Essentials of Modern Hearing Aids

Selection, Fitting, and Verification

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Preface

Expertise is sometimes an elusive concept when applied to clinical skills. In the 1950s famed psychologist Paul Meehl demonstrated that expert clinical opinion can often be less accurate than a simple unbiased algorithm. This led to his introduction (along with Lee Crohnbach) of construct validity, which in part provided the foundation for evidence-based practice. Later work by Daniel Kahneman and others demonstrated that clinical opinion can be important too, but it must be given limited weight and considered along with more heavily weighted unbiased data. Importantly, the more a clinical opinion is a guess that is not supported by evidence (limited validity), the more likely it is to lead to an erroneous conclusion. For example, Kahneman describes the error that wine experts make when tasting immature wine when trying to predict the quality when it will be mature. It turns out the two are unrelated, and that ignoring the actual taste—and focusing instead on valid and objectively measurable factors like temperature, moisture patterns, and soil conditions—provides a more accurate prediction.

So how much expertise is needed for selecting and fitting hearing aids? At the most basic level, provision of amplification is rather simple. Provide enough gain but not too much, so that patients have improved audibility without loudness discomfort. Programming a hearing aid using the automated manufacturer-recommended first fit, based on the patient's audiogram, will likely improve audibility for at least some sounds, and generally will keep loud sounds from being too loud. Application of a little science and expertise, however—and the addition of the probe microphone verification of modern, validated prescriptive gain methods—will lead to significantly better outcomes.

We have an incredible myriad of advanced hearing aid features, many of which provide benefits only in specific situations, and a few of which have some pro and con tradeoffs. Making things even more challenging is that many features interact with listening differently, depending on the manufacturer and the specific setting chosen. In addition, emerging data demonstrates that some features can have differential effects on speech recognition, localization, sound quality, listening effort, and other facets of the listening experience. Consequently, we believe evaluating individual listening needs, and then selecting, fitting, adjusting and counseling based on those listening needs are necessary to optimize patient benefits from hearing aids. In other words, assuming good patient rapport and people skills, the greater the expertise, the better chance at optimal outcomes. Of course, we must accomplish all this as efficiently as possible.

There have been around 2000 research articles published in the last decade related to the selection and fitting of hearing aids, and countless additional white papers and other manufacturer documents produced. In the last few years, we have authored three other textbooks that have focused on individual sections of the provision of hearing aids including hearing needs assessment, hearing aid selection, verification, counseling and outcomes. In this text, we put it all together in an updated form and add discussions of hardware,

signal processing, and hearing aid features. We attempt to synthesize our current evidenced-based knowledge about hearing aids and the provision of hearing aid services with the goal of providing the reader a one-stop source. We again provide this information in a clinician-friendly step-by-step manner: Audiological pre-fitting testing; needs assessment and treatment planning; hearing aid hardware, software, and features; hearing aid selection, verification, orientation and counseling; post-fitting follow-up; and real-world validation. Of course, next year there will be another 200 or so hearing aid articles published, and maybe some changes in hearing aid features—but we hope this text will serve as a useful foundation going forward.

Putting forth the effort to develop an entire textbook is a rather daunting task, and we are all pretty busy. In teaching our hearing aid courses we were never satisfied, however, with what was available. None of the texts offered all of the material we wanted to include in a way that was accessible to audiology students. Also, we wanted to have a textbook that took a student through the entire hearing aid process from beginning to end in a logical and clinically applicable manner. So we set out to write a book that we would be able to use in its entirety in all of our hearing aid coursework, rather than needing different texts for different classes and picking a chapter here and a chapter there. We think we have achieved our goal and hope you also find it a good one-stop-shop for all clinical hearing aid courses. Of course we will be using articles from the research literature to supplement this text going forward, but all of the core material we talk about in our current classes is here. Given that many in our target audience are audiology students and busy clinicians, we also knew that we had to ensure the book's readability. We wanted to present our material in a manner that was a little unique but not distracting. Consequently, we followed a similar structure that we introduced previously and provided call-outs where we could to add or emphasize a given point. Throughout the text, you will see short paragraphs that we have identified as Technical Tips, Things to Remember, Key Concept, and Points to Ponder. To keep the book manageable in size and weight, we have placed some related content on the PluralPlus companion website rather than include it in appendices. There you will find many of the forms and scoresheets needed to facilitate the pre- and post-fitting measures we describe in this text, as well as PowerPoint slides with all of the figures from the text arranged by chapter.

This is now the fourth book that the three of us have co-written. Fortunately, when it comes to hearing aid issues, we think pretty much the same, so when we say "we" we usually do really mean "we." Moreover, if you simply follow what has been carefully thought out and published in evidence-based best practice guidelines, the provision of hearing aid service is not as debatable as some people try to make it. That said, from new algorithms to new types of patient outcomes, discovery in the area of hearing aids marches on rapidly, and the evidence base remains limited for some of the newer techniques. As you might guess, the three of us are strong-willed, which often made for some fun debates in areas where research evidence is limited. Reaching consensus takes time—not as much time as generating content, but time nonetheless. As with a good scotch or wine, attentive blending and 12 years of aging (from concept to completion) was necessary to finish this work—we hope you enjoy every sip!

