Pharmacy Implementation of OTC and DTC Hearing Aid Devices: Expanding public access to hearing aids

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Disclosures

Employee of the University of Pittsburgh Co-owner of Embarx, LLC





Past, current, and future implementation models for OTC and DTC hearing aids sold at community pharmacies will be outlined. Emphasis will be placed on how audiologists and hearing aid dispensers can work collaboratively with pharmacies to reach populations underserved by existing hearing aid dispensing locations.



Acknowledgement

Elaine Mormer, PhD, CCC-A Professor Vice Chair for Clinical Education University of Pittsburgh





Learning Assessment

- 1. Which of the following locations in the pharmacy would require a conversation with a pharmacy employee?
 - a. On the shelf, unsecured
 - b. On the shelf, secured
 - c. Behind the front register
 - d. Behind the pharmacy counter



Learning Assessment

2. During "Assess", pharmacists evaluate patients for red flag conditions, also known to pharmacists as which of the following?

- a. Boxed warnings
- b. Contraindications
- c. Exclusions for self-care
- d. Precautions



Learning Assessment

- **3.** Audiologists and hearing aid dispensers may refer patients to pharmacists for which of the following?
 - a. Patient dissatisfaction with OTC hearing aids
 - b. Self-treatment of dermatitis of the external ear
 - c. Refined customizations of OTC hearing aids
 - d. Conditions excluding patient use of OTC hearing aids



Case Study – The Pharmacy

A 71-year-old retired male approaches the pharmacy counter to purchase an OTC hearing aid. His spouse notes that he watches television too loudly. The patient's primary goals are to obtain OTC hearing aids quickly given his excitement for an affordable hearing solution. He is seeking a style that would fit in the ear canal versus behind the ear. He would also like a rechargeable battery feature, but he's not sure which model would be right for him.



Why Pharmacy?

- Pharmacies are destinations for health & wellness
- All pharmacists follow a standard patient care process
- Nonprescription models expand patient access
- Pharmacists are collaborators



The "Counter"





Case Study – cont.

A 71-year-old retired male approaches the pharmacy counter to purchase an OTC hearing aid. His spouse notes that he watches television too loudly. The patient's primary goals are to obtain OTC hearing aids quickly given his excitement for an affordable hearing solution. He is seeking a style that would fit in the ear canal versus behind the ear. He would also like a rechargeable battery feature, but he's not sure which model would be right for him.



Pharmacies are destinations for health and wellness.

PUBLIC HEALTH INITIATIVES

- Diabetes education and lifestyle coaching
- Naloxone for opioid overdose
- Test and treat (e.g., COVID-19, influenza, sexually transmitted infections, group A strep)
- Tobacco and nicotine cessation
- Vaccinations



Pharmacies are accessible to most Americans.



90% of Americans live within 5 miles of a community pharmacy
Nationwide networks of corporate chain pharmacies
Open nights, weekends, holidays and sometimes 24 hours



Berenbrok et al. JAPhA. 2022.

Hearing aids can be found near pharmacists.



Hearing professional located nearby pharmacist Hearing professional performs telehealth in pharmacy

DTC

OTC

Pharmacist assists with self-care



Products are intentionally placed in pharmacies.

LOCATION	EXAMPLES	ID REQUIRED?	ENCOUNTER TYPE
On the shelf, unsecured	OTC medications and dietary supplements	NO	Optional conversation with pharmacist
On the shelf, secured	Men's razor blades	NO	Required request to non-pharmacy employee
On the shelf, display only	Wheelchairs and walkers	NO	Required request to non-pharmacy employee
Behind the front register	Cigarettes	YES age verification	Required request to non-pharmacy employee
Behind the pharmacy counter	Pseudoephedrine	YES quantity limits	Required conversation with pharmacy employee

Case Study – cont.

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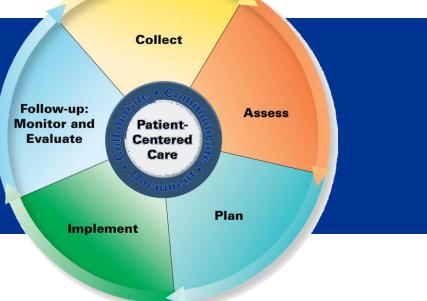


All pharmacists follow a standard patient care process.

