion of individuals with hearing loss to pursue the potential benefits of amplification, the data shows that simply offering a more affordable OTC option will not lead to all or even a majority of those with hearing loss to begin using hearing aids.

OTC Initiatives

FDA rules and regulations

The FDA released its proposed rules and regulations of OTC hearing aids on October 20, 2021 (United States Food and Drug Administration [U.S. FDA], 2021). A 90-day comment period was then given to allow any interested party the opportunity to provide comments on the proposed rules. The comment period ended on January 18, 2022, with more than 1,000

comments being submitted to the FDA. After seven months of deliberation, the FDA released its final rules and regulations in the federal register on August 17, 2022 (U.S. FDA, 2022). The FDA provided the following summary of the 65-page document.

> The Food and Drug Administration (FDA, we, or the Agency) is establishing a regulatory category for over-the-counter (OTC) hearing aids and making related amendments to update the regulatory framework for hearing aids. Specifically, we define OTC hearing aids and establish applicable requirements; amend existing rules for consistency with the new OTC category; repeal the conditions for sale applicable to hearing aids; amend the existing labeling requirements for hearing aids; and update regulations relating to decisions on applications for exemption from Federal preemption that will become obsolete as a result of changes to the hearing aid requirements. In creating a regulatory category for OTC hearing aids and amending existing rules, we intend to provide reasonable assurance of safety and effectiveness for these devices as well as foster access to, and innovation in, hearing aid technology, thereby protecting and promoting the public health (U.S. FDA, 2022).

Among other things the most notable aspects of the ruling set forth the device classification, marketing rules, labeling requirements, establish device requirements such as output limits and other electro-acoustical parameters, and establish the conditions for the sale of OTC devices. The ruling went into effect on October 17, 2022. The depth and breadth of the final ruling is extensive. As such, the reader is referred to the actual document of the final ruling for a detailed exploration https://www.federalregister.gov/documents/2022/08/17/2022-17230/medical-devices-ear-nose-and-throat-devices-establishing-over-the-counter-hearing-aids (U.S. FDA, 2022).

OTC Technology and Cost

As explained previously, the Over-the-Counter Hearing Aid Act defines an OTC hearing device as one that "uses the same fundamental scientific technology as air conduction hearing aids… or wireless air conduction hearing aids…, allows the user to control the over-the-counter hearing aid and customize it to the user's hearing needs…[and] may use wireless technology; or include tests for self-assessment of hearing loss" (Warren, 2017). According to this definition OTC hearing aids function similarly to current prescription hearing aids. The exact level of digital sound processing and other features available from different OTC products varies widely. Both rechargeable and battery powered options exist, and the outward physical appearance is similar to current styles of prescription hearing aids (i.e., BTE's, mBTE's, ITE's, etc.). Since OTC hearing aids became legal for sale in October 2022, a plethora of manufacturers have created and begun to sell them directly to consumers. It seems the introductory price range for the vast majority of OTC devices is $100 to $1,800 based upon an informal review.

OTC Dispensing Models and Personnel

Section two of the Over-the-Counter Hearing Aid Act of 2017 specifically indicates that OTC hearing aid will be "available over-the-counter, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online" (Warren, 2017). As the name implies and as the bill indicates, OTC hearing aids are available for purchase at local storefronts and pharmacies without the involvement of hearing healthcare professionals. Ordering OTC hearing aids online and receiving them through the mail is another dispensing avenue amongst the most common methods for obtaining devices in this category. While OTC hearing aids are mostly available via purchase avenues that are direct-to-consumer, they can also be purchased in the same settings

and locations where prescription hearing aids are currently dispensed by licensed professionals in private audiology practices, ENT practices, and from hearing aid dispensers.

Over the counter hearing aids are also available at the clinical practices of audiologists, as well as the dispensing storefronts of hearing instrument specialists. At the time of this writing, dispensing OTC hearing aids at these locations is less common and could take time before many practices choose to incorporate these devices as viable treatment options for mild to moderate hearing loss. For many audiologists, the choice to incorporate OTC hearing aids into their practice requires a great deal of consideration. Many questions have to be answered, and in many cases, significant adjustments need to be made to the dispensing model, clinic personnel, clinic protocols, and other features of business operation. These issues will be addressed in chapter two of this work.