Acknowledgments

Regarding the contents of this book, it is important that we again acknowledge the tireless efforts of Elizabeth Stangl, AuD, from the Hearing Aid Lab at the University of Iowa. As was the case in our previous efforts, she is responsible for the construction of many of our figures, and she managed all the details regarding references, permissions, and overall organization of the book. Thanks, Elizabeth! Kade Schemahorn provided graphic design, and a number of other students in the Hearing Aid Lab at the University of Iowa were invaluable for their contributions: Curtis Hartling, Caitlin Sapp, Britany Barber, Kassie McLaughlin, Kelly Bailey, Erik Jorgenson, and Amy Carlson. In addition, Erin Picou, PhD, from Vanderbilt University, also provided a number of helpful suggestions and contributions. We also thank our families for putting up with years of hearing about "That Big @#$% Book"!

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Evidence-Based Practice

The selection and fitting of hearing aids have always included components of both art and science. Although the field continues to push toward an increased evidence base, the ratio of art versus science favored art for a number of decades. Why? The science has not always kept up with the technological advances. With the current and forecasted health care reimbursement models, all clinicians must be prepared to offer true evidence of effectiveness, satisfaction, and/or benefit, if we want to be paid for our services! In this chapter we review the principles of evidence-based practice (EBP) and how we can apply them to our own practices.

Several studies have demonstrated the importance of EBP with regard to provision of hearing aid services. For starters, in the late 1990s, there was an overwhelming belief that "We have arrived!" with the first digital hearing aid release in the United States. Consumers and audiologists alike were yearning for hearing aids that provided better reproduction of sound, better hearing in noise, and better overall user satisfaction; many believed that these new digital products were the solution. An early, well-designed investigation of differences in outcomes over time, however, showed that we actually had *not* improved the likelihood of better hearing for the listener (Bentler & Duve, 2000) despite some pretty significant improvements in the technology. In that study, the 25 subjects were each fitted with hearing aids that spanned 100 years of practice, using the fitting approach appropriate to the era. A number of measures were taken with the hearing aids alone and with the hearing aids on the subjects.

The findings of the Bentler and Duve (2000) study were generally hard to swallow for many. Word recognition scores showed no significant difference across any of the conditions of testing, which included unaided, a nonelectronic ear trumpet, an old original body-style hearing aid, and the more recent analog and digital hearing aids used in the study. The only significantly different score was found with the 1930s body hearing aid, which was likely due to its inherent narrow bandwidth and high distortion. The ratings for sound clarity —assessed in the laboratory with cafeteria, office and traffic noise—did not differentiate the hearing aids in use from 1960 onward. Finally, the "real world" rating of ease of listening suggested that in difficult listening environments, such as a fast-food restaurant and a church service, none of these hearing aid processors worked better than the other. Although this all sounds negative for our efforts, the point to be made is: Newer is not always better. And if clinicians are to know what is better, we need to keep the evidence coming. A similarly eye-opening series of articles regarding today's technology recently was published by Cox et al. (2014, 2016)—more on that later.

Several studies have also shown that clinical intuition is often incorrect. Bias, either from the clinician or the hearing aid recipient, has been shown to cloud the true results. One study that clearly showed the strong

biasing effects that are present by simply the labeling of hearing aids was completed more than a decade ago, and is often referred to as the "Bentler Hype Study" (Bentler, Niebuhr, Johnson, & Flamme, 2003). As part of this study, one group of hearing-impaired listeners had two one-month trials with hearing aids. For one month, participants wore the hearing aids labeled "state-of-the-art digital," and for the other month they wore hearing aids labeled "conventional." In reality the hearing aids were exactly the same hearing aids! It is important to note that digital hearing aids were still relatively new at the time of that study and were getting a lot of marketing press relative to their benefit over the older analog hearing aids. At the end of the first month-long trial, the participants completed a battery of speech recognition and self-report measures. After the testing was completed, the hearing aids were removed, the investigator left the room and came back, and participants were refitted with exactly the same hearing aids. Participants were then told they were wearing the opposite condition (conventional or digital) and sent out for another trial, after which the test battery was repeated. As expected there were no differences in speech recognition scores across the conditions; however, labeling clearly affected self-perception. The fitting labeled "digital" was scored significantly higher on some self-report subscales of the Abbreviated Profile of Hearing Aid Benefit (APHAB), and 33 of 40 participants expressed a preference for the fitting labeled "digital."

This type of placebo effect labeling bias was confirmed by a more recent study (Dawes, Hopkins, & Munro, 2013) during which 75% of participants expressed a preference for a hearing aid when it was labeled "new" over the same hearing aid model when it was labeled "conventional." Even though the effect was small (~4 percentage points), a striking additional finding was that the speech recognition performance was significantly better when the same hearing aids were labeled "new." This suggests that, in addition to differences in self-reported outcomes and preferences, the placebo effect can be so strong that patients may actually try harder (and consequently perform better) on objective outcome measures!

