

WHEN STANDARDS AND CLINICAL PRACTICE COLLIDE

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In Accredited Standards Committee S3, Bioacoustics, standards impact clinical practice. In some cases, clinical practice and standards development work synergistically, whereas in other instances they are antagonistic processes. The current scope of S3 includes: “Standards, specifications, methods of measurement and test, and terminology in the fields of psychological and physiological acoustics, including aspects of general acoustics which pertain to biological safety, tolerance and comfort.” It does not, however, allow us to dictate clinical practice. Many of the S3 standards are relevant to the discipline of clinical audiology. For example, ANSI S3.6¹ describes details about the technical specifications and calibration of clinical audiometers. As virtually all audiology clinics in the United States have audiometers that are manufactured and calibrated to meet ANSI S3.6, this is clearly an important standard related to the clinical measurement of hearing. As such, it is relevant to the field of clinical audiology. It does not, however, dictate clinical practice. ANSI S3.6 does not tell the clinician how to perform clinical tests, nor does it tell the clinician how to interpret the results of these clinical tests. In this case, the standards process is complementary to clinical practice. A standard that does cross over the line into clinical practice is ANSI S3.21 *American National Standard Method for Manual Pure-Tone Threshold Audiometry*.² In this standard, a common procedure for determining audiometric threshold is described. This is similar to the procedure recommended in most audiology textbooks for obtaining audiometric threshold. This standard clearly crosses over into the domain of clinical practice, and yet this standard has not been controversial. In this instance, the standard dictates a procedure that is used to obtain threshold in many clinical venues. It does not dictate when to use this procedure, nor does it tell the user how to interpret the results clinically. Perhaps this is why this standard has been around for a while (since 1978), and why it has not been problematic.

ANSI S3.45³ describes the protocol used for testing vestibular function. The development of this standard was contentious, and remains somewhat controversial. Several aspects of the standard were fiercely debated while it was under development. First, the adequate bandwidth for recording eye movements was debated. The standard states that for digital devices, the electrical potential measured when the eye moves should be sampled at no less than 100 Hz (giving a bandwidth of ~50 Hz). This specification was controversial, as at the time the standard was being developed, several commercially available systems digitized at a lower rate. This issue

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was complicated by the fact that there was no clear literature that dictated this minimum sampling frequency to resolve the slow phase of eye movements. This specification could have potentially led to a serious conflict between the opinions of experts in the field (including those in the working group that was developing this standard) and the manufacturing community. The resolution to this potential conflict involved a grandfather clause, giving the manufacturers five years until the revision of this standard to meet this minimum digitization rate. This issue did not directly impact clinical practice, but did affect which instrumentation met the minimum requirements of the standard. Another contentious issue surrounding this standard does actually get closer to the clinical practice line. For the clinical subtest of caloric testing, the temperature of the inner ear is changed, and the resulting eye movements (nystagmus) are recorded. In the literature, both water and air have been used to produce this temperature change. If one looks at the clinical literature, there are champions for the use of both air and water. There are those who argue that air is problematic unless air temperature is monitored at the tip of the probe that is placed in the ear canal. Others believe that air produces a less robust response, and for that reason its use should be discouraged. To summarize the clinical literature, there is no clear agreement as to whether the use of air for calorics is a good or bad clinical practice. Now let us see how this lack of clinical agreement on the use of air calorics affected the development and approval of this standard. At least a subset of the members of the working group developing this standard fell in the “don’t like air calorics” camp. One important principle of standards development is the notion of consensus. As the members of the working group could not agree that the use of air calorics was good clinical practice, the use of air calorics was not included in the standard. This omission might be interpreted as the standard dictating clinical practice. This actually is true, as you cannot follow the ANSI Standard and use air calorics, due to the omission. On the other hand, it is common to leave out controversial issues in a standard, issues on which consensus cannot currently be developed, in order to get the positive vote (consensus) needed to approve the standard. In this particular instance, the worlds of clinical practice and standards development collided. From numerous phone calls and emails made to the S3 Chair (me) near the time this standard was approved, it is clear that a lot of people disagree with leaving air calorics out of the standard.

I write this brief article to point out that while it is not the charge of Accredited Standards Committee S3 to dictate clinical

cal practice, it is inevitable that standards will in fact influence clinical practice. The scientific literature should serve as the basis for both standards development and for clinical practice. A hot topic in clinical research these days is evidence-based practice. This means that our clinical practices should be dictated by a body of evidence supporting the use of specific practices and/or procedures. Evidence-based practice is also relevant to the development of ANSI standards. In the case of air calorics and ANSI S3.45, there are no published studies comparing the results of air and water calorics in a large number of subjects including both those with normal vestibular function as well as those with various clinical problems. When such studies are available, it should be clear whether air calorics should be used clinically. Further, this published data should resolve this issue for some future revision of ANSI S3.45. Clinical practice and standards development should both be data driven. In the absence of adequate clinical data, decisions concerning both clinical practice and standards development are problematic. On the other hand, both efforts are works in progress, and as the requisite clinical data emerges, both clinical practice and ANSI standards evolve.



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Robert F. Burkard (on right) and Paprika

References

1. ANSI S3.6-2004, American National Standard Specification for Audiometers (Acoustical Society of America, Melville, NY, 2004).
2. ANSI S3.21-2004, American National Standard Methods for Manual Pure-Tone Threshold Audiometry (Acoustical Society of America, Melville, NY, 2004).
3. ANSI S3.45-1999, American National Standard Procedures for Testing Basic Vestibular Function (Acoustical Society of America, Melville, NY, 2004).

S3/WG 35, Audiometers, is seeking a few clinical audiologists to participate in the next revision of ANSI S3.21-2004 *American National Standard Methods for Pure-Tone Threshold Audiometry*. Clinicians interested in participating in this working group should contact the Working Group Chair, R.L. Grason at grason@mindspring.com. Please copy the Secretariat (sblaeser@aip.org).



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