Public and Professional Viewpoints Towards OTC Hearing Aids

The AAA has published a position statement entitled, The Role of Audiologists with Over-the-Counter Hearing Aids (AAA, 2021b). This position statement outlines the viewpoint of the AAA as the only professional organization run by and for audiologists in America. In summary, the statement acknowledges that individuals have the right to control their healthcare decisions including the hearing care they receive. Ensuring the safe and effective use of OTC hearing aids falls under the primary role of audiologists as health professionals who "optimize hearing health" (AAA, 2021b, p. 2). This includes the support of individuals who choose to use OTC hearing aids through counseling and education that helps consumers understand the risks and benefits of OTC hearing aid technology. In all situations, audiologists should make sure that the safety and care of patients is the highest priority by objectively measuring the functional outcomes and benefit of any hearing aids. AAA concludes by stating, "consumers are best served

when they receive a comprehensive audiologic assessment prior to the use of any hearing aid. Additionally, hearing loss and auditory system deficits are best mitigated through the development of a safe and effective treatment plan that may or may not include OTC hearing aids or other devices" (AAA, 2021b, p. 2). This position statement indicates that AAA acknowledges OTC hearing aids as a viable treatment option for those to whom audiologists could provide safe and effective support.

There is no shortage of skepticism and opposition to the development of OTC hearing aids. "Critics argue that individuals cannot self-diagnose their hearing loss and contend that it will compromise consumer safety to allow access to hearing aids over the counter" (Warren & Grassley, 2017). They question "How will someone know their degree of hearing loss without a hearing exam, or how will someone know if they need surgery or a hearing aid?" This concern arises from the possibility that some individuals suffering from medically treatable hearing loss could go undetected leading to serious health complications in some instances (Kleindienst et al., 2016). Many professionals and professional organizations emphasize the value of and need for audiologic assessment prior to the use of any kind of hearing aids as described in the AAA position statement.

Positive public perception towards OTC hearing aids seems to be motivated mainly by the prospect of expanded options for affordable hearing healthcare. Many view OTC hearing aids as the solution to the low hearing aid adoption rate. As stated earlier, cost is only one factor that contributes to an individual's decision to pursue hearing aids. Data from MarkeTrak10 provides intriguing insight into the views of potential OTC users. Carr (2020) describes the perceptions of respondents with hearing difficulty that were asked to rate their comfort level of performing certain tasks that would be required of OTC hearing aid users on a scale from 1 (not at all

comfortable) to 4 (very comfortable). The tasks included the following: “Assessing your level of hearing loss, selecting an appropriate hearing aid for your needs, getting started using the hearing aid, using the features to adjust settings, cleaning/maintaining the hearing aid, and troubleshooting if a question or issue arose.” Fifty-three percent of the respondents indicated that they were “not at all comfortable” or “not very comfortable” assessing their own hearing loss, with only 15% stating that they were “very comfortable.” With regard to selecting the appropriate hearing aid, 52% said they were “not at all comfortable” or “not very comfortable”. Again, only 15% indicated that they felt “very comfortable” doing this. Fifty-four percent stated that they were “not at all comfortable” or “not very comfortable” troubleshooting if a question or issue arose, with only 14% saying that they were “very comfortable”. This data indicates that while many have looked forward to the availability of OTC hearing aids, the realities of owning and operating these devices without the help of a hearing healthcare professional are underestimated. A significant portion of individuals who may choose to pursue OTC hearing aids will be uncomfortable trying to navigate the use and maintenance of such devices. As such, it can be expected that support from hearing health professionals will not only be desired but needed. Unfortunately, there is currently no planned support for these devices beyond that provided by manufacturers, who may not be able to provide “hearing care” in the states that require professional licensure.

The development of OTC hearing aids will inevitably lead to their widespread availability. Moving forward audiologists will need to consider whether to integrate OTC hearing aid technology into their practices. Questions of how this can and should be done in the context of other professional services and hearing aid types will be addressed in the following chapter.

