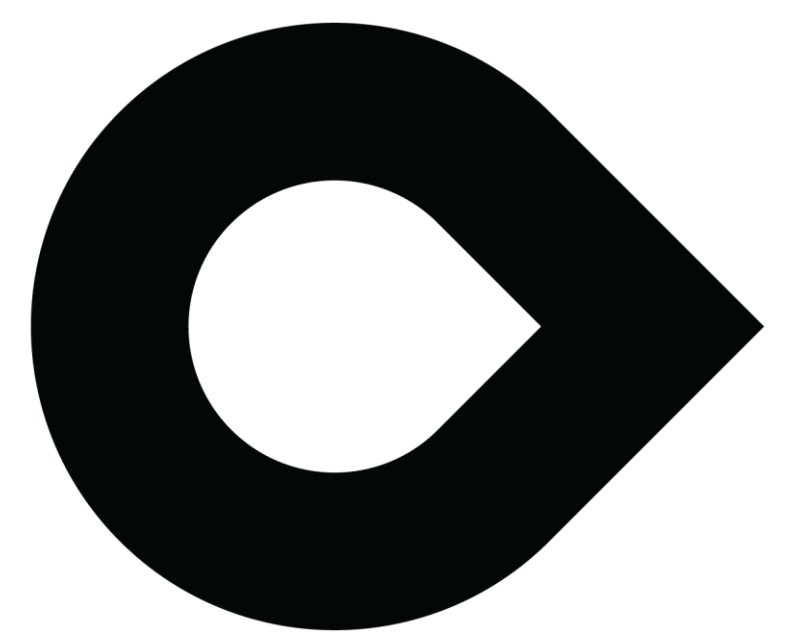


# Assessing the Impact of the FDA's OTC Hearing Aid Regulations: A Survey of User Experience and Perception of OTC Self-Fitting Hearing Aids



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## INTRODUCTION

In 2022, the US Food and Drug Administration issued final regulations to establish a category of over-the-counter (OTC) hearing aids. One-year post-enactment, progress toward more widespread adoption of hearing aids and perspectives from OTC users are not well understood.

The main goal of this study is:

- To investigate if the availability of self-fitting OTC hearing aids provided by a direct-to-consumer delivery and support model may help to facilitate the fulfillment of the FDA's intent behind OTC regulations.

Survey results from users of one company's OTC devices were analyzed, aiming to shed light on users' experiences and determine whether there have been improvements in factors such as adoption time, accessibility, affordability/ value, destigmatization, and competition/ innovation, while continuing to validate the efficacy of OTC devices.

## METHODS

- Survey was sent to those who had purchased a set of OTC hearing aids directly from Eargo via the Internet or phone between October 17, 2022 and May 31, 2023
- 884 full responses were collected
- Individuals did not receive any compensation for participating in the survey

