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Consideration for Expanding the Audiology Scope of Practice to Include Prescription Medication Authority

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CONSIDERATIONS FOR EXPANDING THE AUDIOLOGY SCOPE OF PRACTICE TO INCLUDE PRESCRIPTION MEDICATION AUTHORITY

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ABSTRACT

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The demand for medical professionals rises in conjunction with the rise of prescriptions written annually in the United States, but there are not enough physicians to meet the demand for patient prescriptions (Mohamadloo et al., 2019). In the United States, 2.4 million healthcare visits for acute otitis externa were recorded in 2007; approximately half were between the ages of 5-14 years old. Healthcare providers were estimated to have spent about 600,000 hours treating acute otitis externa.

Prescriptive authority is the ability of healthcare providers to prescribe specific medications, including controlled substances. Prescriptive authority is legally allocated by federal and state governments. Many other healthcare professionals have some degree of involvement in the prescribing and administering drugs and vaccines in the U.S. These include naturopathic doctors, nurse practitioners, physician's assistants, optometrists, and physical therapists. Audiologists are not authorized to practice medicine or prescribe medications, but there may be a need to do so in the future, especially in the context of non-systemic drugs. Topical otic drugs are reviewed in this manuscript as this would be the most likely drug class to be relevant to an audiologist gaining prescriptive authority. There is a lack of research regarding the need for audiologists to have prescriptive authority, the status of Au.D. educational preparation in the area of otologic pharmacology and the professional perspectives, attitudes, and

initiatives that would need to be undertaken should audiologists prescribe topical otic medications. If the future of audiology is to consider this role in the future scope of practice, there is much information to be obtained, long-term initiatives to be undertaken and financial resources to be accrued.

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LIST OF ABBREVIATIONS

AAA	American Academy of Audiology
ABR	Auditory Brainstem Response
ACAOM	Accreditation Commission for Acupuncture and Oriental Medicine
ACIP	Advisory Committee on Immunization Practices
CCC-A	Certificate of Clinical Competence in Audiology
CEU	Continuing Education Units
CHEA	Council for Higher Education Accreditation
DEA	Drug Enforcement Administration
DO	Doctor of Osteopathic Medicine
EMT	Emergency Medical Technician
FDA	Food and Drug Administration
HLC	Higher Learning Commission
ICD	International Classification of Diseases
MD	Doctor of Medicine
NP	Nurse Practitioner
PA	Physician's Assistant
PE	Pressure Equalization

PSE	Pseudoephedrine
SSA	Social Security Act
WHO	World Health Organization

CHAPTER I

REVIEW OF LITERATURE

In 2009, 3.95 billion prescriptions were dispensed in the United States. In 2021, the number had grown to 6.47 billion prescriptions. Between 2009 and 2021, the number of prescriptions dispensed has increased by 63.79% and is expected to continue to rise significantly by the year 2025 (IQVIA, 2022). With this rise in demand for prescription medication, the demand for patients to see prescription-writing medical professionals has increased as well; in 2009, there were 972,376 active physicians in the United States (US Department of Health and Human Services, 2018), and in 2022 there are 1,073,616 active physicians in the United States, which is an increase of about 10.41% (Kaiser Family Foundation, 2022). The demand for medical professionals rises in conjunction with the rise of prescriptions written annually in the United States, but the demand for prescriptions has outgrown the addition of physicians (Mohamadloo et al., 2019).

To address the higher demand for prescription medications, other medical professions have increased their scope of practices to include diagnoses and prescription-writing in the context of their field. Examples of these professionals include optometrists, physical therapists, mental health professionals, physical therapists, and more (Division Information and Programs, n.d.). Additionally, non-doctorate holders have increased their prescriptive authority as well, such as Emergency Medical Technicians (EMTs), physician assistants (PAs), and registered

nurses (RNs). There is a need for a broader understanding of pharmacology in other allied health professionals in the context to relieve expanding demands for prescription drugs.

Pharmacology

Introduction to Pharmacology

Pharmacology is the study of drugs and their origin, nature, properties, and effects on living organisms. It is the responsibility of healthcare professionals, including audiologists, to know why drugs are given, when they should be given, how they work, and what influence they have on a living being (DiSogra, 2019).

Physicians and other medical professionals, such as nurses, optometrists, and physical therapists are qualified to prescribe, dispense, and/or administer medications. To "prescribe" medication means to diagnose a problem and choose an appropriate drug treatment plan. To package and deliver the medication in a container with its proper information is to "dispense" medication. To provide medication in an injection, inhalation, or ingestion is to "administer" medication. Once a medication is administered, its effect on the body begins.

Pharmacodynamics and Pharmacokinetics

The effects of drugs on a living organism are commonly described in terms of pharmacodynamics and pharmacokinetics. Pharmacokinetics and pharmacodynamics work symbiotically to determine the relationship between the dose of the drug and its therapeutic and potency effects that vary from person to person (Moini, 2018). It is the responsibility of the healthcare professional to make informed decisions about a patient, considering all aspects of medical history, before properly prescribing and dispensing medications to the patient.

Special considerations for drug administration must be taken with high-risk populations, including pediatric, geriatric, and pregnant patients. Pharmacokinetics differ in each of these

populations due to differences in cardiac performance, kidney performance, liver capacity, body fat composition, hydration, and more (Moini, 2018).

Pharmacodynamics

Pharmacodynamics describes the actions of a drug on the body, including therapeutic effects and adverse effects. The term "therapeutic" refers to the response of a treatment used to alleviate disease or illness that yields a positive outcome. Additionally, an adverse effect is one that yields a non-favorable response, also referred to as a "side effect." Naming an effect as either "therapeutic" or "adverse" depends on the goal of the treatment. Therapeutic or adverse responses can be behavioral, physical, or both (Colbert & Woodrow, 2019). The relationship between the probability of the desired outcome and toxicity is called therapeutic index (Tamargo et al., 2015). The therapeutic index can be caused or affected by the drug moving throughout the body in a process called pharmacokinetics.

Pharmacokinetics

The movement, metabolism, and absorption of drugs and medications through the human body is known as pharmacokinetics. When introduced to the body, drugs go through a four-phase transformation. They are absorbed through a membrane into the bloodstream, distributed to other tissues and fluids around the body, metabolized, and then excreted (Colbert & Woodrow, 2019). Understanding of these biologic mechanisms is crucial to keeping consumers safe from dangerous side effects and undesirable drug interactions.

Drug Administration

There are two major classifications of drug administration: local and systemic. Local administration describes the direct application of a drug to the site of desired therapy, reducing the risk of potential systemic, or whole body, side effects. Additionally, localized drug

administration allows for the optimal drug level to be managed for controlled periods of time, reducing the likelihood of toxicity (Vinay & KusumDevi, 2016). Examples of locally administered medications include antibiotic ointments/creams, eye drops, and ear drops.

Systemic administration refers to drugs that travel through the circulatory system. The most widely used route of administration for systemic drugs is through oral delivery (Shakya et al., 2011). The primary site of drug absorption is the small intestine, and the strength of the medication is influenced by the amount of drug absorbed across the intestinal epithelium. Drugs taken orally are affected by first-pass metabolism. First-pass metabolism refers to the drug concentration being significantly diminished before it reaches the circulatory system due to its metabolism in the liver. Certain administration routes, such as sublingual or buccal administration, bypass the first-pass metabolism by being absorbed directly into the bloodstream (Kim & De Jesus, 2022).

Drug Forms

Drugs are transformed into a variety of administrative mediums in a process called pharmaceutics. Drugs can have multiple formulations, allowing the medical professional to choose the best medium depending on the patient. The Food and Drug Administration (FDA) recognizes 158 types of drug dosage forms, including a variety of solid, liquid, gaseous, and more (U.S. Food and Drug Administration, 2022). Choosing the right drug form is important in ensuring the correct site of the medication application and avoiding medication errors.

Solid drugs, including pills, tablets, and capsules, are an easy way to administer unpleasant tasting drugs, and have a systemic effect on the body. Solid drugs are widely produced and distributed and are highly praised due to their ease of storage, portability, and ease of administering (Center for Drug Evaluation and Research, 2015; Kim & De Jesus, 2022).