Although the presence of these biases is clear and must be considered in research design, their interactive effect on clinical perceptions may be less clear. A good example of the potential clinical implications is demonstrated by the findings of a study David Gnewikow completed as part of his dissertation at Vanderbilt University (Gnewikow, Ricketts, Bratt, & Mutchler, 2009). In this study, 90 patients were selected who all were fitted with the same model of omnidirectional hearing aid (old-HA) that were programmed to NAL-R targets prior to testing. A variety of outcome and preference measures were completed and compared to the same measures following another trial with a new hearing aid fitted exactly to exactly the same prescriptive gain targets (new-HA). The new-HA and old-HA were therefore identical in every way except that the new-HA could be programmed to use either fixed directional or fixed omnidirectional microphones (a trial with each of the microphone settings was completed). In addition, there was no labeling of "old" and "new"; however, participants were aware they were receiving new instruments. As expected, speech recognition in noise scores with noise sources surrounding the listener were identical for the new hearing aid and old hearing aid (both in omnidirectional mode) since they had essentially identical hearing aid responses. Somewhat surprisingly, however, there were no significant differences in subjective outcomes or preferences between the new-HA in directional and omnidirectional mode, but instead subjective outcomes were significantly higher for the new-HA over the old-HA (regardless of microphone type). These data demonstrate that the effect of bias can have a much greater effect on outcomes than a change of technology! Clinically, this same type of effect can happen. Is a new technology really better than an older one, or do patients report the new technology is better because we tell them it is? Although we can (and in our opinion should) let our patients know that we believe we have selected the best technologies for them, the actual effect size (ES) on outcomes must be based on evidence rather than our clinical intuition!

Are We Grounded in Evidence?

Evidence-based practice (EBP) has its roots in medicine. By definition, it is "the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients . . . (by) integrating individual clinical expertise with the best available external clinical evidence from systematic research" (Sackett,

Rosenberg, Gray, Haynes, Richardson et al., 1996, p. 71). The literature is full of examples from medicine wherein practices deemed to be "best practice" at the time have turned out to be wrong or even harmful when scientific rigor was used to evaluate the effects. Examples include the ancient Greek practice of bloodletting for a variety of ailments, including hypertension. In the 19th century, opium was used to treat diabetes. In the 1940s, premature infants were "oxygenated" to prevent retrolental fibroplasia, a condition later found to be *caused*, not cured, by the treatment. The list goes on. The application of EBP principles in audiology has taken root in the past decade. Academic settings, clinicians, and manufacturers have important roles in the use of these principles for sound decision-making. Understanding our roles, as well as our roadblocks, is important for the successful move into everyday practice.

Concurrently, the field of audiology has witnessed an explosion in the availability of both technology and published literature. Clinicians have access to new diagnostic tools, measurement tools, processing schemes, and even style designs every few months. In addition, research publications have become increasingly abundant. A decade ago, it was reported that the number of papers published in the primary audiology journals had grown from 200 a year in 1960 to 1700 a year in 2003 (Thorne, 2003). At that rate, a clinician would need to read more than five papers a day for 365 days a year in order to keep up. If hearing science literature had been included, the total would increase to 4,350 papers per year and would require reading 12 papers per day. With today's online publishing and the increased number of professional journals, that number could easily exceed 10,000. In 2016, for example, more than 200 papers were published specifically related to hearing aid technology and fitting, in 17 different journals. The task of keeping up is daunting to any clinician. Yet, in this era of increased accountability (e.g., third party payers, legislation, and *ethics*), the clinician is often forced to make clinical management decisions without, in many cases, good available and supporting data.

In 2005, the American Speech-Language-Hearing Association (ASHA) first conducted a Knowledge-Attitude-Practices (KAP) survey on EBP among members. That survey was repeated in 2008, 2011, and 2014. Here are a few of the most recent findings (R. Mullen, personal communication, 2015):

- Most members could correctly define EBP and most members thought EBP was a good idea.
- "Insufficient time" was cited as a major or moderate barrier to EBP by more than 50% of audiology respondents (more than any other barrier).
- 59% of audiology faculty cited "lack of available evidence" more than any other barrier to the use of EBP.
- Respondents reported being "very likely" to use continuing education offerings (52%) and journals (56%) as sources of information to help make clinical decisions. These options followed "colleagues" (69%) by a considerable margin.
- It was often not clear to the clinician whether data provided from the hearing aid manufacturers are actual evidence or marketing copy.

All of these factors present significant roadblocks to the use of EBP principles. Nonetheless, we must consider that, if our profession is to survive, our practices must be based on data, and not educated guesswork. What may not be clear to the busy clinician is that the whole concept of EPB depends on three sources of information to inform clinical decision-making. Each can be considered one leg of a three-legged stool; all three must be functioning in order for the process (or stool) to work:

- Empirical evidence, or evidence from well-controlled research experiments;
- Clinical experience, or evidence gathered by repeated trials and tests with clinic patients;
- Patient characteristics, the specific needs and expectations of the patient for whom management plans are being considered.