CHAPTER 2

Application to the Field of Audiology

As OTC hearing aids emerge and become available for purchase, many changes will occur that will undoubtedly affect all audiology practice settings in some way. The focus of this chapter is on private audiology practices and how the advent of OTC hearing aids will impact them specifically. Owners of private audiology practices will have to choose how they will react. The individual circumstances, local market, geographic area, and personal preferences of private practice owners will all factor into the decision to embrace or not embrace OTC hearing aids. The goal of this chapter is to present three different models of integration that private practice owners will need to assess and choose from moving forward. To aid in the decision-making, the overall advantages and disadvantages of integrating OTC hearing aids into private audiology practice will be discussed.

Bundled or Unbundled Fees

The reality of integrating OTC hearing aids into a private audiology practice could actually be seen as a decision to bundle or unbundle product and service fees. As explained in chapter one, page 21, an unbundled model of care allows for products and services to be sold separately. Each product and service is itemized and patients are charged or billed only for what they receive at each appointment. A bundled model of care combines the cost of products and services into a bundled package for a large up-front cost with the guarantee of care throughout a given time frame. The choice to integrate OTC hearing aids essentially necessitates that at least some form of an unbundled model be used if a lower price point is to be maintained for these

devices. Two of the three models that will be proposed for OTC integration utilize an unbundled approach to some degree. Regardless of the model of care utilized by a practice, professional services and support may be requested by individuals who purchase OTC hearing aids from other vendors. Practice owners will need to decide if care will be provided to these patients or if they will be referred elsewhere. The unbundled model of care allows for ease in accommodating these patients as there will already be an established fee for any services that may be provided.

Models of Integration

There are three models of OTC integration that private practice owners may consider moving forward: full integration, non-integration, and hybrid integration. Each model utilizes unique service strategies and product portfolios that will be discussed in detail.

Full Integration Model

The full integration of OTC hearing aids into private audiology practice is a model of care that completely embraces the changes and new options that OTC hearing aids create for individuals with mild to moderate sensorineural hearing loss. This model adds OTC hearing aids to the line of amplification options available for patients to purchase and creates a broad product portfolio. Practices that implement the full integration model would be able to offer a wide collection of product options ranging from affordable OTC hearing aids all the way to high-end premium hearing aids. An unbundled fee for service model of care would be implemented in the full integration model. This model would allow the practice to easily provide professional services to patients who purchase OTC hearing aids from other vendors and seek care through the practice. These patients would simply be charged the already established itemized professional fee for whatever service they receive. For audiology practices that already utilize an unbundled model of care, the process of fully implementing OTC hearing aids would require

little change. They could simply add one or multiple OTC hearing aid options to their product portfolio and make a few, if any other changes to their operations. For audiology practices currently utilizing a bundled approach, the process of switching to the full integration model could be extensive and disruptive to their current patients.

Non-Integration Model

The non-integration model rejects the inclusion of OTC hearing aids as a viable product option offered for sale through a private audiology practice. This model would most likely utilize or maintain a bundled model of care and service delivery, although it is feasible that practices using an unbundled model of care could also reject the addition of OTC hearing aids. A limited specialty product portfolio of traditional hearing aids would be the only options available for patients to purchase. OTC hearing aids would not be offered for sale and patients looking for these devices would likely be referred to a local pharmacy, big box retailer, or online dealer who could provide them with the product. Any private practice owners that choose the route of non-integration are choosing to continue operating as they always have. Little to no change or adaptation would occur.

Under the non-integration model, practice owners must also decide what their clinic protocols will be for individuals who have purchased OTC hearing aids and seek professional support and services through their clinic. Will the private practice clinic provide service and support to these individuals or refer them to other providers for care? If the practice chooses to see these patients, professional fees should apply for the time and services provided.