## PARTICIPANTS

Table 1. Survey Respondent Demographics†

	All (N = 884)	<65 years (N = 215)	Actively Employed (N = 333)	New Users (N = 606)
<b>Gender</b>				
Male	667 (75.5)	173 (80.5)	273 (82.0)	460 (75.9)
Female	212 (24.0)	40 (18.6)	58 (17.4)	142 (23.4)
Non-binary	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Prefer not to say	5 (0.6)	2 (0.9)	2 (0.6)	4 (0.7)
<b>Age</b>				
18-29	2 (0.2)	2 (0.9)	1 (0.3)	1 (0.2)
30-39	8 (0.9)	8 (3.7)	8 (2.4)	7 (1.2)
40-49	20 (2.3)	20 (9.3)	20 (6.0)	14 (2.3)
50-59	85 (9.6)	85 (39.5)	77 (23.1)	64 (10.6)
60-69	305 (34.5)	100 (46.5)	143 (42.9)	211 (34.8)
70-79	364 (41.2)	0 (0.0)	73 (21.9)	255 (42.1)
80-89	92 (10.4)	0 (0.0)	10 (3.0)	50 (8.3)
90-99	4 (0.5)	0 (0.0)	0 (0.0)	2 (0.3)
Other	4 (0.5)	0 (0.0)	1 (0.3)	2 (0.3)
<b>Marital Status</b>				
Single	48 (5.4)	21 (9.8)	22 (6.6)	29 (4.8)
Married/ Domestic Partner	707 (80.0)	179 (83.3)	276 (82.9)	490 (80.9)
Divorced	54 (6.1)	9 (4.2)	17 (5.1)	34 (5.6)
Widowed	54 (6.1)	2 (0.9)	12 (3.6)	39 (6.4)
Prefer not to say	21 (2.4)	4 (1.9)	6 (1.8)	14 (2.3)
<b>Education</b>				
Did not graduate high school	7 (0.8)	1 (0.5)	4 (1.2)	5 (0.8)
High school degree or equivalent	63 (7.1)	19 (8.8)	27 (8.1)	43 (7.1)
Some college	163 (18.4)	35 (16.3)	55 (16.5)	97 (16.0)
Finished college	232 (26.2)	77 (35.8)	93 (27.9)	163 (26.9)
Some postgraduate education	81 (9.2)	12 (5.6)	24 (7.2)	52 (8.6)
Postgraduate or professional degree	330 (37.3)	68 (31.6)	127 (38.1)	241 (39.8)
Prefer not to say	8 (0.9)	3 (1.4)	3 (0.9)	5 (0.8)
<b>Employment</b>				
Employed full-time	276 (31.2)	165 (76.7)	276 (82.9)	204 (33.7)
Employed part-time	57 (6.4)	9 (4.2)	57 (17.1)	44 (7.3)
Retired	535 (60.5)	34 (15.8)	0 (0.0)	347 (57.3)
Not employed, not looking for work	8 (0.9)	3 (1.4)	0 (0.0)	6 (1.0)
Not employed, looking for work	3 (0.3)	2 (0.9)	0 (0.0)	2 (0.3)
Unable to work	5 (0.6)	2 (0.9)	0 (0.0)	3 (0.5)