Not all patients can take solid drugs due to young age or swallowing difficulty. Liquid drugs, including solutions, emulsions, gels, and lotions are drugs that have been dissolved or suspended in a medium. A solution is a drug dissolved in an appropriate solvent. Emulsions are mixtures of two things that do not mix very well, water and oil, and are commonly used to make creams and lotions. Lotions are suspensions of a drug in a water base that are patted into the skin, such as an anti-itch medication. Gels are semisolid substances in a nonfatty base that contain fine particles and are applied to the skin (Moini, 2018). Lotions and gels are applied locally, meaning they intend to only affect the area to which they are applied. However, drugs applied topically to the skin can get absorbed into the bloodstream in small amounts. Solutions are ingested orally and affect the body systemically.

Injectable drugs are utilized when a medication is needed to take rapid effect or when a patient is unable to take the medication orally. These medications are often powders dissolved in a sterile water or saline solution and can be injected by a variety of routes. Examples of injectable drug routes of administration include intra-articular (joint), epidural (spine), intradermal (inbetween layers of skin), subcutaneous (in fat), intramuscular (in muscle), and intravenous (in veins) (Rizzo & Kehr, 2021). Injectable drugs can either be local, such as local anesthesia and epidurals, or systemic, such as insulin and vaccines.

Other drug forms include topical, semisolid, patches, gaseous, ophthalmic, otic, nasal, vaginal, and rectal. They are classified by the means they are applied to the body (i.e., through the dermis, dissolvable suppositories, through the nasal membrane, etc.) (Adepu & Ramakrishna, 2021). Otic medications are medications that are applied to the outer ear. They are used to control localized redness, itchiness, irritation, and/or swelling by dropping a small amount of

antibiotic or steroid liquid medication onto the affected area in the ear canal in an attempt to relieve the ailment.

Consumer Safety and Drug Regulations in the United States

The government first attempted to oversee food and drug manufacturing in 1906 with the Pure Food and Drug Act (Pure Food and Drug Act, 21 U.C.S. § 768, 1906). Since then, the importance of consumer safety has grown exponentially into what is known today, with organizations like the FDA and the Drug Enforcement Administration (DEA). The role of the FDA is to approve drugs for medical use in the United States while the DEA regulates the laws and handling of all controlled substances.

Drug Names

Each drug has three names that it can be referenced by: generic name (also called "approved name", "official name", or "nonproprietary name"), trade name (also called "brand name" or "proprietary name", and the chemical name (describing the chemical makeup of the drug). For example, the drug ciprofloxacin is used to treat ear infections. Ciprofloxacin is the generic name, one brand name is Proquin XR, and the chemical name is 1-cyclopropyl-6-fluoro-4-oxo-7-piperazin-1-ylquinoline-3-carboxylic acid (Zhang et al., 2018)

Legal Accessibility to Drugs

It is the responsibility of the DEA to enforce the legal accessibility of drugs and medications (Center for Drug Evaluation and Research, 2017). There are two legal ways to dispense drugs and medications: "over the counter" (OTC) or with a prescription from a medical professional. Over the counter drugs have no consumer restrictions by the FDA and can be purchased most places without requirements or restrictions on who can purchase them. Over the counter drugs that carry purchase requirements are called "behind the counter" (BTC) drugs. "Legend drugs"

are drugs that can be administered to the public by a pharmacist after receiving a prescription from a healthcare provider. Lastly, drugs that have a high risk of addiction or abuse and require close monitoring by healthcare professionals are called “controlled substances” (Colbert & Woodrow, 2019).

Over-The-Counter Drugs

Over-the-counter drugs do not require a prescription from a medical professional. These medications are sold in most major grocery, drug, and convenience stores with little-to-no restriction on who can purchase them in the U.S.. When a drug is prescribed by physicians for several years with little to no concern for safety, that drug may be eligible to become available OTC (Jacobs, 1998).

Many people prefer OTC treatments due to its lower financial burden, both from the cost of the medication itself as well as the avoidance of seeing a physician to receive a diagnosis and/or prescription. In 2021, the estimated number of sales for OTC medications was 37 billion dollars in the United States (CHPA, 2022). The most common OTC medication purchased in 2020 was cold and allergy sinus tablets (Winsight Grocery Business, 2020). Other common OTC medications categories include analgesics, weight control, gastrointestinal, and adult incontinence.

Patients are able to treat themselves safely with OTC medications as long as the instructions are respected. Failure to follow the specified instructions can lead to serious adverse effects and abuse. Additionally, OTC medications can impair the consumer’s ability to drive a motor vehicle, cause drowsiness, and cause allergic reactions without the patient’s knowledge. Over-the-counter medications can interact with other OTC medications, prescription

medications, and even foods, leading to injury or illness for the consumer. For these reasons, it is important to consult a physician about OTC medications before taking them.

Behind-the-Counter Drugs

Behind-the-Counter drugs were introduced in 2006 with the Combat Methamphetamine Epidemic Act of 2005 (USA Patriot Improvement and Reauthorization Act of 2005 (Public Law 109-177)). This Act sought to temper the U.S. methamphetamine epidemic by banning the sale of OTC medications containing ingredients commonly used to make methamphetamine, including pseudoephedrine, ephedrine, and phenylpropanolamine (Brzeczko et al., 2013). Medications containing these ingredients, specifically PSE, can now be bought behind the counter, meaning there are limits on the quantity of medications containing these ingredients that can be purchased by a single person and individuals are required to present photo identification prior to purchase. Additionally, retail stores are required to maintain information about purchasers for at least two years (Center for Drug Evaluation and Research, 2017).

Legend Drugs

Legend drugs are medications that require a prescription due to their risk of being abused if sold OTC. These drugs are still able to be picked up by a patient/consumer and self-administered but require the pre-approval and prescription of a medical professional prior to sale. Examples of these medications include birth control pills, antibiotics, and hormonal therapies (Colbert & Woodrow, 2019).

Controlled Substances

Controlled medications, also called “scheduled drugs” or “scheduled medications,” receive special treatment in law because of their potential for abuse, dependence, and diversion. These drugs are sorted into five distinct categories based on risk of abuse (see Table 1.1).

Table 1.1

United States of America Drug Enforcement Administration Drug Schedule

Schedule	Definition	Drug Examples
V	Low potential for abuse. Most commonly used for antitussive, antidiarrheal, and analgesic purposes.	Robitussin A-C Motofen Lyrica
IV	Low potential for abuse and low risk of dependence.	Xanax Ambien Valium
III	Moderate to low potential for physical and psychological dependence.	Ketamine Anabolic Steroids Testosterone
II	High potential for abuse, with use potentially leading to severe psychological or physical dependence.	Vicodin Cocaine Methamphetamine
I	High potential for abuse with no accepted medical use in the United States	Cannabis Heroin Lysergic Acid Diethylamide (LSD)

Source: Drug Enforcement Administration Drug Scheduling website https://www.dea.gov/druginformation/drug-scheduling

Medication Errors

Medication errors are defined according to the stage of treatment where the error occurred: prescribing, dispensing, or administration of a medication. *Drug administration errors* are defined by the American Society of Hospital Pharmacists as "a dose of medication that deviates from the physician's order as written in the patient's chart or from standard hospital policy and procedures" (Gourley et al., 1982). In 2012, the avoidable healthcare costs due to medication errors in the United States totaled 20 billion dollars (Intercontinental Medical Studies

Health, 2013). There are three major classifications of medication errors: prescribing errors, dispensing errors, and administration errors.

Prescribing Errors

Prescribing errors happen when the incorrect drug is selected for a patient. Errors can be made regarding the dose, quantity, indication, or potential drug interactions. For example, if a patient were prescribed penicillin despite being allergic to it, that would be a prescription error. Lack of knowledge of the prescribed drug, its recommended dose, and of the patient details contribute to such errors.

Dispensing Errors

Drug dispensing errors occur between when the drug has been prescribed and when the patient receives the drug. These errors can occur from an incorrect drug, incorrect drug dosage, or when drugs are given to the wrong patient. For example, if a patient were prescribed amoxicillin by their healthcare professional, but received ciprofloxacin instead, that would be a dispensing error.