Hybrid Integration Model

The hybrid integration model allows private practice owners to incorporate OTC hearing aids into their product portfolio while also allowing them to maintain many of the same

operations and benefits they may appreciate about a bundled model of service care and delivery. The hybrid model would offer multiple purchase options to best fit the patients' needs and circumstances. Both unbundled and bundled approaches could be offered in the hybrid model. All products and services in this model could be itemized and bought separately as it is done in an unbundled model of care. This would accommodate patients with lower budgets to purchase what they can, when they can. It would also allow for the practice to provide support to patients who purchase OTC hearing aids elsewhere and seek professional service at the practice. Service packages of varying lengths (i.e., one year, three years, or five years) would also be available for purchase to accommodate patients with the financial means and desire for unlimited care during the duration of the service package. Finally, complete bundled product and service packages would also be offered to patients who prefer a bundled model of care.

The hybrid model is recommended as the optimal model of integration for most private practices as it offers all the benefits of both bundled and unbundled service delivery. Options and flexibility made available to the patient are maximized as they are free to choose the model of care that best meets their personal needs and circumstances. Service can be provided to all patients regardless of their choice in amplification, and practice revenue is maintained or possibly increased as all products sold, and services delivered, are appropriately compensated no matter the patient's preference. While the hybrid model may not work for every private practice owner it does seem to offer the most advantages in the changing landscape of treatment options available to those with hearing loss.

OTC Integration: Advantages and Disadvantages

Advantages

Integrating OTC hearing aids into a private audiology practice offers a variety of potential advantages not only to practice owners but also for patients who could utilize and benefit from these devices.

Financial

From a financial standpoint applying some form of an unbundled model of care by implementing either the full or hybrid integration model creates a revenue stream where profitability is less attached to the sale of devices or products. Practices receive a constant revenue stream no matter who the patient is or the service that is being provided on any given day. There is no risk of losing time and revenue to patients who need frequent follow-up and care as long as the fee structure is based upon operating costs and revenue generation models. Practice owners can then rest assured that appropriate compensation is received for the professional time and services given to each patient.

Completely integrating OTC hearing aids could also lead to a new revenue stream and potential future revenue. It is possible that OTC hearing aids could serve as an introduction or entry point for many patients who otherwise would have procrastinated or completely avoided the adoption of hearing aids all together. This is likely to occur as OTC hearing aids will provide a low-cost option and help to overcome the financial barrier experienced by many patients (Carr, 2020). As such, this group of patients could provide a new revenue stream as they receive services and an OTC product. Although the profit would likely be smaller than what is made from the sale of a traditional hearing aid it would still be income that did not otherwise exist previously. With regards to the creation of future revenue, it is likely that a portion of patients

who begin their hearing health journey with OTC hearing aids could realize that they obtain benefit from amplification, yet not everything they need. When the time arrives for these patients to consider new amplification options, they may be more open to considering prescriptive hearing aids as their desire for a higher quality listening experience leads them to realize a need for better technology to properly treat their individual hearing loss. Patients with gradually progressive hearing loss could also potentially upgrade to prescriptive hearing aids in order to accommodate their need for increased amplification.

Ethical

There are a variety of ethical advantages that come with OTC integration. To begin with, a much broader range of patients could be served rather than only those who can afford a bundled model of care. Providing patient centered care for all who enter the practice seeking help could be given. Recommendations and solutions could be customized to fit each patient's personal circumstances. With complete transparency of pricing, the practice would be able to provide services, care, and maintenance to all who need it, including patients who choose OTC hearing aids as their rehabilitation amplification option. In their position statement on OTC hearing aids, the AAA (2021b) states the following: "Audiologists should incorporate support of persons who pursue OTC hearing aid technologies, including offering supportive counseling on appropriate care and use, and developing educational and clinical practices to assist consumers in understanding the benefits and risks associated with use of OTC hearing aids." They also state in their code of ethics that "individuals shall not limit the delivery of professional services on any basis that is unjustifiable or irrelevant to the need for the potential benefit from such services" (AAA, 2021a). While these statements do not indicate an ethical obligation for audiologists to

dispense OTC hearing aids, they clearly state that audiologists have the ethical duty to provide service and care for individuals who choose to pursue OTC hearing aids.