## RESULTS

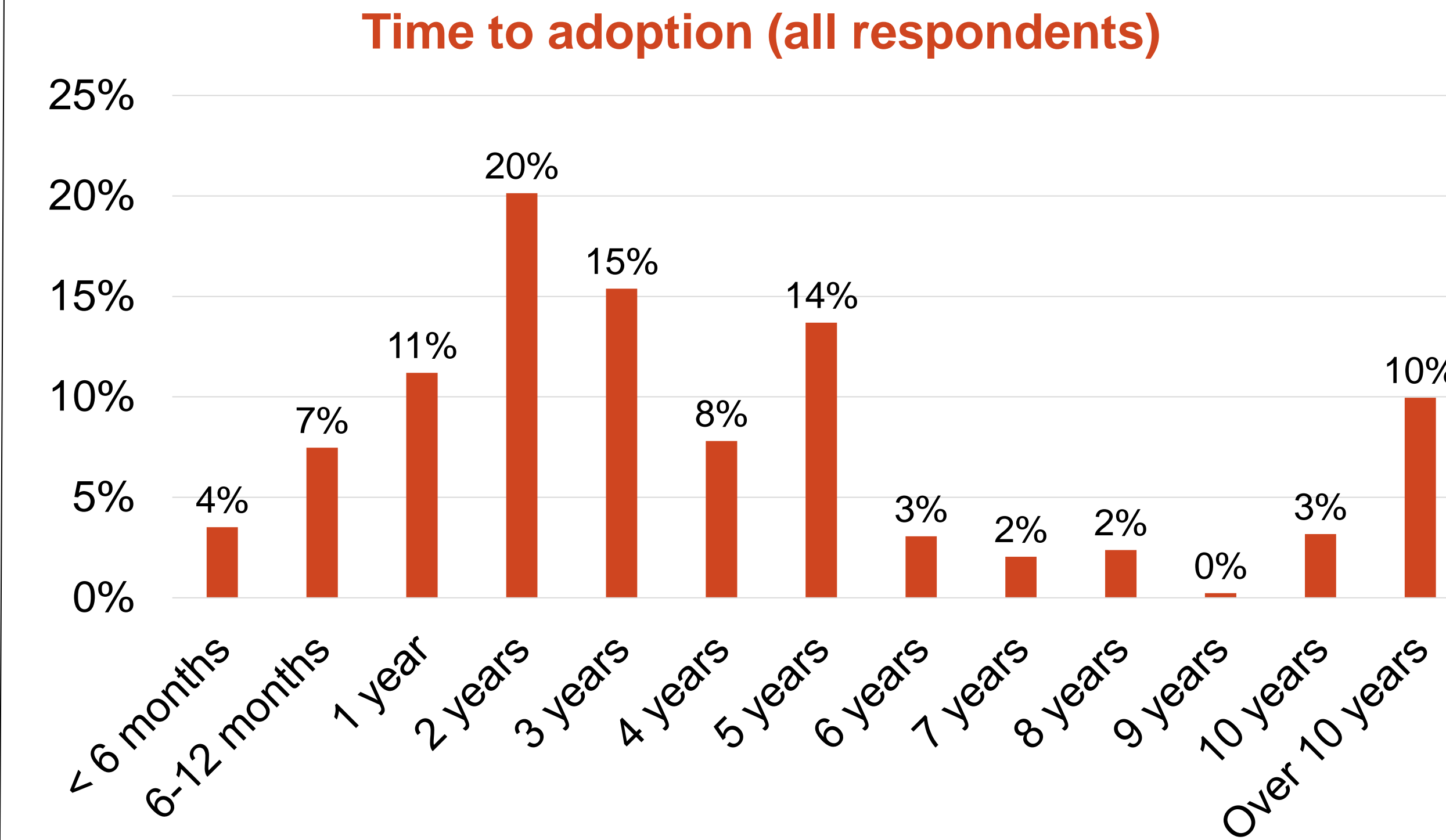


Figure 1. Distribution of time to adoption. The average time from when individuals recognized they had a hearing loss to getting their first hearing aid was approximately 4 years, with 80% adopting in 5 years or less and 42% adopting in 2 years or less. This is much shorter than the literature estimate of 8.9 years.<sup>1</sup>