Administration Errors

Administration errors occur when a drug is applied to a patient in the incorrect manner from how it was prescribed. For example, if a medication should be injected subcutaneously but was injected into the muscle instead, that would be an administration error.

Topical Drugs Used for Auditory Pathologies

Audiology clinical service delivery areas includes the diagnosis and treatment of hearing, balance, and other related disorders (American Speech-Language-Hearing Association, 2023). Using an otoscope, or video otoscope, and immittance audiometry, audiologists can also evaluate the integrity of the pinna, external ear canal, tympanic membrane and ossicular chain. Examples

of identifiable dermatologic pathologies of the outer ear and tympanic membrane that likely require medical intervention from a physician include seborrheic keratosis, seborrheic dermatitis, chondrodematitis nodularis helicus chronicus, psoriasis, actinic keratosis, basal cell carcinoma, squamous cell carcinoma, melanomas, herpes zoster oticus, and exostosis (Öztürkcan & Öztürkcan, 2014). Examples of identifiable otologic pathologies of the outer and middle ear that require medical intervention from a physician include impacted cerumen, blocked pressure equalization (PE) tubes, otitis externa, otitis media, bullous myringitis, and granular myringitis (Alenezi et al., 2022). Once the pathologies are identified, they can be treated accordingly with the appropriate medications or other treatments.

Topical Otic Preparations

Topical otic drugs are medications that are applied to or inside of the outer ear in order to treat conditions of the outer ear. Topical otic preparations do not always contain drugs. Different types of otic preparations include home remedies, cerumenolytics, otic anesthetics, otic anti-infectives, otic steroids, and combination otic steroids with anti-infectives.

At-Home Treatments for Otitis Externa

Vinegar is commonly used in at-home healthcare, as it has been shown to have antioxidant and antimicrobial properties because it contains up to 8% acetic acid (Johnston & Gaas, 2006). Ear canal rinses with equal parts white vinegar and water are sometimes recommended for patients with mild otitis externa due to the vinegar's ability to aide several skin diseases including bacterial and fungal infections, warts, dermatitis to restore a normal pH in the ear canal and reduce swelling (Jung et al., 2002). Other recommendations require half white vinegar and half rubbing alcohol; the vinegar provides antibacterial benefits while the alcohol evaporates any remaining moisture trapped in the ear canal (Agrawal et al., 2017). The use of

vinegar alongside topical steroids has been shown to lead to the highest cure rates for otitis externa (Elhage et al., 2022). However, people with tympanic membrane perforations, allergies to acetic acid, history of ear operations, and middle ear disease should not use vinegar as an at-home treatment for otitis externa (Prakairungthong et al., 2021). Because these options are low cost, can be administered at home, and contain no drugs, they are often the first treatment option advised by a physician for many who experience ear pain.

The OTC version of at-home vinegar treatments is called acetic acid otic solutions, which are localized antibiotics that can treat both bacterial and fungal infections of the outer ear, such as Swimmer's ear (bacterial) and otomycosis (fungal) (Gupta et al., 2014; van Balen et al., 2003) or act as a preventative treatment by drying the ears out. Brand names of acetic acid otic solutions are Vosol and Borofair (Borofair also contains aluminum acetate). In the United States, acetic acid is available by prescription only and is self-administered by the patient or the patient's caregiver under order from their prescriber. (Shamanna & Ganga, 2018).

The recommended dosage for adults for the treatment of acute otitis externa is to keep a cotton wick in the affected ear canal(s) for at least 24 hours and to keep it moist by adding 3 drops to 5 drops of acetic acid otic solution every 4 hours to 6 hours. The wick may be removed after 24 hours but the patient should continue to instill 5 drops of acetic acid otic solution 3 times or 4 times daily until ordered to cease by the prescriber. In pediatric patients, 3 drops to 4 drops may be sufficient due to the smaller capacity of the ear canal. Safety and effectiveness in pediatric patients below the age of 3 years have not been established. Potential adverse effects include itching, burning, and irritation at the site of application. Acetic acid otic solutions should not be administered if there is a hole in the tympanic membrane, such as a perforation or a PE tube.

Cerumenolytics

Cerumen impaction affects approximately 10% of children, 5% of normal healthy adults, up to 57% of older patients in nursing homes, and 36% of patients with intellectual disabilities (McCarter et al., 2007). This equates to approximately 8 million cerumen removal procedures annually in the United States. Cerumenolytics are softening agents made of oil, emulsifying agents, glycerin, and other lubricating substances that are placed in the ear canal to soften hardened cerumen, making removal easier (Aaron et al., 2018). The drops work by releasing oxygen to soften and encourage spontaneous extrusion of cerumen. Patients who have a history of anticoagulant therapy, immunocompromised state, diabetes mellitus, prior radiation therapy to the head and neck, ear canal stenosis, exostoses, and nonintact tympanic membrane should not utilize cerumenolytics for cerumen management (Schwartz et al., 2017).

Cerumenolytics do not contain drugs and are available for purchase OTC, meaning the buyer is responsible for their self-care. The generic name for cerumenolytics is carbamide peroxide and sample brand names include Debrox, Murine, Mollifene, Auro, and Auraphene-B. The recommended dosing for carbamide peroxide is five to 10 drops placed twice daily for up to four days. However, the duration of treatment has also been shown to have little impact (Hand & Harvey, 2004). Cerumenolytics used alone or in combination with irrigation can be effective and available at a low cost but are not always effective in at-home cerumen removal (Keane et al., 1995). No cerumenolytic agent has been shown to be more effective than water or saline (Aaron et al., 2018).

Otic Anesthetics

Otic anesthetics are ear drops that relieve pain in the ears, called otalgia. Some of these agents are available with other medicines such as analgesics or decongestants. They are available in liquid form and applied as ear drops (El Feghaly et al., 2023). Different formulations of otic anesthetics include antipyrine and benzocaine; antipyrine, benzocaine, and zinc acetate; and chloroxylenol and pramoxine. In the United States, otic anesthetic ear drops are available by prescription only and drops are self-administered by the patient or the patient's caregiver under the direction of their prescriber. However, people with a perforated tympanic membrane, PE tubes, diabetes, immunocompromised state, or history of prior radiotherapy should not use otic anesthetics (Rosenfeld et al., 2014).

A study of the efficacy of topical administration of an otic anesthetic found improvement in pain symptoms by 25% reduction in pain after only 30 minutes (Hoberman et al., 1997). Local or topical pain treatment is desirable because the side effects noted in systemic medications would not present themselves, and pain relief could be faster and more intense and last longer (Michel, 2021). However, a different study found the topical anesthetic benzocaine may cause contact dermatitis that can worsen or prolong otitis externa (Rosenfeld et al., 2014). Additionally, if a topical anesthetic drop is prescribed for temporary pain relief, the patient should be reexamined within 48 hours to ensure that otitis externa has responded appropriately to the medication.

Otic Anti-Infectives

Otic anti-infectives are ear drops containing either antibacterial or antifungal agents. These agents either kill or inhibit bacterial or fungal growth and are used to treat bacterial (e.g.

otitis externa, furunculosis, perichondritis, lupus vulgaris) or fungal (e.g. otomycosis) infections of the ear (Woo et al., 2020).

Common generic names of otic anti-infectives include acetic acid, ciprofloxacin, and ofloxacin.

The American Academy of Otolaryngology-Head and Neck Surgery supports the notion that topical antibiotics alone are an appropriate first treatment for most patients with common outer ear diseases (Hannley et al., 2000). Additionally, they found no evidence that systemic antibiotics in combination with topical preparations improve treatment outcomes compared with topical antibiotics alone. Side effects of otic anti-infectives include mild stinging or burning at the application site.

Deciding which drug or drug combination to use to treat ear infections is up to the discretion of the prescriber and is often based on what type of bacteria, virus, or fungus is causing the infection. In more severe or resistant cases, this may require the physician to culture the infected site for laboratory analysis.

Ciprofloxacin Otic Solutions

Ciprofloxacin otic solutions are localized antibiotics that are used to treat bacterial otitis externa and otitis media (Mösges et al., 2011). Brand names of ciprofloxacin otic solutions include Otiprio and Cetraxal. In the United States, ciprofloxacin is available by prescription only and is self-administered by the patient or the patient's caregiver under order from their prescriber.

