Research Assessment Exercise 2020
Impact Case Study

University:	The University of Hong Kong
Unit of Assessment (UoA):	UoA 41 education (incl. curriculum & instruction, education administration & policy and other education)
Title of case study:	Over-the-counter hearing aids: Improving life experience

(1) Summary of the impact

Around 466 million people worldwide have disabling hearing loss. Only 10% of these individuals have access to hearing aids. As hearing is essential to cognition, this is a significant problem for education throughout the lifespan, from schoolchildren to the elderly. In developed economies, recent policy recommendations have been made to improve access by reducing the regulatory burden on the sales of low-cost over-the-counter (OTC) hearing devices. This change will only benefit consumers if OTC hearing devices are appropriate for an individual's hearing loss. The hearing health policy of the World Health Organisation (WHO) for low- and medium-income countries also notes that the devices must suit the consumers' needs. Research conducted at HKU's Faculty of Education between 1998 and 2015 has highlighted the serious mismatch between the amplification pattern often provided by OTC hearing devices and that needed by those with hearing impairment. This research has shaped international policy (by the WHO and the National Academies of Science, Engineering and Medicine) and practice (OTC designers) by emphasising the need to develop products congruent with the consumer's auditory status and by signposting how this goal can be achieved.

(2) Underpinning research

Most adult hearing loss (HL) is due to presbycusis. In other words, it is related to ageing. This form of HL cannot be reversed but can often be effectively treated with hearing aids. The potential need for hearing devices in this group is very large. For example, it is estimated that more than two thirds of adults in the US over 70 years of age have clinically significant HL. The research at HKU focuses on presbycusis and considers whether available OTC devices provide amplification that meets the needs of elderly persons with HL. OTC devices are basic hearing aids that are considered affordable—often costing no more than approximately US$200, as compared to professionally fitted devices, which can cost US$2,000-6,000 per pair—and are available at retail stores and online without professional mediation.

Unlike many jurisdictions, Hong Kong places no restrictions on the sale of OTC hearing devices, which enables researchers to obtain OTC devices directly from retail outlets. The electroacoustic characteristics of these devices are then measured. The type of HL these devices best fit can be estimated using evidence-based hearing aid prescription procedures. The HKU researchers (all within the Faculty of Education and led by Bradley McPherson, employed since 1996) use a novel 'reverse prescription' calculation method to predict the type of HL that each evaluated device would best suit. The team evaluates these devices and their electroacoustic performance against the typical hearing needs of persons with presbycusis. This research was the first to measure the performance of OTC hearing devices from the perspective of the typical elderly user [R1].

The research group found that the OTC devices they sampled (i.e., most devices on the Hong Kong market) were not acoustically appropriate for their primary user market – elderly adults with predominantly high-tone HL. Indeed, many such devices provide an amplification pattern (low tone emphasis) that is the inverse of that needed by elderly listeners. The devices also have inadequate levels of sound output and other design flaws that mitigate against effective fitting for this target group. HKU's initial paper [R1] noted that a wide range of low-cost OTC devices had serious functional limitations. Later work by the group noted that a more sophisticated device that was better designed to provide effective amplification had positive functional outcomes when fitted in a group of elderly persons in Hong Kong despite its relatively low cost [R2]. Further research [R3] explored the factors that act as barriers to the purchase of hearing aids by elderly Chinese individuals in Hong Kong. These factors include, but are not confined to, cost and indicate the potential for innovative OTC devices to expand the take-up of amplification options among elderly persons.

In 2015, the group examined a new generation of low-cost OTC products [R4] and again found that these products mostly failed to meet the amplification needs of elderly listeners with HL. The researchers provided guidance for developers on how future products could better meet those needs. In particular, they highlighted that manufacturers must consider the typical hearing status of the primary target market for these products. HKU's detailed analyses and recommendations to improve OTC device functionality for elderly wearers are among the only evidence-based reports that inform new approaches in this area [R5 and R6].

(3) References to the research

R1. Cheng, C.M. & McPherson, B. (2000). Over-the-Counter Hearing Aids: Electroacoustic Characteristics and Possible Target Client Groups. *International Journal of Audiology,* 39(2), 110-116. DOI: 10.3109/00206090009073062.