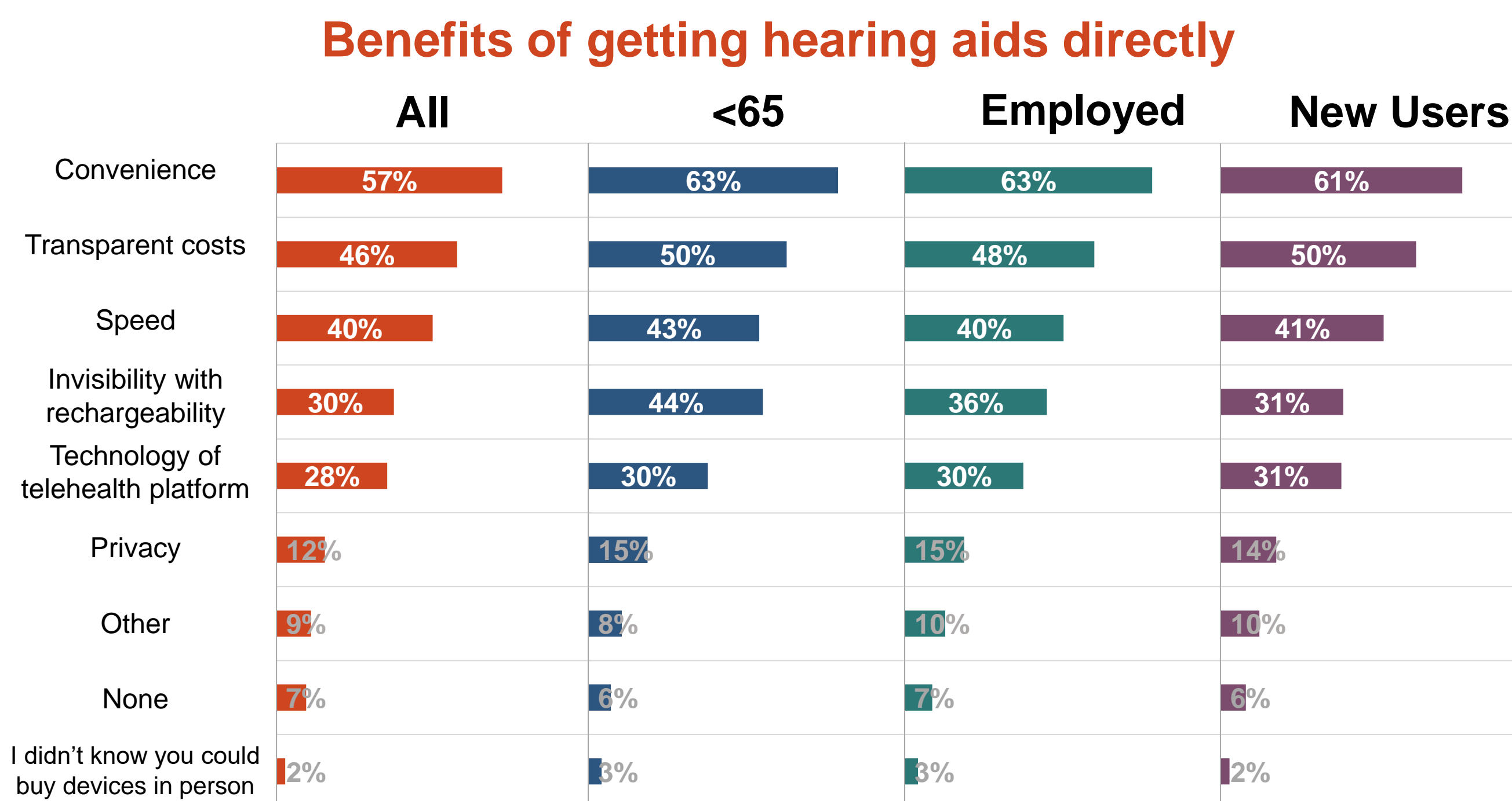


Figure 3. Benefits noted of getting hearing aids directly. The biggest benefits from purchasing directly were: convenience, transparent costs, speed, invisibility/ rechargeability of devices, and the technology of the virtual platform. Only 7% of respondents indicated they did not perceive any specific benefit to the direct-to-consumer service-delivery model.

## Invisibility and Form Factor‡

- 86% of respondent users ranked invisibility as very or moderately important when choosing a hearing aid
- Only half of respondents indicated with certainty that they would still purchase a hearing aid if no invisible options were available
- When shown pictures of form factors, respondents had a strong (87%) preference for CIC devices, with only 7% preferring a RIC style device.



## Group Definitions

- All: all survey respondents
- <65: all survey respondents under 65 years of age
- Employed: all respondents who reported full- or part-time employment
- New Users: all respondents who reported being a new hearing aid user