The average dosage and administration of ciprofloxacin ear drops is 0.25mL into the affected ear(s) two times a day, or every 12 hours, for 7 days. The maximum plasma concentration of ciprofloxacin is hypothesized to be less than 5 ng/mL. Side effects of ciprofloxacin include itching, headache, otitis media, and ear pain (Drehobl et al., 2008).

Ofloxacin Otic Solutions

Ofloxacin otic solutions are localized antibiotics that are used to treat bacterial otitis externa. The brand name for an ofloxacin otic solution is Floxin Otic. In the United States, ofloxacin is available by prescription only and is self-administered by the patient or the patient's caregiver under order from their prescriber.

The recommended dosage regime of ofloxacin otic solution is ten 0.5mL drops administered into the affected ear(s) once a day for ten days. For pediatric patients, administer five 0.25mL drops into the affected ear(s) once a day for seven days (Jones et al., 1997; Simpson & Markham, 1999). The most common adverse effects seen with ofloxacin otic solutions are itchiness, earache, and application-site reactions (Torum et al., 2004).

Otic Steroids

Otic steroids are products that contain steroids, or corticosteroids, and the liquid drops can be placed in the ears. Corticosteroids are effective anti-inflammatory agents and are used to treat pain and inflammation, and eczema or dermatitis. The generic name for otic steroids is fluocinolone and brand names include Flac and DermOtic Oil and the recommended dosage is 0.025% drops applied twice daily for 7 days (Spektor et al., 2022). Reported side effects of otic steroid include burning, pain, irritation, and loss of hearing (van Balen et al., 2003).

Fluocinolone Acetonide Oil

Fluocinolone acetonide oil is a localized steroid oil used to treat atopic dermatitis/eczema and psoriasis because it exhibits anti-inflammatory, anti-itch, and vasoconstrictive characteristics (Pradhan et al., 2015; Pauporte et. al., 2004). In the United States, fluocinolone otic oil is available by prescription only and is self-administered by the patient or the patient's caregiver under order from their prescriber.

The average dosage and administration of fluocinolone acetonide oil is 5 drops into the affected ear(s) twice a day for 7 to 14 days as directed by the prescriber. This should not be used in children under 2 years old and patients who present complicated otic eczema, fungal or bacterial otitis media or otitis externa, or significant concomitant diseases such as tuberculosis or psoriasis (Montoro et al., 2018). Additionally, patients with history of otologic surgery within the past 2 months, cerumen impaction in the past 2 weeks, use immunosuppressant drugs, antihistamines, or topical non-steroidal drugs, or history of adverse reactions to any component of the medication should not use this medication. Adverse effects include burning, itching, irritation, dryness, folliculitis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, skin atrophy, striae, and miliaria. Fluocinolone acetonide oil also contains peanut oil, so patients who have allergies to peanuts should not utilize this treatment option.

Otic Steroids with Anti-Infectives

Otic steroids with anti-infectives are localized ear drops that have both steroids and anti-infective agents. The addition of a topical steroid to topical anti-infective drops has been shown to hasten pain relief in some randomized trials, but others have shown no significant benefits (Shrestha et al., 2019).

Acetic Acid and Hydrocortisone

Acetic acid and hydrocortisone are a combination medicine used to treat bacterial otitis externa and to relieve the symptoms of redness, itching, or swelling (Wiegand et al., 2019). Acetic acid is an antibiotic and hydrocortisone is a steroid (van Balen et al., 2003). In the United States, acetic acid and hydrocortisone ear drops are available by prescription only and are self-administered by the patient or the patient's caregiver under order from their prescriber.

The recommended dosage for adults for the treatment of acute otitis externa is to keep a cotton wick in the affected ear canal(s) for at least 24 hours and to keep it moist by adding 3 to 5 drops of acetic acid otic solution every 4 hours to 6 hours. The wick may be removed after 24 hours but the patient should continue to instill 5 drops of acetic acid otic solution 3 times or 4 times daily until ordered to cease by the prescriber (Kaushik et al., 2011). In pediatric patients, 3 drops to 4 drops may be sufficient due to the smaller capacity of the ear canal. Safety and effectiveness in pediatric patients below the age of 3 years have not been established. Potential adverse effects include stinging or burning at the site of application.

Ciprofloxacin and Dexamethasone

Ciprofloxacin and dexamethasone are often combined in treatment for bacterial acute otitis externa and bacterial acute otitis media (Mösges et al., 2011; Ku et al., 2020; Roland et. al., 2004). Ciprofloxacin is an antibiotic and dexamethasone otic is a steroid. One brand name for ciprofloxacin and dexamethasone is CiproDex. In the United States, ciprofloxacin and dexamethasone ear drops are available by prescription only and is self-administered by the patient or the patient's caregiver under order from their prescriber.

The recommended dosage for adults for the treatment of acute otitis externa is 4 drops (0.14mL) into the affected ear(s) twice a day for seven days. This should not be done in children under 6 months of age. Contraindications of ciprofloxacin and dexamethasone are acute or chronic otitis media, TM perforation or PE tubes, otorrhea, otitis externa, fungal or viral ear infections, congenital abnormalities of the external auditory canal, obstructive bony exostoses, seborrheic dermatitis of the external auditory canal, a current or prior history of immunosuppressive disorders (Mösges et al., 2011).

Ciprofloxacin and Fluocinolone

Ciprofloxacin and fluocinolone otic is a combination medicine used to treat bacterial otitis media in children at least 6 months old with PE tubes (Mösges et al., 2011; Lorente et al., 2014; Wiegand et al., 2019). Ciprofloxacin is an antibiotic and fluocinolone is a steroid. In the United States, ciprofloxacin and fluocinolone ear drops are available by prescription only and is self-administered by the patient or the patient's caregiver under order from their prescriber.

The recommended dosage for children older than 6 months with PE tubes for the treatment of acute otitis media is 0.25mL into the affected ear canal(s) twice a day for seven days. Following drop administration, the tragus should be pumped inward 4 times to facilitate movement of medication into the middle ear space. Potential adverse effects include itching or burning at the application site (Mösges et al., 2011). Systemic side effects of local application occasionally include dizziness and headaches.

Ciprofloxacin and Hydrocortisone

Ciprofloxacin and hydrocortisone are often combined to treat bacterial otitis externa (Mösges et al., 2011; Dohar, 2003). Ciprofloxacin is an antibiotic and hydrocortisone is a steroid. In the United States, ciprofloxacin and hydrocortisone ear drops are available by prescription only and is self-administered by the patient or the patient's caregiver under order from their prescriber.

The recommended dosage for adults and children 2 years and older for the treatment of acute otitis externa is 3, 10mg drops into the affected ear(s) twice a day for seven days. Potential adverse side effects include blistering, crusting, irritation, itching, or reddening of the skin at the application site. Contraindications for use include perforated TMs or PE tubes, acute otitis

media, dermatitis of the affected ear, known fungal infections, or an immunocompromised condition (Miró & Spanish Ent Study Group, 2000).

Neomycin, Polymyxin B, and Hydrocortisone

Neomycin, polymyxin B, and hydrocortisone are a combination of ear drops used locally to treat bacterial otitis externa (Roland et al., 2004; Tong et al., 1996). Hydrocortisone is a steroid and neomycin and polymyxin B are antibiotics. In the United States, neomycin, polymyxin B, and hydrocortisone ear drops are available by prescription only and is self-administered by the patient or the patient's caregiver under order from their prescriber.

The recommended dosage of neomycin, polymyxin B, and hydrocortisone is 3 drops for children or 4 drops for adults aged 12 years and older three times daily for seven days. Contraindications for utilizing neomycin, polymyxin B, and hydrocortisone includes acute or chronic otitis media, current TM perf or PE tubes, otorrhea, congenital abnormalities of the external auditory canal, obstructive bony exostoses, seborrheic dermatitis of the external auditory canal, and a current or prior history of immunosuppressive disorders (Roland et al., 2004).

Summary

The therapeutic index of many treatments for otitis externa have been studied extensively. It is the responsibility of healthcare professionals, including audiologists, to know why drugs are given, when they should be given, how they work, and what influence they have on the body. The topical medications used to treat acute otitis externa are extensive, peer-reviewed, and have no systemic effect on the body.