Evidence-based practice is not viable without each of the three components outlined above. Often, audiologists "look to the research" for evidence that a particular signal processor should be used or that a new hearing aid feature is better than the previous one. Instead, all three sources of information should be considered in our daily work.

THINGS TO REMEMBER:
"IF IT'S PUBLISHED, SHOULDN'T IT BE GOOD?"

Most new students—and some not-so-new clinicians—assume that if the information is published somewhere/anywhere, it must be true. We need to remember that there are many levels of "publication." Given the ease of desktop publishing and electronic dissemination, many things get published without much scientific scrutiny. Some things are published, but not subjected to peer review (i.e., a critical review by other scientists prior to acceptance for publication). On the other hand, a publication doesn't necessarily have to be peer-reviewed to be relevant to clinical decision making. And, even when something is peer-reviewed, the clinician must still take a critical look at what was done and its relevance to ongoing clinical decision making. The clinician needs to take responsibility for making this judgment, and that is more or less the main point of this chapter. In a hearing aid purchase, many would consider the patient to be the "consumer," but in fact, in most cases the consumer is really the clinician, as he or she will be making the important decisions for the patient—quite the responsibility.

What Is Good Evidence and How Do I Access It?

In most training programs, there is a course called *Introduction to Research* or the like. Although most clinicians do not pursue a career in research, all clinicians need to understand—or be able to differentiate—good research from not-so-good research. For example, good research has the following components:

- Study purpose
- Background literature
- Appropriate design including appropriate controls
- Sample size following power analysis
- Psychometrically sound outcomes used
- Intervention strategy explained
- Results, including dropouts
- Biases discussed
- Conclusions and clinical implications

As we discuss different types of evidence in this chapter, we will be referring to several different terms used in statistics and the critical review of research. We have summarized some of the terms in Table 1–1, adapted from Palmer et al. (2008).

Important Definitions

In the eyes of some, *research* and *evidence* might seem to be interchangeable terms. They are not. The different levels of the evidence that we draw from to help support our EBP don't always involve research. As shown in the well-known pyramid in Figure 1–1, evidence comes in many flavors; compelling evidence, however, comes from good and strong research. Let's review those EBP levels of evidence, starting with the lowest.

Expert Opinion

There are plenty of "experts" out there with opinions. Unfortunately, this is the lowest level of evidence that is considered in hearing aid research. Expert opinion can take the form of a workshop or lecture, an editorial in a journal, statements made in a book chapter (gulp), or even a manufacturer's trainer showing the newest design to a community of clinicians. In the world of EBP, there is little value placed on expert opinions without the supporting data. Expert opinion is a lot like clinical intuition: It is often unconsciously biased and introduces error into a process. For a very interesting discussion of these biases and their effects, consider Nobel Prize-winning Daniel Kahneman's excellent, *Thinking Fast and Slow*. While the focus of this book is examining

Table 1–1. Commonly Used Terms Used for Assessing Evidence

Sample Size	A sample is a subset of a population used to make inferences about the characteristics or behavior of the population. The size of the sample is the number of observations or measurements made. Typically, a larger sample size leads to more precise estimates of various population properties (see power).
Alpha	Probability level chosen by the researcher. Alpha = 0.05 means there is a 95% chance that a performance difference demonstrated between two sample study groups does truly exist in the general population.
Effect Size (ES)	The amount of difference the researcher is actually interested in detecting with a given study. For example, one study may be looking to detect a difference of 1.5 dB between groups (small ES), whereas another may be interested in only a 20 dB or greater difference between groups (large ES)
p value	The probability that a difference in sample group results would occur by chance even when there is no true difference in population groups (see alpha). Typical chosen as $p = 0.01$ or 0.05.
Power	The probability that study results will find a difference between sample group performance scores when a true difference between population scores does exist. Great power (≥0.80) is desirable in interpreting research results.
Statistical Significance	A finding considered to be statistically significant means that it is highly unlikely the finding would have occurred by chance, based on the chosen alpha level and ES.
Practical Significance	A finding can meet the requirements of statistical significance but not have practical value. For example, a study with a large enough sample size might find a statistically significant difference in scores of 5%, when a 5% difference has no real impact on a listener's overall function.

Note. Adapted from Palmer et al. (2008).