## Actions taken prior to obtaining OTC device

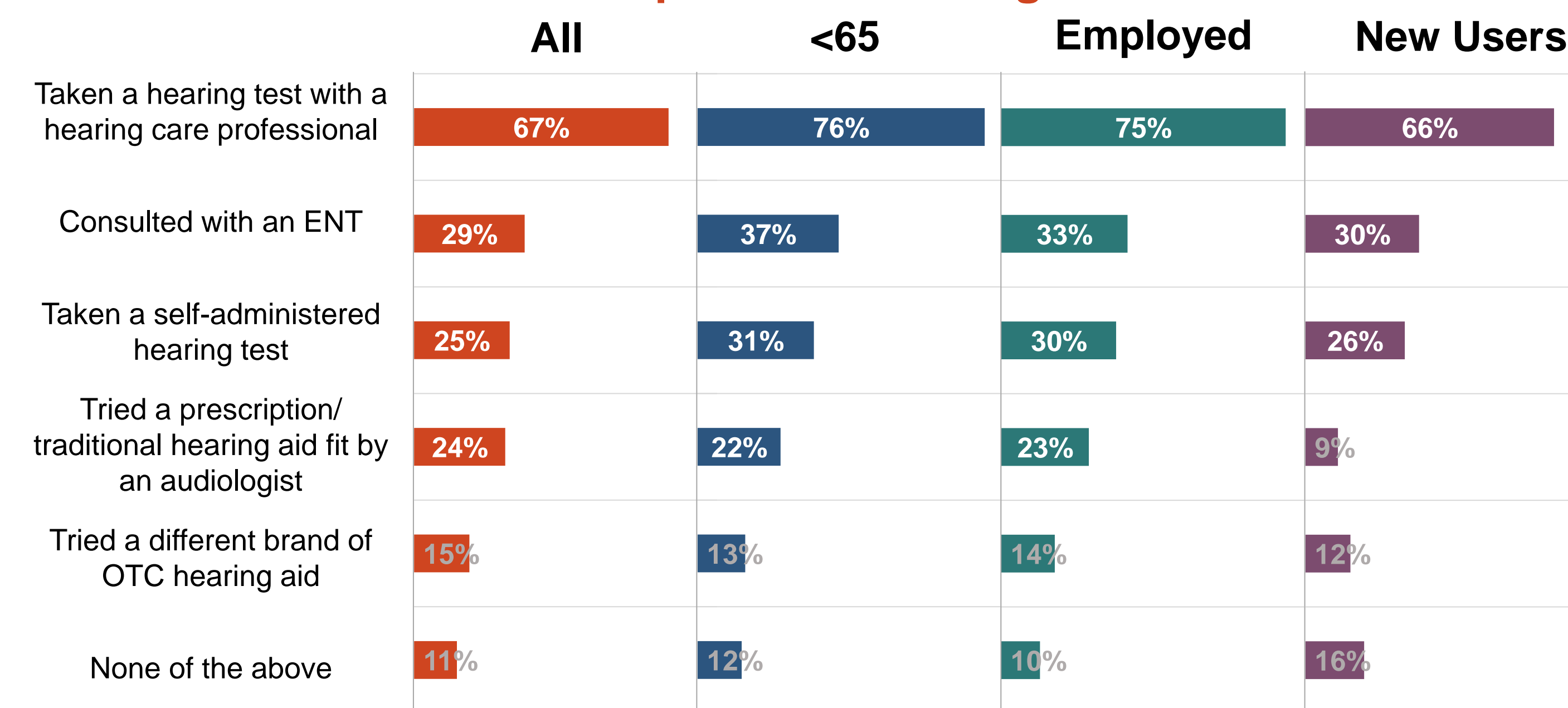


Figure 2. Actions taken prior to obtaining OTC device. Interestingly, most respondents had previously sought care in-person from a hearing care professional, despite ultimately purchasing through a direct-to-consumer service-delivery model.