CHAPTER II

APPLICATIONS TO THE FIELD OF AUDIOLOGY

Prescriptive Authority

When OTC medications are not enough to bring relief to a patient's ailment, the next step is most often consulting a healthcare professional. Healthcare professionals may include the patient's primary care physician, a NP or PA at a local clinic, or a family care provider. Depending on the healthcare provider, the patient may be diagnosed with an infection or illness and prescribed a drug or medication to attempt to solve the pathology.

Introduction to Prescriptive Authority

Prescriptive authority is the ability of healthcare providers to prescribe specific medications, including controlled substances. Doctor of Medicine (MD) and Doctor of Osteopathic Medicine (DO) have the highest prescriptive authority and can prescribe any type of medication, regardless of its schedule. In addition, physicians are able to prescribe Schedule II to V medications with a valid DEA license (Zhang & Patel, 2022). Other healthcare providers also have varying degrees of authority to prescribe medications. Examples of these professionals include nurse practitioners, physical therapists, optometrists, acupuncturists, and more.

Medical procurement is the process of purchasing medical equipment, services, and supplies for the diagnosis, curing, treatment, and rehabilitation of diseases (Procurement Partners, 2022). For physicians and other healthcare providers, it is the ability and authority to obtain a drug or medication from an in-state prescription drug outlet, Board-registered

prescription drug wholesaler, or drug manufacturer for which there is an authority to prescribe the drug (Lingg et al., 2016).

Prescriptive authority is obtained by completing a number of educational and experience requirements, including multiple degrees, state licensure, professional organization accreditation, and the completion of required Continuing Education Units (CEUs). Each of these educational requirements are discussed below.

Council for Higher Education Accreditation

Universities receive the right to award degrees from the Council for Higher Education Accreditation (Eaton, 2015). Accreditation is the process of self-review and peer review for improvement of academic quality and public accountability of institutions and programs. This accreditation ensures that a neutral, third party has expertly reviewed the quality of education provided by a college or university, as well as offering suggestions for improvement. This peer review happens every 3 to 10 years.

There are six accreditation regions in the United States: New England, Middle States, North Central, Southern, Western, and Northwestern (Regional Accrediting Organizations: Council for Higher Education Accreditation.) The State of Colorado falls under the Higher Learning Commission (HLC) (Higher Learning Commission, 2018). There is an optional accreditation institutes called the Council on Academic Accreditation in Audiology and Speech-Language Pathology and the Accreditation Commission for Audiology Education (ACAE) for universities offering degrees in communication sciences and disorders (Accreditation Commission for Audiology Education, 2023; American Speech-Language-Hearing Association, 2022).

Degree Conferral

Colleges and universities are authorized to confer degrees following the students' completion of the educational requirements and submission to the Office of the Registrar for approval. This authorization comes from the Degree Authorization Act, which authorizes institutions to offer degrees and/or degree credits (Colorado Revised Statute Title 23, 2023). Academic transcripts are reviewed by a board of faculty members and determined to either meet or not meet the requirements of degree completion. At the commencement ceremony, the President or the Dean of the college/university will authorize that the academic requirements were met. In addition to classroom requirements, the board will also review additional requirements for the student's intended authorizations, including completion of research and defense, associated endorsements or minors, additional certification, etc.

State Licensure

Completion of the educational requirements and obtainment of a degree authorizes a professional candidate to move forward with state licensure applications. A license is a state's grant of legal authority to practice a profession within a designated scope of practice. It is required in order to practice or to call oneself a licensed professional. Licensure requirements differ for each profession. In some professions, one license can span several states, while in other professions, a new license is required to practice in each state. The state of Colorado Division of Professions and Occupations requires a number of specialists to be licensed by the state, including physicians, audiologists, optometrists, nurses, entry-level midwives, acupuncturists, psychologists, podiatrists, physical therapists, pharmacists, dentists, and more (Professions and Occupations Act, 2019).

Certification by Professional Organization

After obtaining state licensure, some professionals are required to become certified through national professional organizations. Certification is frequently used to set the criteria for meeting training and experience licensure requirements for these professionals in most states. Audiologists obtain a Certificate of Clinical Competence (CCC) in audiology; holders of the CCC-A have demonstrated knowledge and competency to fulfill an independent audiologist's role successfully.

Additionally, professionals often join professional organizations as a way to grow professionalism and expand networking. Professional organizations offer opportunities for professional development by offering national conferences, seminars, research presentations, and CEUs are all ways to expand knowledge of the field and keep educational relevance in the field.

Responsibilities and Principles of Drug Administration

Management of medication carries moral, ethical, and legal responsibilities. It is the duty of the healthcare professionals to ensure safe administration by familiarizing themselves with current research regarding all medications, including potential side effects and possible interactions with other drugs.

Healthcare providers must have wisdom and educated judgment to accurately assess the patient's needs for medications, evaluate their response to medications, and plan appropriate intervention as needed such as deciding whether a treatment should be administered systemically or locally. Healthcare providers must be proficient in the delivery of the medication, have the best interests of the patient in mind, and document adequately. Lastly, they must provide the necessary information to the patient and their support people about why, how, and when medications are to be administered and their potential side effects (Holmboe et al., 2010).

Professions with state licensure only allowed to practice in the state in which their license belongs to. Each state has the right to decide who gets issued a professional license and what the qualifications are.

Professional Ability to Prescribe Medications in Colorado

Physicians

Physicians are medical professionals who hold an MD or a DO degree from an accredited university. Medical institutions are accredited by the World Federation of Medical Education (WFME) and/or the Liaison Committee on Medical Education (LCME). Physicians have the highest degree of prescriptive authority and can prescribe medications including controlled substances with valid DEA licenses.

State licensure is required in order for physicians to practice. For example, the state of Colorado Medical Board requirements includes proof of graduation from medical school, the passage of nationally recognized exams, satisfactory completion of postgraduate education, and submission of reference letters from previous practice locations (CO Rev Stat § 12-240-10, 2020).

The American Medical Association Code of Ethics states that, in general, physicians should not treat themselves or members of their own families (AMA Code of Medical Ethics, 2012). However, it may be acceptable to do so in limited circumstances, such as emergency settings or isolated settings where there is no other qualified physician available, or for short-term, minor problems. When treating themselves or family members, physicians have a further responsibility to document treatment or care provided and convey relevant information to the patient's primary care physician (AMA Journal of Ethics, 2022). However, some states may prohibit physicians from prescribing, dispensing, or administering certain medications to

themselves or family members (CO Rev Stat § 12-240-121, 2020). Additionally, physicians may also be disciplined at the state level for writing prescriptions outside their scope of practice, which could include self-prescriptions.

Advanced Practice Registered Nurses (APRNs)

An advanced practice registered nurse (APRN) is a registered professional nurse who obtains specialized education or training from an accredited institution, and who applies to and is accepted by the board for inclusion in the advanced practice registry. Advanced practice registered nurses may also hold the title "certified nurse midwife (C.N.M.)", "clinical nurse specialist (C.N.S.)", "certified registered nurse anesthetist (C.R.N.A.)", or "nurse practitioner (N.P.)" as authorized by the state board of nursing (CO Code § 12-255-111, 2022).

Advanced practice registered nurses require state licensure. In the state of Colorado, the requirements for professional nurse licensure include the successful completion of an appropriate graduate degree, passing of an examination, and national certification from a nationally recognized accrediting agency, such as the American Nurses Association (ANA) (CO Code § 12-255-110, 2022).

Advanced practice registered nurses who are listed on the advanced practice registry have a license in good standing without disciplinary sanctions issued pursuant to section 12-255-110, and have fulfilled requirements established by the board may be authorized by the board to prescribe controlled substances or prescription drugs (CO Rev Stat § 12-255-112, 2020). Licensed physicians are able and encouraged to serve as mentors for advanced practice registered nurses who are applying for prescriptive authority (CO Code § 12-240-108, 2022). Advanced practice registered nurses with prescriptive authority must have their own DEA registration number.