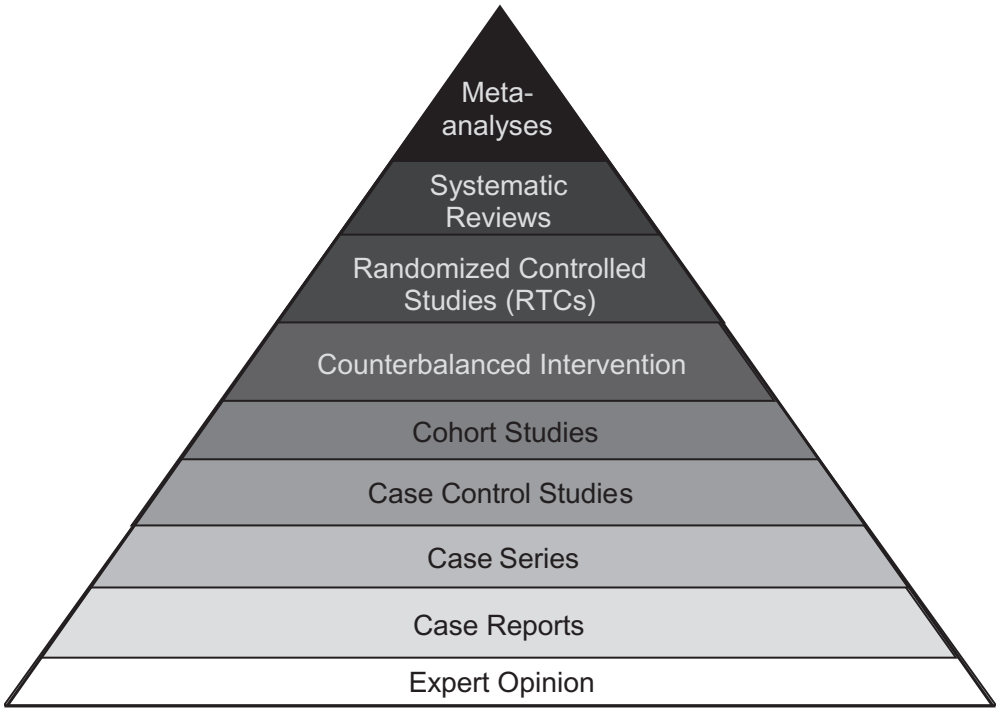

Figure 1–1. The pyramid of levels of evidence. Note that expert opinion is the lowest level of evidence, meanwhile meta-analysis offers the highest level of evidence.

how we make decisions, it provides many examples that demonstrate that expert opinion, on the average, is less accurate than a simple unbiased algorithm that includes expert opinion as just one equally weighted factor. In addition, many examples are given that demonstrate that clinical judgment is inherently biased by factors that are less important and more fluctuating than are the factors evidence shows to be the most important. A manufacturer who proclaims, "Two hearing aids should always be the goal in a fitting scheme," is really expressing an opinion favorable to company sales. The same would be true when a manufacturer recommends premier models (with a higher profit margin) over entry-level hearing aids. On the other hand, if that same "expert" were to produce data—of good quality—suggesting the same, the level of the evidence goes up significantly.

Case Reports or Case Series

Case reports or case series are also considered to be lower levels of evidence, but they are also often important to the development of the bigger questions of efficacy and effectiveness. A well-written case report will be clear about the importance of the observation; when multiple case reports show something similar, the next step might be a case-control study to determine if there is a relationship between the relevant variables. By themselves, case studies are nearly equivalent to testimonials.

Case studies include the following advantages:

- Can help in the identification of new trends in outcomes
- Can help detect new side effects and potential uses (adverse or beneficial)
- Are often educational—a way of sharing lessons learned
- Help identify unusual outcomes

Case studies include the following disadvantages:

- May not be generalizable
- Are not based on systematic studies
- Causes or associations may have other explanations
- Can be seen as emphasizing the bizarre or focusing on misleading elements

With respect to hearing aids, one of our favorite case studies of recent years was "The Case of the Missing Ping" (Mueller & Hawkins, 2006), which described the step-by-step procedure needed to determine why a golfer could hear the "ping" of his drive when he was not using his hearing aids, but could not hear the ping when they were inserted. Following sound-level meter measurements and extensive probe microphone testing with the patient, RECDs and RETSPLs, the "evidence" provided revealed that a low setting for the front-end AGCi limiting compressor of digital hearing aids can have a more fluctuating impact on real-world listening (see Chapter 10).

Case-Controlled Studies

A study that compares patients who have a disease or outcome of interest (cases) with patients who do not have the disease or outcome (controls) is known as a case-controlled study. Case-controlled studies are observational because no intervention is attempted and no attempt is made to alter the course of the outcome. Case-controlled studies can also be "retrospective studies" and "case-referent studies."

Advantages of case-controlled studies include the following:

- Require less time to conduct the study
- Can simultaneously look at multiple outcomes
- Are useful as initial studies to establish an association

Disadvantages of case-controlled studies include the following:

- May display more problems with data due to many uncontrolled variables (because these are often retrospective studies)
- Can be difficult to find a suitable control group

An example of a case-controlled study in our field could be comparing the quality of life of hearing aid users to that of non-hearing aid users with the same demographic makeup. These studies have shown that when compared to their peers, individuals who have treated their hearing loss with the use of hearing aids have better emotional stability, family relations, and sense of control over life events (Ciorba, Bianchini, Pelucchi, & Pastore, 2012; Swan et al., 2012).

Cohort Studies

A study design where one or more samples (called cohorts) are followed prospectively, and subsequent status evaluations with respect to a disease or outcome are conducted to determine which of the initial participants' exposure characteristics (risk factors) are associated with it, is a cohort study. As the study is conducted, outcomes from participants in each cohort are measured and relationships with specific characteristics determined.

