Make Listening Safe Workgroup

Comment to the FDA OTC-hearing aids proposal: 20th of November 2021

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Dear FDA team,

We welcome the initiative to improve access hearing aid technology for people with mild to moderate hearing loss, by the new category of over-the-counter (OTC) hearing aids, especially for those who are currently unable to access them due to the cost of services, when they are not refunded. This initiative is potentially good step as it is in line with the recommendation in the WHO world report on hearing, at stated on page 7 of the report "*To guide future action, the World report on hearing outlines a package of interventions for Member States to adopt, and proposes strategies for their integration in national health systems to ensure equitable access to ear and hearing care services for all those who need them, without financial hardship, in accordance with the principles of universal health coverage*."

However, we have concerns about the safety aspects of the current draft proposal, which proposes a limit of 120 dB SPL for an OTC hearing aid that implements input-controlled compression and a user-adjustable device volume control. With only this limit being required, OTC hearing aid users may be exposed to a significantly higher weekly sound dose than the 1.6 Pa^2h (equivalent to 80 dBA exposure for 40 hours), as required in the ITU/WHO H.870 (''Guidelines for safe listening devices/systems'') and ITU H.871 ("Safe listening guidelines for personal sound amplifiers") standards.

As stated in both ITU H.870 and H.871, the best solution would be to use smart devices with the capacity to measure weekly sound dose, so the user is informed and warned when the exposure is getting closer to 1.6 Pa^2h (equivalent to 80 dBA exposure for 40 hours).

If this is not possible, as when the devices don't have the capacity to measure weekly sound dose, ITU H.871 requires limiting the maximum output to 95 dBA. (a user then is unlikely to use the device at a level higher than 80 dBA since the dynamic range of speech has a crest factor of 12 to 17 dB.)

The fact that people have a hearing loss doesn't remove the risk of sound induced hearing loss.

Goel et al. (2021), in a longitudinal study involving 401 adult patients, found that the use of amplification resulted in a significantly higher (5dB) decline of hearing ($PTA_{3\text{-}freq}$) compared to the non-aided ears. In the discussion, the authors state that "*there are likely patients exposed to unsafe sound levels despite a prescribed safe MPO, including those who manually increase amplification due to preference for increased volume, spend significant time in environments with high ambient noise levels, and experience random technology error*"

Dolan & Maurer (1996), in "Noise exposure associated with hearing aid use in industry", conclude that "*Both methods demonstrated that even when amplified by mild-gain hearing aids, noise*

exposures rose from time-weighted averages near 80 dBA to well above the OSHA maximum of 90 dBA. The OSHA maximum was also exceeded when moderate and high gain instruments were worn in non-occupational listening environments. The results suggest that current OSHA regulations that limit noise exposure in sound field are inappropriate for hearing aid users"

Macrae (1995), in "Temporary and permanent threshold shift caused by hearing aid use", states that "*Excessive amplification by hearing aids causes temporary threshold shift (TTS) and permanent threshold shift (PTS)*"

Humes & Bess (1981), in "Tutorial on the potential deterioration in hearing due to hearing aid usage", conclude that "*Recommended gain settings established to protect the hearing of a person wearing a hearing aid from further decline following various durations of hearing aid usage are also provided*"

Johnson (2017), in "Safety limit warning levels for the avoidance of excessive sound amplification to protect against further hearing loss", recommends to set the max output level for people with normal hearing (0 dB 4FA dB HL) at 90 dBSPL, for mild hearing loss (WHO between 20 and < 35 $dBHL_{4\text{-}Freq}$) (20 dB 4FA dB HL) at 97 dBSPL, for moderate hearing loss (WHO between 35 and < 55 $dBHL_{4\text{-}Freq}$) (35 dB 4FA dB HL) at 103 dBSPL up to (50 dB 4FA dB HL) at 109 dBSPL.

Therefore our recommendation is:

As stated in both ITU H.870 and H.871, the best solution would be to use smart devices with the capacity to measure weekly sound dose, so the user is informed and warned when the exposure is getting closer to 1.6 Pa^2h (equivalent to 80 dBA exposure for 40 hours).

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References:

ITU-T H.870 (2018), Guidelines for safe listening devices/systems hiips://www.itu.int/rec/T- REC-H.870-201808-I

ITU-T H.871 (2019), Safe listening guidelines for personal sound amplifiers. hiips://www.itu.int/rec/T -REC-H.871-201907-I

Goel AR, Bruce HA, Williams N, Alexiades G. Long-Term Effects of Hearing Aids on Hearing Ability in Patients with Sensorineural Hearing Loss. J Am Acad Audiol. 2021 Jun 3. doi: 10.1055/s-0041-1731592. Epub ahead of print. PMID: 34082459.

Dolan TG, Maurer JF. Noise exposure associated with hearing aid use in industry. J Speech Hear Res 1996;39(02):251–260

Macrae JH. Temporary and permanent threshold shift caused by hearing aid use. J Speech Hear Res 1995;38(04):949–959

Humes LE, Bess FH. Tutorial on the potential deterioration in hearing due to hearing aid usage. J Speech Hear Res 1981;24(01): 3–15

Johnson E. (2017), Safety limit warning levels for the avoidance of excessive sound amplification to protect against further hearing loss, International Journal of Audiology, 56:11, pp. 829-836.

WHO. Safe listening devices and systems: a WHO-ITU standard. hiips:// www.who.int/publications/i/item/safe-listening-devices-and-systems-a-who-itu-standard

WHO. World Report on Hearing. hiips://www.who.int/publications/i/item/world- report-on-hearing