Naturopathic Doctors

A naturopathic doctor (ND) is a person who practices a system of health care for the prevention, diagnosis, evaluation, and treatment of injuries, diseases, and conditions of the human body through the use of education, nutrition, naturopathic preparations, natural medicines and other therapies, and other modalities that are designed to support or supplement the human body's own natural self-healing processes (CO Code § 12-250-103, 2022). Naturopathic doctors are required to obtain a bachelor's degree, a naturopathy degree from an approved naturopathic medical college, successfully passed a comprehensive competency-based national naturopathic licensing examination administered by the North American Board of Naturopathic Examiners, and has not had a previous health care license revoked (CO Code § 12-250-107, 2022).

Naturopathic doctors are authorized to obtain, dispense, administer, order, and prescribe epinephrine to treat anaphylaxis, barrier contraceptives excluding intrauterine devices, oxygen in emergency use, vitamins B6 and B12, vaccines in accordance with the Advisory Committee on Immunization Practices (ACIP) guidelines, and substances that are regulated by the FDA and do not require a prescription to be dispensed. An ND shall not prescribe, dispense, administer, or inject a controlled substance or device identified in the federal "Controlled Substances Act", 21 U.S.C. Section 801 et seq. (CO Code § 12-250-106, 2022).

Optometrists

An optometrist is a healthcare professional who examines, diagnoses, treats, and manages diseases and disorders of the eye. Additionally, they can detect systemic diseases, and diagnose, treat, and manage ocular manifestations of those diseases.

To become a licensed optometrist, applicants must have graduated with a degree of Doctor of Optometry from a school or college of optometry accredited by CHEA. Additionally, applicants must pass a written examination from the National Board of

Examiners in Optometry and must not have a substance use disorder (CO Code § 12-275-110, 2022). Optometrists have the authority to prescribe Schedule II controlled narcotic substances limited to hydrocodone combination drugs and Schedule III, IV, and V controlled narcotic substances for ocular disease. Optometrists are not authorized to perform surgery of the eye, prescribe Schedule I or II narcotics, except for hydrocodone combination drugs, treat posterior uveitis, or use injectable drugs, except for the use of an epinephrine auto-injector to counteract anaphylactic reactions (CO Code § 12-275-103, 2022).

Physicians Assistants

Physicians Assistants (PAs) are state-licensed, nationally certified medical professionals who assistants to diagnose illness, develop, and manage treatment plans, prescribe medications, and often serve as a patient's principal healthcare provider. To be licensed as a physician assistant, applicants must have successfully completed an education program for physician assistants that conforms to standards approved by the Colorado Medical Board and have successfully completed the national certifying examination for physician assistants that is administered by the National Commission on Certification of Physician Assistants or a successor organization (CO Code § 12-240-113, 2022).

Licensed physicians can delegate PAs to perform medical acts, including the authority to prescribe medication, including controlled substances. The acts must be consistent with sound medical practice. Each prescription for a controlled substance issued by a licensed PA shall be imprinted with the name of the PA's supervising physician. For all other prescriptions issued by a PA, the name and address of the health facility and, if the health facility is a multi-specialty organization, the name and address of the specialty clinic within the health facility where the PA is practicing must be imprinted on the prescription (CO Code § 12-240-107, 2022). In 43 states, PAs are regulated by the medical board. However, in 8 states (Arizona, California, Iowa,

Massachusetts, Michigan, Rhode Island, Tennessee, and Utah), PAs have a separate and independent regulatory board (American Medical Association, 2018).

Podiatrists

A podiatrist is a healthcare professional who is authorized to treat, prescribe for, palliate, correct, or prevent any disease, ailment, pain, injury, deformity, or physical condition of the human toe, foot, ankle, tendons that insert into the foot, and soft tissue below the mid-calf, by the use of any medical, surgical, mechanical, manipulative, or electrical treatment (CO Code § 12-290-102, 2022). Podiatrists are required to have graduated from a podiatric medical school, passed the part I and part II examinations by the National Board of Podiatric Medical Examiners or its successor organization, and has completed a one-year residency program approved by the Colorado Medical Board (CO Code § 12-290-107, 2022). Podiatrists who are certified by the American Board of Podiatric Surgery are authorized to perform surgery on the ankle below the dermis. A podiatrist may possess, order, prescribe, dispense, or administer medicines and/or drugs in order to treat a patient's toe, foot, ankle, and/or tendons. Podiatrists may not administer an anesthetic other than a local anesthetic.

Emergency Medical Service Providers

Emergency situations requiring immediate response may delegate authority to healthcare providers to provide medical care, including drug administration (Nissen et al., 2010). Emergency medical responders (EMRs) are health emergency professionals who answer emergency calls, provide effective and immediate care to ill and injured patients, prepare the scene for the arrival of the ambulance and emergency medical service providers (EMSPs), and aid EMSPs as directed (CO Code § 25-3.5-1101, 2022).

For any person responsible for providing direct emergency medical care and treatment to patients transported in an ambulance, the minimum requirement is possession of an EMSP

certificate or license issued by the department (CO Code § 25-3.5-202, 2022). The Colorado Department of Public Health and Environment shall design and establish specialized curricula for personnel who respond routinely to emergencies. The board of county commissioners may select from the various curricula available those courses meeting the minimum requirements established by said board (CO Code § 25-3.5-201, 2022). Requirements for EMR applicants include certification of the applicant through a nationally recognized emergency responder certification organization, training requirements, and criminal history record checks (CO Code § 25-3.5-1103, 2022).

EMSPs shall perform in-scope tasks and procedures pursuant to orders or instructions from, and under the medical supervision of, a medical supervisor, including administering medications. Medical supervisors must be immediately available and physically present at the clinical setting where the care is being delivered to provide oversight, guidance, or instruction to the EMSP during their performance of in-scope tasks and procedures (CO Code § 25-3.5-207, 2022). EMSPs are not authorized to prescribe medications.

Physical Therapists

A physical therapist (PT) is an expert in movement who improves quality of life and mobility through exercise. These exercises are designed to fit a patients' individual needs to improve their ability to move, reduce or manage pain, restore function, and prevent disability.

PTs oversee the administration, evaluation, and interpretation of tests and measurements of bodily functions and structures, the planning, administration, evaluation, and modification of treatment and instruction, the use of physical agents, measures, activities, and devices for preventive and therapeutic purposes, and the administration of topical and aerosol medications consistent with the scope of PT practice (CO Code § 12-285-104, 2022). PTs are not authorized to practice medicine or perform surgery (CO Code § 12-285-108, 2022).

PTs are required to hold a license in the state they are practicing in (CO Code § 12-285-109, 2022). License applicants must successfully complete a nationally accredited physical therapy program and pass a written examination (CO Code § 12-285-110, 2022).

Acupuncturists

Acupuncture is a system of health care based upon traditional Chinese medical concepts that employs oriental methods of diagnosis, treatment, and adjunctive therapies for the promotion, maintenance, and restoration of health and the prevention of disease through injection therapy (CO Code § 12-200-103, 2022). Injection therapy is the practice of inserting very thin needles through the skin at strategic points on the body to stimulate nerves, muscles, and connective tissue.

To become an acupuncturist, three to four academic years of education at an acupuncture program accredited by the Accreditation Commission for Acupuncture and Oriental Medicine (ACAOM) is required. ACAOM is the only accrediting body recognized by the United States Department of Education as the authority for quality education and training in acupuncture and Oriental medicine. If the rigorous criteria are met following completion of the accredited education, certification is awarded through the National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM) (Chon & Lee, 2013). Following completion of an education program, acupuncturist candidates may apply for state licensure, including paying the license, renewal, and reinstatement fees (CO Code § 12-200-106, 2022).

In the state of Colorado, acupuncturists are authorized to perform injection therapy, including the injection of sterile herbs, vitamins, minerals, homeopathic substances, or other non-IV injections into acupuncture points. Additionally, acupuncturists are authorized to administer oxygen and epinephrine for the purpose of addressing allergic reactions. Acupuncturists are not

authorized to perform surgery, spinal adjustments, manipulations, mobilization, or any other form of medicine (CO Code § 12-200-103, 2022).