Advantages of cohort studies include the following:

- Subjects in cohorts can be matched, which limits the influence of confounding variables
- Standardization of criteria/outcome is possible
- Easier and cheaper than a randomized controlled trial (RCT)

Disadvantages of cohort studies include the following:

- Cohorts can be difficult to identify due to confounding variables
- No randomization, which means that imbalances in patient characteristics could exist
- Blinding/masking is difficult
- Time required to obtained outcomes of interest can be considerable

An example of a cohort study related to hearing aids could involve research following groups of individuals with different technologies to determine adjustment timelines, preferred settings, and so on. One such study was conducted by Bentler and others in the early 1990s (Bentler, Niebuhr, Getta, & Anderson, 1993a and 1993b). In that study four groups of subjects using different analog "noise reduction" schemes were followed and tested over a period of one year to see if the benefit was different in some way across the groups. It was not.

Counterbalanced Intervention (CBI) Studies

One of the most common research questions is not whether a specific intervention works at all but, rather, which of multiple interventions works best. In this study design two or more intervention options are compared within a single group of participants. For example, do patients benefit more from one hearing aid or two? In order to offset timing and learning effects, the intervention (condition) the participant starts with and the order of conditions are counterbalanced across participants. For example, if we were comparing three interventions (A, B, and C), the number of participants that started with condition A would be equal to the number that started with condition B and the number that started with condition C. Furthermore, an equal number of participants would have conditions A, B, and C second and equal number would have conditions A, B and C third as well. Since this "within-subjects" design allows patients to serve as their own control group, these studies do not suffer from concerns that subject groups are not perfectly matched; therefore, group differences may be due to factors other than the specific intervention that are associated with some between-group studies. Due to the efficiency of having patients serve as their own control group, the CBI design is one of the most commonly used research designs found in the peer-reviewed literature of our field. Although there are some advantages to the CBI design, there are also several limitations that affect how we interpret the results of these studies.

Advantages of CBI studies include the following:

- Tight control over subject factors due to participants' serving as their own controls allows identification of fairly small differences.
- Not requiring a matched control group makes these studies much easier and quicker to complete, as well as more cost effective than the randomized controlled trials (RCTs) we describe in the next section.

Disadvantages of CBI studies include the following:

- Interpretation of longitudinal CBI studies is challenging, particularly in children, because the lack of control group does not allow the investigator to account for changes due to development and maturation. This limitation can greatly diminish the ability to make generalizations and the validity of the results.
- While offset by counter-balancing, learning effects can be present and contribute to variability. This can in turn weaken statistical power.

- If there is no control group we sometimes can't answer the question of whether the intervention works at all. That is, Intervention A could be better than B, but both could be worse than doing nothing at all.

Research of this type on hearing aids is often completed in a laboratory. The validity and applicability of the findings to clinical practice can be greatly strengthened, however, if the research is designed to have a real-world component. A recent example of this type of research is Cox Johnson & Xu, (2014) (more details are provided in Cox, Johnson and Xu, 2016; Johnson, Xu and Cox, 2017), in which outcomes with "premium" hearing aids and basic hearing aids are compared for speech understanding and quality of life. In that study, 25 participants, including both new and experienced hearing aid users, completed blinded, month-long trials with four pairs of hearing aids each: two basic and two premium. Their results indicated that all participants reacted very positively to the hearing aids (the good news); however, there were no statistically significant or clinically meaningful differences in improvement between the premium and basic-level hearing aids (the somewhat surprising news).

Randomized Controlled Trial (RCT)

Considered to be a very high level of evidence, RCTs are rare in hearing aid–related research. In this study design, participants are randomly assigned into an experimental group or a control group. The only expected difference between the control and experimental groups in a RCT is the outcome variable being studied. Commonly used in pharmaceutics research, an example might be investigation to determine whether a new drug has a different outcome than a sugar pill (*placebo*). Another type of RCT is comparison of an old intervention to a new intervention in two different groups. With this design however, it is often also important to include a third group (true control group) with either no intervention or a placebo to account for some of the weaknesses of the CBI designs described above. That said, there are many studies that use an RCT without a true control group. We think of this as sort of a hybrid design RCT—essentially a between-group version of the CBI design. This design can be quite appropriate, albeit depending on the experimental question, as demonstrated by the example study following. As with all experimental designs, RCTs have advantages and disadvantages.

Advantages of RCTs include the following:

- Randomization should eliminate population bias
- Statistical analyses can be clearly planned

Disadvantages of RCTs:

- Expensive to carry out in terms of time and money

THINGS TO REMEMBER:
RESEARCH EVALUATING NEW TECHNOLOGY

Robyn Cox (2005a) reminds us that there are some specific things that we should think about when we are evaluating research that addresses new technology. When you read about research evaluating new technology, ask yourself the following questions:

- How many subjects participated?
- How were they recruited?
- Are they representative of your patients?
- Is there a potential for bias in the way the study was conducted?
- Was there appropriate blinding of both subjects and data collectors?
- If the new technology was statistically better than the old, was the ES large enough to warrant the additional cost of this technology?