Expanded Choice for Patients

Incorporating OTC hearing aids in a private practice would provide a broad range of product options. Patients would have a great deal of flexibility in choosing an amplification option that works best for their personal circumstances. Practice owners and audiologists working at the practice could feel confident in offering a variety of options that would help patients improve their quality of life while still fitting within whatever price range is appropriate for the patient.

Filling A Gap

As discussed in Chapter 1, page 20-21, hearing aid adoption and use is not only delayed but also low among Americans with hearing impairment who could benefit from a hearing aid (Jorgensen & Novak, 2020; Simpson et al., 2019). This represents a significant gap in the hearing healthcare market. OTC hearing aids will help to fill this gap by providing increased accessibility to at least some form of hearing healthcare. They will likely serve as an entry point for millions of Americans dealing with untreated hearing impairment and could lead many to begin using prescriptive hearing aids earlier. Private practices who integrate OTC hearing aids can know they are positively contributing to the effort to make quality hearing healthcare accessible to more individuals with hearing loss. These efforts could also be seen as a contribution to the greater good of the profession of audiology as they help maintain audiology as the primary profession that provides non-medical hearing healthcare.

Disadvantages

Staffing & Logistics

Increasing accessibility to hearing healthcare by providing OTC hearing aids as an option within a private practice creates a variety of challenges. For some private practice owners, these are factors and challenges that could cause significant hesitation when making the decision to incorporate OTC hearing aids into their practice.

With increased accessibility comes an increased number of patients seeking care over time. With this increase comes the necessity of managing a larger workload. Providing patients with care in a timely manner is critical to running a successful private audiology practice. Undoubtedly the increased workload would create the need for additional staff in the form of a second or third audiologist, potentially an audiology technician, and other front office staff to provide the appropriate level of care and practice support. Adding new staff requires a significant investment of time and money on the part of practice owners, however as noted previously, the newly generated revenue stream could offset these added expenses.

Other challenges created by incorporating OTC hearing aids are logistical in nature. There is the issue of finding physical space within a practice to store products, supplies, and the additional staff needed to accommodate more patients. Offering a wide range of product options also means that more products and all of the supplies needed to service those products will need to be accounted for and stored appropriately. Adding additional stock also increases the likelihood of practices being stuck with outdated technology. To add more staff, there must also be physical space for them to work (i.e., sound booths, offices, and front office areas). The staff would also need to receive training and become familiarized with the additional OTC products

that are added to the clinic's product portfolio. This would require an additional investment of time on the part of all staff, and a financial investment from the practice owner.

A unique challenge that comes with implementing the hybrid model of integration is competent recording and correct identification of patients. Some patients would need to be billed fee for service each time they come in, while others would be covered under a service package or bundled plan and would not be charged for their follow-up care. Front office staff would need to thoroughly understand whatever system and protocols are in place so that patients would not be mischarged or not charged for their appointment when they should. There could also be additional legal fees associated with the need to create a waiver that would be signed by patients who choose OTC's.

User Experience

While OTC hearing aids are designed for individuals with a mild to moderate hearing loss, it is possible that individuals with a greater degree of hearing loss could still seek out and choose to use an OTC hearing aid from other vendors. In this situation it is quite possible that the device would under amplify the speech and sounds they desire to hear and provide a negative experience for the patient. There is also the question of what level of control (if any) hearing healthcare professionals will have over the programming of OTC hearing aids. If control over programming is limited, the ability of hearing healthcare professionals to customize the sound delivered to a patient's ear will also be limited. These factors could lead to some patients who utilize OTC hearing aids to perceive less benefit from the devices and potentially their experience with the provider who fit the hearing aids. While such a conclusion would be erroneous on the part of the patient, it is still none the less a potential risk for private practice owners who depend on word-of-mouth marketing in small communities. There may be practice

owners who place significant value on their ability to more or less control the quality of experience their patients have with hearing aids. As such, they may be uncertain about sending a patient out of their clinic with a product they perceive as suboptimal. Some practice owners who decide to incorporate OTC hearing aids may decide to implement clinic protocols that only allow OTC hearing aids to be sold and dispensed according to manufacturer recommendations (i.e., dispensing only to patients with mild to moderate sensorineural hearing losses.) If any exceptions are made to this protocol, a waiver would need to be clearly explained and signed by the patient indicating they understand that the OTC hearing aids are being dispensed outside of manufacturer recommendations and document the reasons why. Legal requirements would always have to be followed without exceptions.

