

On The PCAST Report And The FDA Hearings

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Downstream Consequences of Aging is a bi-monthly series written by guest columnist Barbara Weinstein, PhD.

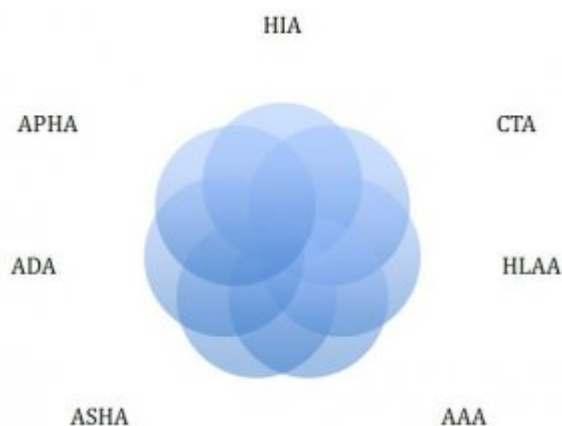
Today's post is especially timely, on the heels of the IOM final report and anticipating the FDA review process that generated 160 stakeholder comments.¹

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The focus of the public workshop hosted by the FDA on April 21, entitled “Streamlining for Good Manufacturing Practices (GMP) for Hearing Aids” was the recent report from the President’s Council of Advisors on Science and Technology (PCAST).

The PCAST report and the FDA hearing prompted responses from stakeholders across the quality enterprise (Figure 1) including the Hearing Loss Association of America (HLAA), American Public Health Association (APHA), the Hearing Industries Association (HIA), the Consumer Technology Association (CTA), and professional associations representing audiologists including ADA, ASHA, and AAA.²



Can't We All Just Get Along?

The responses from the stakeholders were mixed, hailed by some groups and denounced by others. To facilitate a meeting of the minds between the different organizations, I would like to play mediator in an attempt to amicably resolve some of the differences across stakeholders orienting the focus on responsible innovation and the consumers we serve.

All parties agree that:

Figure 1 Stakeholders in the Hearing Health Quality Enterprise

- health care expenditures
- rate of hospitalizations
- risks for functional limitations, morbidity and mortality.
- The needs of the majority of persons with age related hearing loss are not being met especially those with mild to moderate hearing loss.
- Hearing aid use is dose related, greatest among persons with moderate to severe hearing loss.
- There are social barriers associated with hearing loss and hearing aid use.
- There are marketplace changes marked by a revolution in digital technology and price reductions in consumer electronics.
- People are living longer, retiring later, remaining in the workforce longer.
- Social engagement is critical to quality of life and mortality.

Stakeholder's Solutions Differ

Stakeholders are driven by the missions of their organizations and therefore differ in their perspective on hearing health care and its solutions.

American Public Health Association

The APHA works to optimize the **health of all persons and all communities** and to advance prevention, to reduce health disparities, and to promote wellness. Working with the CTA foundation, the mission of the CTA is to **empower older adults and persons with disabilities** to promote accessibility of technologies designed to enhance well-being.

Hearing Loss Association of America

The HLAA advocates for the **consumer with hearing loss** and its strategic intent is to both eradicate the stigma of hearing loss and to help persons with hearing loss gain access to resources and affordable technology which work seamlessly allowing them to live successfully, without having to compromise.

Hearing Industries Association

Recognizing the importance of hearing health to health, productivity, and well being, the HIA coordinates with the Better Hearing Institute (BHI) to conduct research and hearing health education with the goal being **to help people with hearing loss** to benefit from treatment.

Audiology Professional Membership Organizations

Representing audiologists in a variety of settings, the American Speech-Language-Hearing Association (ASHA), the American Academy of Audiology (AAA), and the Academy of Doctors

of Audiology (ADA) have competing missions which have worked to the disadvantage of the consumer and to the advantage of the remaining stakeholders shown in Figure 1 (with the exception of the HIA).

Representing audiologists working in a variety of settings, the AAA is dedicated to providing quality hearing care services through professional development, education, research, and increased awareness of hearing and balance disorders. Representing autonomous and private practitioners, the ADA is dedicated to the advancement of practitioner excellence, professional autonomy, high ethical standards, and sound business practices in the provision of quality audiologic care. Finally, the American Speech-Language-Hearing Association (ASHA) has as its mission the empowering of professionals in communication disorders through advancing science, setting standards, fostering excellence in professional practice, and advocating for members and those they serve.

Consumers Are Stakeholders, Too

The mission statements of our professional organizations rarely include the person with hearing loss. Yet, it is that person who should be the driver of the work for which I hold a passion — namely making a difference in the lives of persons with hearing loss and their communication partners. This, my friends and colleagues, could be a major reason that audiology is ripe for disruptive innovation.

So here is my take. Professionals and the associations to which we belong, must be driven by the “wants” and “needs” of the consumers we serve. Present day consumers are educated and savvy about available hearing health care interventions and are increasingly insistent on accessible and affordable hearing health care. Value based care is a buzz word, a driver of reimbursement systems, and private payers. When considering a treatment plan, our patients want to know what the service will cost, what he or she can expect based on ?rm data, and above all will want to be involved in decisions about their hearing healthcare.

Informed choice and treatment options based on patient readiness, communication challenges, ability and willingness to pay are integral in the present day hearing health care environment.

Use Evidence-Based Questions to Design and Align

In conclusion let’s reflect on how well-aligned the needs of our patients are with our goals as a profession. Consider my revisionist version of the *expectations performance theory*. Our expectations must be aligned with those of our patients. Our patients’ wishes regarding communicative priorities must be aligned with the patient reported outcomes on how they are functioning that we should be gathering.

By sharing the evidence that our patients’ needs are being met with stakeholders, the word of mouth about the good and important work we do will be positive and referrals should flow. The sustainability of our profession and treatments we advocate rely on the collective responsibility of all stakeholders.

The acceptability and desirability of marketable hearing health care products is key to our quality enterprise. Responsible innovation demands that we ask the right product-, process- and purpose questions. Examples of potential question of each type are:

Product question: “How might future products change to meet the needs of persons with age related hearing loss and optimize the skills of audiologists as the professionals of choice?”

Process question: “How should standards be drawn up and applied to protect consumers and professionals?”

Purpose question: “Are our motivations transparent and in the public interest3?”

It is a win-win for all stakeholders to close the gap between the proportion of persons with

untreated age related hearing loss and the proportion of those who enjoy a measurably high quality of life as the result of hearing health care interventions purchased through audiologists.

We are part of the problem and part of the solution. Let's change that balance and remain essential.

References & Footnotes

1. Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products; Draft Guidance for Industry and Food and Drug Administration Staff; Availability.
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3. Stilgoe, J., Owen R., & Macnaghten, P. (2013). Developing a frame for responsible innovation. *Research Policy*. 42: 1568-1580.