R2. McPherson, B. & Wong, E.T.L. (2005). Effectiveness of an affordable hearing aid with elderly persons. *Disability and Rehabilitation*, 27(11), 601-609. DOI: 10.1080/09638280400019682.

R3. Wong P.W.Y. & McPherson, B. (2010). Reasons for non-adoption of a hearing aid among elderly Chinese. *Asian Journal of Gerontology and Geriatrics,* 5, 62-68.

R4. Chan, Z.Y.T. & McPherson, B. (2015). Over-the-Counter Hearing Aids: A Lost Decade for Change. *BioMed Research International*, article ID 827463.

R5. McPherson, B. (2011). Innovative Technology in Hearing Instruments: Matching Needs in the Developing World. *Trends in Amplification*, 15, 209-214. DOI: 10.1177/1084713811424887.

R6. McPherson, B. (2014). Hearing assistive technologies in developing countries: background, achievements and challenges. *Disability and Rehabilitation: Assistive Technology,* 9, 360-364. DOI: 10.3109/17483107.2014.907365.

This research has attracted a number of grants and has made use of facilities within the Speech, Language and Hearing Clinic, Faculty of Education. The grants included HKU Faculty Research Fund – Over-the-counter hearing aids revisited, 2013-2014, HK$13,500; Oticon Foundation, Denmark – Audiology in developing countries, 2006, DKK50,000; Simon KY Lee Research Grant – New hearing aid technology for elderly persons with hearing loss: Is it effective? 2002-2003, HK$50,504; HKU Small Project Grant – Identifying communication disorders in elderly Hong Kong residents, 2000-2001, HK$79,660; and HKU Small Project Grant – Over-the-counter hearing aids: Electroacoustic characteristics and possible target client groups, 1999-2000, HK$120,000. All grants were awarded solely to McPherson as Principal Investigator.

(4) Details of the impact

The initial study [R1] was the first to consider the potential value of over-the-counter (OTC) hearing aids, widely used low-cost devices that form part of a shadow, non-clinical entry point into hearing health care. HKU's work was widely acknowledged considering the under-researched state of this topic. It was one of only 34 studies referenced in the *WHO Guidelines for Hearing Aids and Services for Developing Countries* [S1], the 'cornerstone document' in the field [S2] that has been distributed widely and is available from the WHO website. Following HKU's earlier WHO-cited work, the clinical implications were then further explored in the United States [S3], China [S4] and Australia [S5], with acknowledgement of HKU's pioneering contribution to the field. The practical recommendations from the research group have continued to be considered by other groups writing for the US clinician/consumer audience [S6 and S7]. The research work has been disseminated via conventional channels and presented at WHO and other meetings of professional and non-governmental agencies hosted by international bodies. It has also been noted in professional trade magazines and websites [e.g., S8], created an awareness and understanding of the limitations of many current-generation OTC hearing aids and helped shape initiatives to address amplification needs in a more scientific manner.

The use of OTC hearing aids to increase access to appropriate amplification has gained greater attention in recent years due to the affordability issues associated with conventional, audiologist-prescribed hearing aids. The October 2015 report in the USA – from the President's Council of Advisors on Science and Technology – into hearing health care services recommended that the direct-to-consumer sale of hearing aids be allowed in the United States. This recommendation was supported by the 2016 report of the National Academies of Sciences' *Committee on Accessible and Affordable Hearing Health Care for Adults* [S6]. The report cited and reflected on HKU's 2000 and 2015 research reports and noted that the findings suggest the need to develop minimum performance standards for OTC devices. The NAS report will 'profoundly change' hearing health care policy in the United States over the next decade [S9] – primarily because the report's recommendations led to the Over-the-Counter Hearing Aid Act, which was signed into law in August 2017 [S10], and the new OTC regulations are due to be issued by the Food and Drug Administration in November 2019 [S11].

European researchers [S12] recently developed a new, low-cost OTC hearing aid that was designed to provide elderly persons with appropriate amplification based on scientifically valid prescription principles and successfully trialled this device. This proof-of-concept device explicitly cites the basic standards advocated in HKU's research programme and further demonstrates the wide influence of that research. Further WHO recommendations on desirable hearing aid characteristics – the *Preferred profile for hearing aid technology suitable for low- and middle-income countries* (2017) – include an emphasis on the need for affordable amplification devices that allow effective prescription-based fitting procedures [S13] and reflect the HKU group's research conclusions. McPherson was commissioned co-editor of this important policy document. This WHO document cites our related work that considers the need for *appropriate* amplification for children and adults with hearing loss in developing countries [R5 (world-wide) and S14 (specifically for a hearing aid manufacture facility in southern Africa)]. The research has globally informed remediation efforts, and thus has helped improve health and education outcomes for adults and children with hearing loss.