Regulations and Laws

Some states may have unique laws and regulations for the sale of hearing aids that may or may not encompass OTC devices. This could create conflicts or limitations for private audiology practices who desire to incorporate them. Examples of such issues include trial periods, warranties, return policies, and age verification for the sale of OTC hearing aids. The final ruling from the FDA does not provide exact federal regulations with regard to these issues. Private practice owners who choose to dispense OTC hearing aids will need to research, understand, and abide by any regulations set forth by the respective state where they practice.

Summary

Ultimately the decision of whether or not to incorporate OTC hearing aids into a private audiology practice depends on a myriad of factors unique to each private practice owner and the communities they serve. No two practices are exactly the same, just as no two communities are exactly the same. The goal of this chapter was to provide an overview of the factors that will

impact the decision-making process. Three different models of OTC integration were presented and the overall advantages and disadvantages of incorporating OTC hearing aids were discussed in an effort to support private practice owners as they work through this process. In the end, each private practice owner will need to seriously consider all of these factors in relation to their individual practice settings. Ongoing experience may also change the models or inform alternatives not anticipated in advance of the implementation of OTC hearing aids.

Resources

Adding to the difficulty of this decision is the lack of information and the presence of biased information surrounding OTC hearing aids. There is also a limited collection of evidence-based outcomes to guide practice owners. To further aid private practice owners in their decision-making process, the following resources are provided as trusted references to obtain accurate and up to date information on OTC hearing aids.

Government Resources

- Federal Register OTC Hearing Aid Announcement: https://www.federalregister.gov/documents/2021/10/20/2021-22473/medical-devices-ear-nose-and-throat-devices-establishing-over-the-counter-hearing-aids
- Federal Trade Commission comment on proposed OTC rules: https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-federal-drug-administration-docket-no-fda-2021-n-0555-concerning-over-counter/v220000staffcommentotchearingaids2.pdf https://www.ftc.gov/news-events/news/press-releases/2022/01/ftc-comment-food-drug-administration-supports-agencys-proposed-rule-establishing-over-counter

Legal Documents

- Colorado consumer protection act: https://codes.findlaw.com/co/title-6-consumer-and-commercial-affairs/co-rev-st-sect-6-1-701.html
- Colorado Licensing Requirements for Audiologists: https://www.asha.org/advocacy/state/info/co/licensure/ https://coaudiology.org/co-audiology/state-licensing/

Rules and Regulations

- Federal Register – FDA Final Rules and Regulations: https://www.federalregister.gov/documents/2022/08/17/2022-17230/medical-devices-ear-nose-and-throat-devices-establishing-over-the-counter-hearing-aids
- Colorado Audiology Rules and Regulations: https://www.sos.state.co.us/CCR/GenerateRulePdf.do?ruleVersionId=10212&fileName=3%20CCR%20711-2
- Colorado Hearing Aid Provider Rules and Regulations: https://www.sos.state.co.us/CCR/GenerateRulePdf.do?ruleVersionId=10213&fileName=3%20CCR%20711-1

Professional Organizations

- ASHA – Comparison chart of FDA proposed regulations: https://www.asha.org/siteassets/uploadedfiles/advocacy/otc-proposed-regs-and-consensus-comparison-chart.pdf
- ASHA - OTC Patient Hearing Checklist: https://www.asha.org/siteassets/audiology/patient-hearing-checklist.pdf