- Susceptible to volunteer bias; the subjects participating may not be representative of the population being studied
- No causal relationships can be made

Research of this type was conducted by Palmer (2012), who studied the starting point for using trainable hearing aids. Subjects (new hearing aid users) were randomly assigned to two different groups. The first group started hearing aid training on the day of the fitting; the second group used the hearing aids for a month (all fitted to NAL-NL1), and then started training. At the end of two months, the effects of the training, as measured by trained gain and patient preference, were assessed. Since this study was aimed at examining differences in technologies rather than technology benefit, there was no need for a true control group.

Systematic Reviews

A systematic review is a compilation of all relevant studies on a particular clinical or health-related topic/question. Cox (2005a) provides the flowchart of how a clinical recommendation can be derived from a systematic review in Figure 1–2. Fortunately, there are many search engines available today for assisting in a systematic review. Table 1–2 provides a review of some of the more popular ones. Google Scholar is another popular option; however, since results are ranked based on an algorithm that is not chronologically based, we find

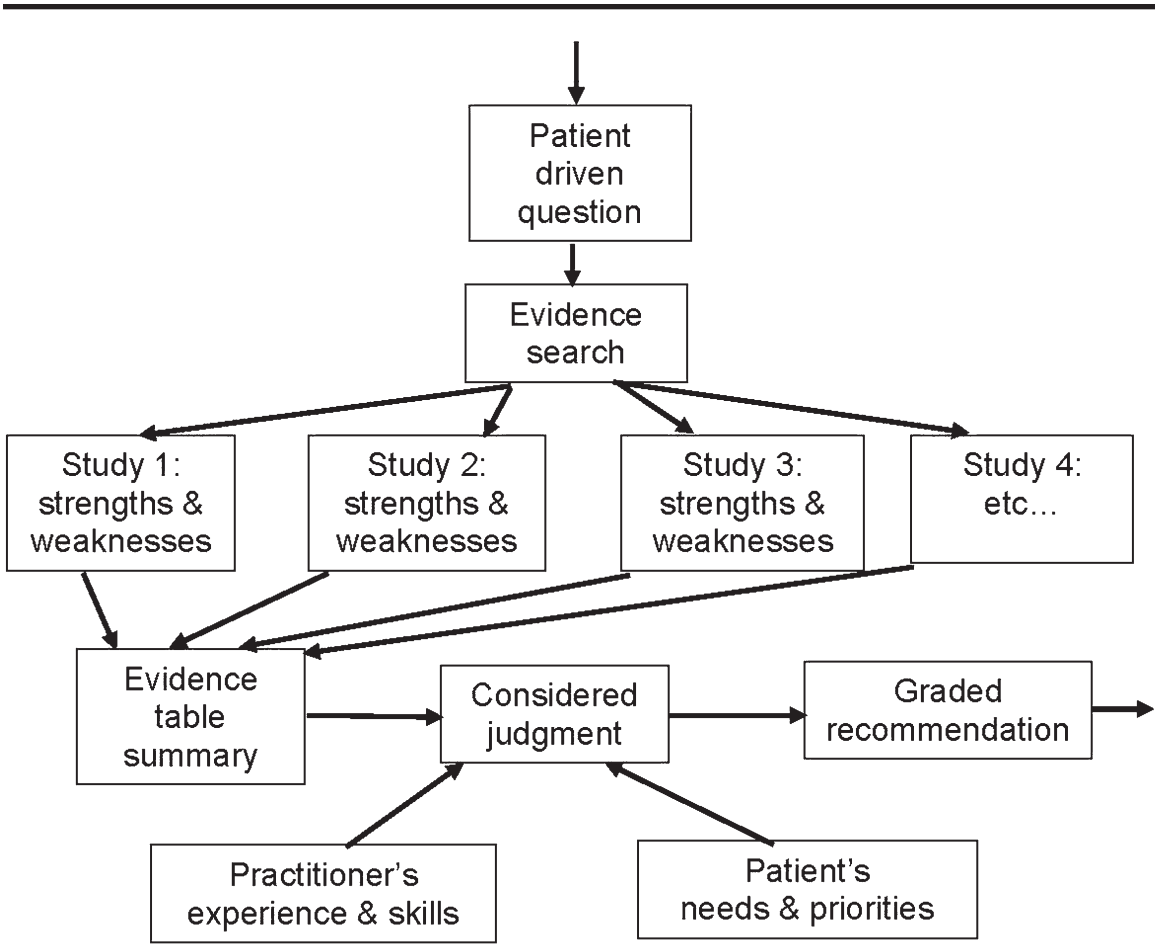

Figure 1–2. Schematic illustration of the application of the EBP method to generate a recommendation. This is consistent with a systematic or critical review, based on a given topic or clinical question. Adapted from Cox, 2005a, with permission.