Audiologists

An audiologist is a professional who applies principles, methods, and procedures related to the development, disorders, and conditions of the human auditory-vestibular system, whether those disorders or conditions are of organic or functional origin, including disorders of hearing, balance, tinnitus, auditory processing, and other neural functions, as those principles, methods, and procedures are taught in accredited programs in audiology (CO Code § 12-210-102, 2022).

Audiologists must have a state license to practice. To qualify for licensure an audiologist, applicants must have earned a doctoral degree in audiology from a program that is accredited by a national, regional, or state agency. Additionally, applicants must obtain a certificate of competency in audiology from a nationally recognized certification agency such as the American Academy of Audiology or the American Board of Audiologists (CO Code § 12-210-105, 2022). Audiologists are not authorized to practice medicine or prescribe medications (CO Code § 12-210-103, 2022).

Summary

The pathways to obtaining prescriptive authority vary from profession to profession. Each has a distinct degree, supervised training, national examinations, and optional professional organizations to verify proper education and clinical competency. Several specialties of medicine authorize healthcare professionals to prescribe and dispense medications appropriate to their field of study. Therefore, audiologists should consider pursuing prescriptive authority for topical medications for outer ear pathologies in order to better serve their patients.

CHAPTER III

CRITICAL APPRAISAL OF THE RESEARCH AND FUTURE DIRECTIONS

Assessment of the Existing Literature

The Colorado Revised Statutes outlines the scenarios in which healthcare professionals can prescribe drugs or medications in varying schedules. Advanced practice registered nurses may be to prescribe controlled substances or prescription drugs (CO Rev Stat § 12-255-112, 2020) and have their own DEA registration number. Additionally, licensed physicians can delegate PAs to perform medical acts, including prescribing medication, including controlled substances. Each prescription for a controlled substance issued by a licensed PA shall be imprinted with the name of the PA's supervising physician (CO Code § 12-240-107, 2022). Audiologists are not authorized to practice medicine (CO Code § 12-210-103, 2022). Audiologists in the state of Colorado would be unable to prescribe topical otic medications, and there is no research considering the risks, costs, or potential benefits of doing so.

The literature regarding the efficacy of topical treatments for acute otitis externa is extensive and peer reviewed. The Center for Drug Evaluation and Research, a division of the FDA, evaluates all new drugs before they can be marketed in the United States. This process ensures that both brand name and generic drugs are safe, efficient, and that the health benefits outweigh the known risks. Companies wanting to manufacturer and sell a drug in the United States must first perform a series of investigations to determine if the drug is safe and effective.

The process of drug development, from initial discovery to market approval, requires 10 years on average (Ciociola et al., 2014). The FDA identifies the appropriate schedule level for the drug and topical otic drugs OTC and not regulated by the FDA since they do not contain drugs. The oversight for OTC substances is not defined and these substances are not regulated in the U.S., so cerumenolytics may need further research to identify their purity and effectiveness. Other topical otic drugs would fall under FDA categorization and monitoring.

Gaps in the Literature

Currently, there is no published literature regarding whether audiologists should possess prescriptive authority in any capacity. Pasko (2022) states that in order to provide optimal, patient-centered care, audiologists must be familiar with commonly prescribed medications, the conditions that said medications are used to treat, and the effects on the body. Therefore, audiologists cannot claim to be able to prescribe topical otic medications at this time. To support the claim that audiologists should be authorized to prescribe topical otic medications in the future, there is a need to generate substantive and supportive peer-reviewed literature. Research needs to emerge investigating an audiologist's clinical competence in correctly identifying outer ear pathologies and subsequently, correctly identifying the optimal and appropriate treatment option, including dosage and possible adverse effects. Similarly, literature supporting changes in audiology doctoral curriculum in successfully educating audiology students in the correct identification and treatment of outer ear pathologies would further support audiology prescriptive authority.

Rationale for Implementation of Prescriptive Authority for Audiologists

Otitis externa is one of the more common diseases in ear, nose, and throat practices, and is also frequently encountered in primary and pediatric care facilities (Schilder et al., 2016). It

ranges in severity from a mild infection to life-threatening malignant otitis externa (Bojrab, et al., 1996). Treatment for acute otitis externa includes pain control, treatment of infection, and avoiding precipitating factors, which are most often accomplished with aural toilet or ear irrigation, topical antibiotics and topical steroids, and over-the-counter oral pain medication. Oral antibiotics are rarely utilized as the first treatment option (Halpern, Palmer, & Seidlin, 1999).

In the United States, 2.4 million healthcare visits for acute otitis externa were recorded in 2007; approximately half were between the ages of 5-14 years old. Healthcare providers were estimated to have spent about 600,000 hours treating acute otitis externa. The public indirect costs of acute otitis externa are likely to be substantial as a result of severe and persistent otalgia that limits activities, including education, work, home life, and social events (Centers for Disease Control and Prevention, 2011).

Due to the growing demand for prescription medications (Mohamadloo et al., 2019) and the substantial burden of acute otitis externa on healthcare facilities and society, audiologists should be considered as a healthcare professional with limited prescriptive authority to treat acute otitis externa and other dermatologic external ear pathologies. Further considerations into the methods of implementation and the legal requirements for authorizing audiologists prescriptive authority should be explored further.

Influential Considerations

There are state, federal, insurance, professional approvals, and third-party payers to consider prior to pursuing prescriptive authority. These requirements pertain to state and federal scope of practice and secure the ability to deliver and be reimbursed for prescriptive activity.

Medicare

Medicare is the federal health insurance program in the United States for people who are 65 or older, qualifying people with disabilities, and people with End-Stage Renal Disease. As of

2022, approximately 18.7 percent of the U.S. population was covered by Medicare (US Census Bureau, 2023).

Physicians and other healthcare professionals have different diagnostic and procedural code sets available to them for billing and reimbursement under the Medicare Physician Fee Schedule, which is the complete listing of maximum fees the Center for Medicare and Medicaid Services (CMS) will reimburse a healthcare provider for an approved service. Audiologists are not recognized as providers of evaluation and management services and therefore do not have access to respective billing code sets (Miller et al., 2022). However, evaluation and management services are recognized for audiologists through the CMS's Merit-based Incentive Payment Scale (MIPS) quality payment program (Centers for Medicare and Medicaid Services, 2020). The limited classification of audiologists as suppliers of "other diagnostic tests" limits reimbursement for audiologists for these types of services, to those which are within their state and federal scope of practice.

Currently, Medicare provides coverage for diagnostic services including hearing and vestibular evaluations and implantable hearing devices such as cochlear implants under Section 1861(s)(3) of the Social Security Act (SSA) (Sec. 1861. [42 U.S.C. 1395x]). Medicare specifically excludes hearing aid provision, including diagnostic assessment for the purpose of obtaining or fitting hearing aids. Additional barriers for Medicare beneficiaries who seek hearing and balance services include requiring medical necessity (such as new signs and symptoms, disruptions in daily life, and safety) and requiring a physician order. It should be noted that other federally funded healthcare systems, such as the Veterans Health Administration, as well as some private healthcare insurances, allow beneficiaries to access audiology services without

requiring a physician's order. However, Medicare drug coverage is a separate, called Medicare Plan D, and is not part of hospital or medical service coverages.

Prior to pursuing prescriptive authority, audiologists will want to ensure they will be able to bill Medicare, as well as other healthcare insurances, in order to be reimbursed for their services. The federal health policy classification of audiologists could be changed through an amendment to the SSA, which depends exclusively on congressional support, which is obtained through lobbying a legislature. The Medicare Audiologist Access and Services Act was introduced in the 118th Congress and proposes amendments to the SSA that would recognize audiologists for their scope of practice within the Medicare program (Medicare Audiology Access Improvement Act of 2023).

Lobbying

In the state of Colorado, *lobbying* means:

> Communicating directly, or soliciting others to communicate, with a covered official for the purpose of aiding in or influencing the drafting, introduction, sponsorship, consideration, debate, amendment, passage, defeat, approval, or veto by any covered official on any matter pending or proposed in writing by any covered official for consideration by either house of the general assembly or a committee thereof (Colo. Rev. Stat. § 24-6-301).