- ASHA – Frequently asked OTC hearing aid questions: https://www.asha.org/siteassets/audiology/otc-hearing-aids-faq.pdf
- NIDCD – OTC hearing aids: https://www.nidcd.nih.gov/news/2017/humes-otc-hearing-aids
- AAA – Over-the-Counter Hearing Aids: https://www.audiology.org/advocacy/legislative-and-regulatory-activities/federal-affairs/over-the-counter-hearing-aids/
- AAA – Hearing Associations Consensus Recommendations: https://www.audiology.org/hearing-associations-release-consensus-recommendations-for-new-over-the-counter-hearing-aid-classification/
- AAA - Position Statement on OTC hearing aids: https://www.audiology.org/wp-content/uploads/2021/09/COMM21-Position_Statement-OTC-FINAL.pdf
- AAA – Comparison chart of FDA proposed regulations: https://www.audiology.org/wp-content/uploads/2021/12/FDAR-FDAProposedRuleComparison.AAA_.pdf
- AAA – Embracing Change in Audiological Treatment: https://www.audiology.org/news-and-publications/audiology-today/articles/embracing-change-in-audiological-treatment-over-the-counter-hearing-devices/
- ASHA – Comparison chart of FDA proposed regulations: https://www.asha.org/siteassets/uploadedfiles/advocacy/otc-proposed-regs-and-consensus-comparison-chart.pdf

- ASHA - OTC Patient Hearing Checklist:

  https://www.asha.org/siteassets/audiology/patient-hearing-checklist.pdf

- ASHA – Frequently asked OTC hearing aid questions:

  https://www.asha.org/siteassets/audiology/otc-hearing-aids-faq.pdf

- Hearing Industries Association Consensus Recommendations:

  https://betterhearing.org/HIA/assets/File/public/Policy/Final%20HIA%20OTC%20Hearing%20Aid%20Comments%20-%20Submitted%201_17_22.pdf

- NIDCD – OTC hearing aids:

  https://www.nidcd.nih.gov/news/2017/humes-otc-hearing-aids

Consumer Advocacy Groups

- Hearing Loss Association of America:

  https://www.hearingloss.org/hlaa-promotes-consumer-protection-in-comments-for-new-over-the-counter-hearing-aid-rule/

  https://www.hearingloss.org/new-hearing-aid-options-are-coming-in-2022/

- Center for Hearing and Communication:

  https://4ff69b48-d3ef-471d-a8b1-e95bbb7cac82.usrfiles.com/ugd/4ff69b_a0f1808d9aed47a0b234f02b09648e71.pdf

CHAPTER 3

Critical Appraisal of the Research and Future Directions

Because OTC hearing aids are in the infancy of their existence, it is no surprise that there is currently little to no peer reviewed research available on the subject. Rather than having gaps in the literature, there is a conspicuous dearth of information regarding nearly all aspects of these devices. This void of knowledge creates an abundance of opportunity for future research to be conducted that could guide and direct the sale, use, programming, counseling, and many other aspects of OTC hearing aids.

Research Challenges

With any type of research comes the need to obtain funding that will fuel the completion of that research. A principal challenge for any future research on OTC hearing aids will surely be the procurement of such funding. Research conducted on prescription hearing aids has primarily been conducted by the major manufacturers of these devices as they carry the financial capacity and motivation to conduct such research. Research has also been conducted by scientists affiliated with academic institutions who typically receive funding through grants from organizations such as the National Institutes of Health (NIH). The question that must be asked moving forward is who will pay for the research that needs to be completed?

Proposed Solutions to Research Challenges

There are a variety of possible solutions to the challenge of funding future research on OTC hearing aids. Many of the major manufacturers of prescriptive hearing aids have either added an OTC option to their line of products or partnered with other companies to develop an associated OTC device. By doing this, these manufacturers have created a financial interest for

themselves in the development and progression of OTC hearing aids. As such, it is likely they will now conduct research on at least their own OTC products in an effort to gain a competitive advantage in the market. In a similar fashion, it is possible that new manufacturers of OTC hearing aids will also conduct research in order to stay competitive.

Another likely avenue of future OTC research could be conducted through the Hearing Industries Association in their MarkeTrak reports. As explained previously in this work, the MarkeTrak reports provide valuable information on the hearing status and interaction with hearing aids of U.S. citizens with hearing loss through national surveys.