(5) Sources to corroborate the impact

S1. World Health Organization. (2004). *Guidelines for Hearing Aids and Services for Developing Countries*. 2nd edition. Geneva, WHO.

S2. Bento, R.F. & Penteado, S.P. (2010). Designing of a Digital Behind-the-Ear Hearing Aid to Meet the World Health Organization Requirements. *Trends in Hearing*, 14, 64-72. DOI: 10.1177/1084713810380934.

S3. Calloway, S. & Punch, J. (2008). An Electroacoustic Analysis of Over-the-Counter Hearing Aids. *American Journal of Audiology,* 17, 14-24. DOI: 10.1044/1059-0889(2008/003). [USA paper that confirmed HKU group's initial research findings.]

S4. Chen, K. & Chan, A.H.S. (2011). The ageing population of China and a review of gerontechnology. *Gerontechnology,* 10, 63-71. DOI: 10.4017/gt.2011.10.2.001.00. [Discusses the need for more appropriate hearing health technology for the Chinese market and shows influence of HKU work in this area.]

S5. Keidser, G. & Convery, E. (2016). *Preliminary observations on outcomes with a self-fitted hearing aid*. National Acoustic Laboratories, Sydney, Australia.

S6. Blazer, D.G., Domnitz, S. & Liverman, C.T. (2016). *Hearing Health Care for Adults: Priorities for Improving Access and Affordability*. *Report of the National Academies of Sciences, Engineering and Medicine Committee on Accessible and Affordable Hearing Health Care for Adults*. Washington DC, National Academies Press.

S7. Kimball, S.H. (2010). Concerns Regarding Direct-to-Consumer Hearing Aid Purchasing. *Volta Review,* 110, 447-457. DOI: 10.17955/tvr.110.3.645. [Review paper that highlights dangers and inadequacies of current OTC devices for potential purchasers, based in part on our research findings.]

S8. Smith, C., Wilber, L.A. & Cavitt, K. (2016). PSAPs vs Hearing Aids: An Electroacoustic Analysis of Performance and Fitting Capabilities. *Hearing Review,* 23(7):18.

S9. Hearing Review (June 2016). *NAS/IOM Committee Recommends New OTC Hearing Aid Class, End to Waiver System, and Unbundling of Hearing Aid Prices.* Available at: http://www.hearingreview.com/2016/06/nasiom-committee-recommends-new-otc-hearing-aid-class-end-waiver-system-unbundling-hearing-aid-prices/.

S10. Jilla, A.M., Johnson, C.E. & Danhauer, J.L. (2018). Disruptive Hearing Technologies and Mild Sensorineural Hearing Loss II: Current Research on Affordable Hearing Technologies and Direct-to-Consumer Models. *Seminars in Hearing*, 39,146-157. DOI: 10.1055/s-0038-1641741.

S11. Hearing Review. (June 2019). FDA to Issue First Proposed Rules on OTC Hearing Aids by November. June 19, 2019. Available at: http://www.hearingreview.com/2019/06/blog-fda-issue-first-proposed-rules-otc-hearing-aids-november/.

S12. Sacco, G. et al. (2016) Clinical evaluation of an over-the-counter hearing aid (TEO First®) in elderly patients suffering of mild to moderate hearing loss. *BMC Geriatrics* 16:136. DOI: 10.1186/s12877-016-0304-4. [Clinical validation study in France of prototype hearing aids explicitly aligned to HKU research group amplification recommendations for elderly adults.]

S13. World Health Organization. (2017). *Preferred profile for hearing aid technology suitable for low- and middle-income countries*. Geneva, WHO.

S14. McPherson B. & Brouillette R. (2004). A Fair Hearing for All: Providing Appropriate Amplification in Developing Countries. *Communication Disorders Quarterly,* 25, 219-23. DOI: 10.1177/15257401040250040601.