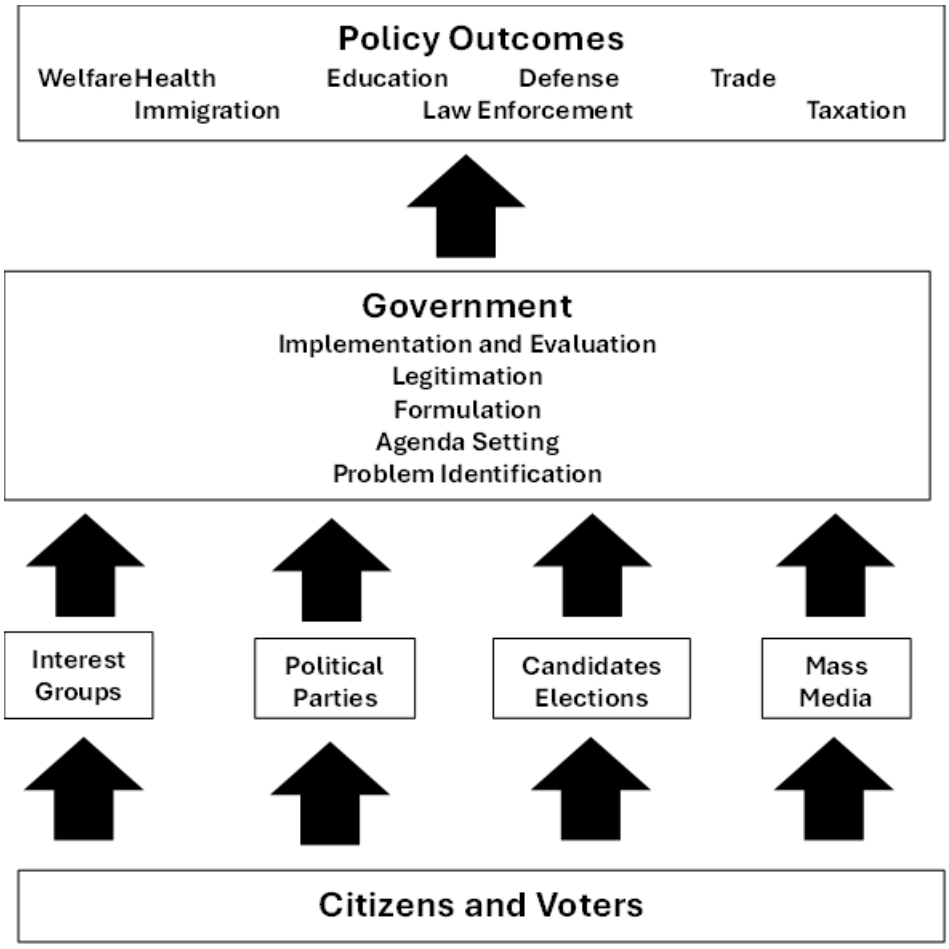
Health care organizations lobby lawmakers to influence health policy and law decisions, including compensation for goods and services, licensing and oversight, and research priorities (Landers & Sehgal, 2004). In 2022, the total lobbying spending in the United States amounted to 4.09 billion U.S. dollars (opensecrets.org, 2023). and "Health Professional" specific lobbying amounted to 95.72 million U.S. dollars (CRP & opensecrets.org, 2023). Lobbying for

prescriptive authority will take grassroots funding to support the political efforts needed to change existing laws and regulations that limit prescriptive authority.

Lobbying would likely need to be pursued on both the federal and at each state level. The process of bottom-up policymaking includes drafting and carrying a bill in conjunction with the legislature. In the state of Colorado, the current licensure bill will go under sunset review in 2031 to decide whether the bill will continue as is or continue with revisions. Prior to including any expansion in federal or state regulations, the professional scope of practice for audiology would need to be expanded to include prescriptive authority for topical otic drugs. Bottom-up policymaking is especially challenging as there are multiple opportunities from citizens, other professions, governing bodies, and political parties to oppose the proposed amendment.

Figure 1.1

Bottom-Up Policymaking



Adapted from "Policymaking from the Top Down," by T. R. Dye, 2001, CQ Press.

Scope of Practice

Audiology professional organizations, such as the American Academy of Audiology and the American Speech-Language-Hearing Association would need to formally expand the scope of practice. This is accomplished by a team or board assembling a draft outlining the proposed changes, with specific requirements for amendment to the scope of practice outlined in each

organization's bylaws. Considerations include how the profession is presently defined and if it has developed over the years, such as evolution of the profession towards the addition of the new skill or service, including evidence of this evolution and how the new skill or service fit within or enhance a current area of expertise. Additionally, education and training, as well as evidence of competency, are necessary before drafting the amendments to the scope of practice.

Strategies for Implementation

Update Au.D. Curriculum

In order to respond to the nationwide demands for acute otitis externa care, along with the discrepancy between prescribing physicians and prescription demands, audiology curriculum could change to include prescription of topical medications for acute otitis externa. Curriculum changes could include added pharmacology and dermatology classwork and clinical experience hours, achieved by the addition of pharmacology and dermatology experiences for students at accredited universities offering the Au.D. degree. Following appropriate education and clinical experience, research on the efficacy of the education in regard to the sensitivity and specificity of diagnoses and treatment should be conducted and evaluated in order to support clinical competency in those areas.

Reduced Prescriptive Authority

A potential method of implementation for audiologist prescriptive authority could be reduced authority while collaborating with otolaryngologists, otologists, and neurotologists in joint practices. Healthcare professionals who do not hold MDs or DOs and have a reduced amount of prescriptive authority include APRNs and PAs. In general, PAs can prescribe medications in collaboration with supervising physicians. (Gadbois et al., 2015) while nurse

practitioner prescriptive authority varies from state to state but overall have a broader scope of practice and fewer limitations on prescriptive authority than PAs (Zhang & Patel, 2022).

Another potential method of implementation would be changing state and federal laws to allow audiologists to have prescriptive authority for a small selection of topical medications for acute otitis externa. Historically, federal laws have changed the legality of drug prescription for non-physician healthcare professionals. Expansion of the drug buprenorphine for opioid abuse disorder is a core factor of opioid epidemic prevention. Buprenorphine is an FDA-approved drug for opioid dependency. The Comprehensive Addiction and Recovery Act (CARA) of 2016 authorized NPs and PAs to obtain a Drug Authorization Treatment Act (DATA)-waiver to prescribe buprenorphine. As a result, the number of buprenorphine prescriptions dispensed increase 9.1% from 2017 to 2018 (Roehler et al., 2020), allowing many opioid-dependent people to receive medical attention.

Summary

The demand for healthcare professionals in the United States is increasing due to the rising number of prescriptions written annually; the prevalence of healthcare visits for acute otitis externa and time spent by healthcare providers in treating this condition is significant. Different medical professionals have different roles in prescribing, dispensing, and administering medications; it is important for all healthcare professionals, including audiologists, to understand why drugs are given, when they should be given, how they work, and their impact on patients. Pharmacodynamics and pharmacokinetics determine the effects of drugs on the body and the relationship between drug dose and therapeutic effects, and there are different types of drug forms, consumer safety, drug names, legal accessibility to drugs, and medication errors. It is important to correctly identify and treat dermatologic and otologic pathologies of the outer and

middle ear with appropriate medications or treatments, such as home remedies, cerumenolytics, otic anesthetics, otic anti-infectives, otic steroids, and combination otic steroids with anti-infectives.

Healthcare providers, such as physicians, advanced practice registered nurses, naturopathic doctors, optometrists, physician's assistants, podiatrists, emergency medical service providers, physical therapists, and acupuncturists have some amount of authority to prescribe specific medications, some including controlled substances, which is allocated by federal and state governments. There is a lack of research on the need for audiologists to have prescriptive authority, educational preparation in otologic pharmacology, and professional perspectives on this topic.

Potential benefits of audiologists having prescriptive authority include improved patient care, increased efficiency in treatment, and enhanced professional autonomy. The current landscape of prescriptive authority for audiologists in various states and the challenges and concerns exist associated with granting audiologists prescriptive authority include the need for additional education and training, legal and ethical considerations, and potential resistance from other healthcare professionals. To pursue prescriptive authority, collaboration among audiologists, professional organizations, legislators, and other stakeholders in advocating for and implementing changes to expand the audiology scope of practice must emerge.

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