Students in the field of Audiology seeking their AuD or PhD could also be a source of future research. Although it is not always true, research conducted by students is typically less costly than most other sources. Finally, the professional organizations of AAA and ASHA could contribute to the collection of data on OTC hearing aids by potentially creating an online repository where real ear measurements, surveys, and other information could be submitted by audiology practices across the nation to create a database for researchers to probe.

Future Directions

Consumer Perceptions and Patient Satisfaction

As OTC hearing aids permeate the market, it will be valuable to understand how they are received by consumers who choose to use them. Future studies such as the MarkeTrak reports should examine all aspects of the consumer experience including but not limited to overall satisfaction, perceived benefit, performance expectations vs. actual performance of the devices, levels of utilization, and much more. It will also be of particular interest to study the overall levels of hearing aid uptake and use in the US, seeing as one of the primary goals of creating the new category of OTC hearing aids was to increase accessibility to hearing healthcare. The rate at

which OTC consumers seek help from and utilize services provided by hearing health professionals such as audiologists could also be studied.

Electro-acoustic Performance & Product Comparisons

A study conducted by Reed et al. (2017) compared the laboratory speech understanding of prescriptive hearing aids against various direct-to-consumer PSAP devices available at the time. As expected, the performance of the PSAP devices varied widely between the products. Studies similar to this one should be conducted with new OTC devices. The electro-acoustical performance, frequency response, actual gain output, and other attributes should be compared amongst OTC devices and against other prescriptive hearing aids. These types of studies will inform consumers and professionals on the actual performance and effectiveness of OTC devices. This type of information would be particularly useful for professionals as they counsel patients on the rehabilitative options available, and help consumers make well-informed decisions about their hearing health.

Medical Considerations

It was previously mentioned in this work that one of the major concerns of developing the OTC category of hearing aids was that consumers with hearing loss who necessitate medical management would more likely be missed. Patients who fit this category of hearing loss may delay or neglect vital medical treatment for issues that could cause serious health issues. Examples include vestibular schwannoma, cholesteatoma, etc. Future studies should investigate whether this concern is valid.

Level of Integration by Audiologists

Future studies should also explore the dynamics of OTC integration within the field of audiology. These studies could evaluate the number of audiologists who embrace or exclude

OTC hearing aids, what model of integration if any is most commonly adopted, and their overall impressions of the impact of OTC devices.

Other Needs

Audiologists will play a crucial role moving forward as they educate and counsel patients on the options they have when it comes to OTC hearing aids. Because of this, training materials for staff members and resources used to counsel patients will need to be developed as these devices are made available through all avenues of distribution.

Graduate programs will need to decide if and how OTC hearing aids will be incorporated into the education and training of future audiologists as they will surely work with patients who choose to utilize these devices. As OTC products penetrate the market, it will be of great value to provide students with a basic working knowledge of OTC hearing aids and how to best help patients who use them.

Private audiology practice owners who choose to incorporate OTC hearing aids will also need to create clinic protocols for return policies and how the repair and maintenance of these devices will be handled, especially if the product was purchased at their practice.

Summary Statement

While change is often lamented by many, it is an opportunity for growth, adaptation, and progression. The new category of OTC hearing aids has certainly brought change to the way hearing health care is delivered in the United States. These changes, brought about by the FDA's Over-the Counter Hearing Aid Act (2017), aim to expand access to hearing health care for millions of Americans by overcoming certain barriers such as affordability and accessibility to hearing aids. The introduction of OTC hearing aids has been met with both positive acceptance and negative rejection by audiologists across the field. Despite personal viewpoints and opinions,

OTC hearing aids are here to stay. Private audiology practice owners now have the opportunity to adapt by integrating OTC hearing aids into their practices and implementing a hybrid model of service delivery. Moving forward, there is a significant need for research to be completed on nearly every facet of OTC hearing aids. Future directions for research have been proposed. Much benefit will come to professionals and consumers as this research is completed and the positive, equivocal, and negative aspects of these devices are learned. OTC hearing aids are a change that can prove to be helpful for many individuals with mild to moderate hearing loss, and if handled correctly, private audiology practices can continue to thrive as they integrate them.

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