## Barriers to getting hearing aids in-person

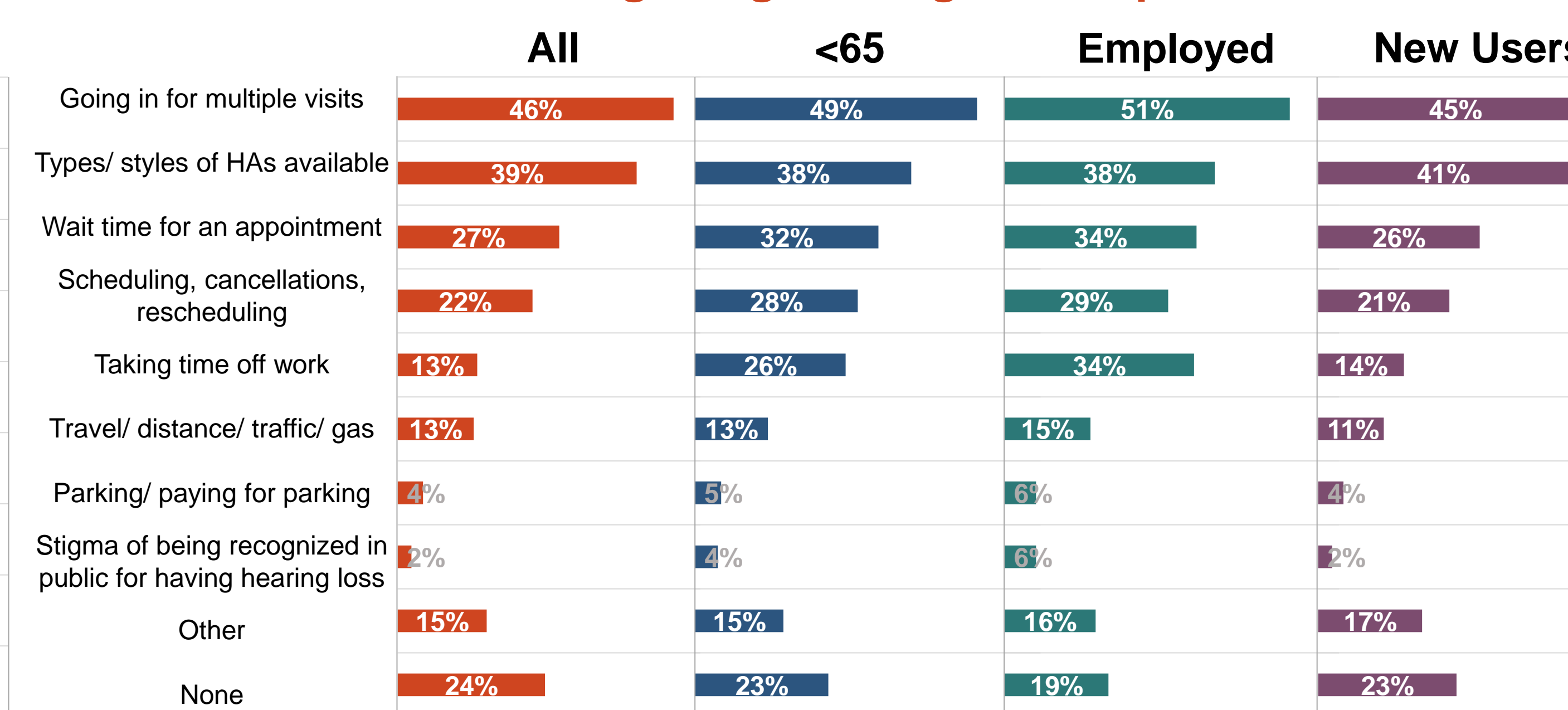


Figure 4. Drawbacks noted of getting hearing aids in-person. 76% of all respondents indicated they believed there were barriers to purchasing hearing aids in-person. The top barriers were going in for multiple visits, the types/ styles of devices available, and waiting for an appointment, which was consistent across subgroups. Those who are employed rated taking time off work as a barrier equal to waiting for an appointment.

## Prior Prescription/ Traditional Hearing Aid Users

- Majority of prior users found OTC devices to be as effective or more effective than their prior hearing aids
- 46% thought the traditional process was quick and efficient, whereas 87% thought the OTC process was quick and efficient

## Other key findings

- 70% of respondents were first-time hearing aid users
- 77% of respondents perceived that devices purchased directly online are more affordable or about the same cost as buying in-person, while only 3% of respondents perceived that devices purchased online are less affordable
- A majority of respondents report benefit from using their OTC devices in social situations, conversations, and their home life and that the devices met or exceeded their expectations

## Limitations

†The subject pool (highly educated, affluent) may impact responses, particularly those related to time to adoption.

‡Perceptions regarding invisibility/ form factor may be skewed as users self-selected to obtain a device only available in CIC form factor.

## DISCUSSION

Survey results suggest certain OTC hearing aids and direct-to-consumer service-delivery strategies are positively impacting accessibility, perception of affordability, stigma, and time to adoption; aiding to fulfill the FDA's intent behind OTC regulations.

This is evidenced by:

- Shorter time to adoption than literature estimates
- Numerous barriers to the traditional pathway and benefits to the direct pathway were reconfirmed
- High rate of first-time users, suggesting good reach to those with previously untreated hearing loss
- Despite prior users utilizing traditional devices for 1+ years (80%), 3+ years (46%), they switch to the direct care model
- Although most respondents participate in the traditional channel, they did not purchase hearing aids through that channel
- Notable benefit with OTC devices, comparable to traditional devices
- High perceived affordability
- Decreased stigma due to innovative technology within a small form factor

## FUTURE DIRECTIONS

- Encouraging wider availability and publication of data from manufacturers providing OTC devices can continue to aid in our understanding of OTC regulation impact and success.

- Continuing to encourage consumer-centric innovation in technology and service-delivery models may deepen the impact of the OTC hearing aid regulations and help to minimize the prevalence of untreated hearing loss in years to come.

## CITATION

<sup>1</sup>Simpson AN, Matthews LJ, Cassarly C, Dubno JR. Time from hearing-aid candidacy to hearing-aid adoption: a longitudinal cohort study. Ear hear. 2019; 40(3):468-476. doi:10.1097/AUD.0000000000000641.

## FOR FURTHER INFORMATION

Survey Questions Used | Hearing Review Publication



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