Pharmacists' Patient Care Process

School of

University of **Pittsburgh**



Pharmacists make between 6-10 OTC recommendations per day.

- **Qu** Quickly and accurately assess the patient
- E Establish the patient is an appropriate self-care candidate
- **S** Suggest appropriate selfcare strategies
- T Talk with the patient

- **S** Symptoms
 - C Characteristics
- H History
- O Onset
 - Location
- A Aggravating factorsR Remitting factors



Pharmacists <u>ASSESS</u> patients for appropriate, safe, and effective medication use.

Exclusions for self-care

OTC medication labeling

- Uses
- Warnings
- Directions



Pharmacists <u>SCREEN</u> patients for chronic disease states.

Physical assessment & Point-of-care testing (vitals & specimen collection)

- Blood pressure hypertension
- Blood glucose diabetes
- Lipids high cholesterol

Reliable and valid screening questionnaires (paper & pencil)

- PHQ9 depression
- GAD7 anxiety
- ACT asthma



Case Study – cont.

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Nonprescription models expand patient access.

Rx-to-OTC SWITCH	THERAPEUTIC AREA	YEAR
OPILL® (norgestrel)	Hormonal contraception	2023
NARCAN® (naloxone)	Opioid overdose rescue	2023
VOLTAREN GEL® (diclofenac)	Arthritis pain	2020
FLONASE® (fluticasone)	Seasonal allergies	2014
ALLEGRA® (fexofenadine)	Seasonal allergies	2011
MIRALAX® (polyethylene glycol 3350)	Constipation	2006
PRILOSEC® (omeprazole)	Acid reflux/heartburn	2003

FDA. Prescription to Over-the-Counter (OTC) Switch List. https://www.fda.gov/aboutfda/center-drug-evaluation-and-research-cder/prescription-over-counter-otc-switch-list

Pharmacists can reach populations in remote areas.

40 of 67 Pennsylvania counties have
<10 hearing aid dispensaries
3 Pennsylvania counties have no
hearing aid dispensaries
At least 1 pharmacy in every county in
PA, including rural counties



Pharmacies have private patient care rooms ideal for telehealth.

Rx

DTC

OTC

Hearing professional located nearby pharmacist

Hearing professional performs telehealth in pharmacy Pharmacist assists with self-care



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Community pharmacists are collaborators.

Referrals from Pharmacists

- Exclusions for self-care
- Complex listening needs
- Refined customizations
- Support or dissatisfaction with OTCs

Referrals to Pharmacists

- Comprehensive medication review
- Purchase of OTC hearing aids
- Purchase of OTC hearing aid batteries
- Self removal of cerumen







Pharmacists are getting ready.

- 79% of pharmacists expect to need 6 months or less for preparation to sell OTC hearing aids
- Supporting factors included:
 - Training and educational resources for pharmacy staff
 - Connections to hearing professionals such as audiologists
 - Expertise of pharmacy colleagues



Pharmacists are learning.



Pharmacy-based OTC hearing aids advanced training program



Elaine Mormer, PhD, CCC-A

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PhA



American Pharmacists Association. Pharmacy-based OTC hearing aids advanced training program. https://www.pharmacist.com/Education/eLearning/Advanced-Training/Pharmacy-based-OTC-hearing-aids.

Pharmacy and audiology professional organizations are collaborating.

American Academy of Audiology

American Speech-Language-Hearing Association

American Pharmacists Association

National Community Pharmacists Association



Case Study – Outcomes

The patient was supplied with SONY CRE-C10 selffitting OTC hearing aids. **BENEFIT** was confirmed by improved scores (before/after) on the Self-Assessment of Communication and Significant Other Assessment of Communication tools. The patient continued to use the device pair for 1 year after first use with no reported issues. The patient continues to report high **SATISFACTION** with the device.



Conclusions

- Hearing aids are now available over-thecounter at community pharmacies
- Pharmacies are ideal locations for public health initiatives due to their unique accessibility
- Pharmacists are interested in working with audiologists to promote hearing care



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