Table 1–2. Example of the Various Search Engines Available for Systematic Reviews

Database and Website	Details
The Becker Library at the Washington University School of Medicine in St. Louis http://beckerguides.wustl.edu/audiology	Includes major databases, journals, and books, as well as other resources in the field of audiology and deaf education.
ComDisDome http://www.comdisdome.com	Includes more than 300,000 records in the communications disorders literature, dated back to 1911.
Cumulative Index to Nursing and Allied Health Literature (CINAHL) http://www.cinahl.com/	Includes journals, books, audiovisual, pamphlets, software, dissertations, and research instruments.
PubMed http://www.pubmed.gov	MEDLINE® is the largest module of PubMed. The biomedical journal citations and abstracts are created by the U.S. National Library of Medicine (NLM). MEDLINE® cites about 5400 journals, including journals in the area of audiological intervention that are published in more than 80 countries.
PsychINFO http://www.apa.org/pubs/databases/psycinfo/index.aspx	Covers the psychological literature since the 1800s. The database also includes some records from the 1600s and 1700s. Among the 42 million cited references, 80% are from journal articles, 8% are book chapters from authored and edited books, and 12% are dissertations and secondary sources.
Scopus http://www.scopus.com/	Contains multidisciplinary journal abstracts and citations, including physics, engineering, life and health sciences, psychology, social sciences and biological, etc. Nearly 18,000 titles are included, of which nearly 16,500 are peer-reviewed journals.
SumSearch http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2000788/	Searches websites with evidence written by qualified experts, with the majority of links from the NLM, the Database of Abstracts of Reviews of Effectiveness (DARE) and the National Guideline Clearinghouse (NGC) and categorized as textbooks, review articles, practice guidelines, systematic reviews, and original research.
TRIP (Turning Research Into Practice) Database http://www.tripdatabase.com/	Searches more than 75 databases, including PubMed, the DARE and the NGC, and other evidence-based materials, such as systematic reviews, peer-reviewed journals, guidelines, e-textbooks, expert opinions, patient information.

Note. Adapted from Wong and Hickson (2012).

it more difficult to ensure a comprehensive list when using this tool.

Advantages of systematic reviews include the following:

- Exhaustive survey of the current literature
- Less costly to pull data from prior studies than to create a new study
- Less time required than conducting a new study
- Results can be generalized and extrapolated to the general population more broadly than can individual studies
- More reliable and accurate than individual studies
- Considered an evidence-based resource for clinicians

Disadvantages of systematic reviews include the following:

- Very time-consuming
- May not be easy to combine studies
- May be difficult to find studies that meet criteria of research question

In Chapter 5 for example, you will find that we frequently recommend the use of unaided frequency-specific loudness measures to determine the patient's loudness discomfort level (LDL). In part, this recommendation is based on the systematic review of Mueller and Bentler (2005). They asked the question: "Are the clinical measurements of LDL for adult patients predictive of aided acceptance and satisfaction of loudness for high inputs in the real world?" Nearly 200 articles were reviewed, and they reported that the evidence supported using unaided LDLs for selecting the maximum real-ear output of hearing aids (no recommendation could be made of aided LDLs—see associated Key Concept).

We are aware that many clinics do systematic reviews on various diagnostic and hearing aid issues; of course, this also is a common project for students in their research methods class or perhaps even a capstone project. These reviews often lead to modifications and improvements in the overall hearing aid fitting process.

Meta-Analysis

As was apparent in Figure 1–1, the highest level of evidence comes from the meta-analysis. In a meta-analysis, a number of studies are combined in order to develop a single conclusion that has greater statistical power. Such a conclusion is statistically stronger than the analysis of a single study, due to increased numbers of subjects, greater diversity among subjects, or accumulated effects and results. Meta-analysis would be used for the following purposes:

- To establish statistical significance with studies that have conflicting results
- To develop a more correct estimate of ES or magnitude
- To examine subgroups with individual numbers that are not statistically significant

KEY CONCEPT: MANY ARTICLES DO NOT MEET CRITERIA FOR REVIEW

As we mentioned, when conducting a systematic review, data from several articles can be used to reach evidence conclusions. Before conducting the review, it is important to formulate a very specific question, develop criteria, and only then use articles that meet these criteria. Although there are more than 200 articles published each year regarding hearing aid technology, selection, and fitting, location of articles that meet a given criteria is not always an easy task. An example of this was reported by Mueller and Bentler (2005). Intuitively, it would seem that assessing aided loudness discomfort behaviorally following the hearing aid fitting, and then making appropriate adjustments when necessary, would result in improved patient satisfaction. This has been recommended in best practice guidelines. But is there evidence to support this procedure? Mueller and Bentler (2005) report that, although they started with 187 articles related to loudness measures with hearing aids, after they eliminated those articles that did not meet the necessary level of evidence, did not assess behavior-aided loudness discomfort levels (LDLs), did not include real-world loudness outcomes, or did not directly compare real-world loudness outcome to clinical measures, no articles remained; hence, they could not reach a concluding recommendation on this seemingly important clinical measure. It is cases like this in which expert opinion may be the highest level of evidence available; if you care to think of us as experts, we've provided a step-by-step method for conducting this testing in Chapter 15.

TECHNICAL TIP: WHAT'S A "QUEASY" EXPERIMENT?

In our world of hearing aids, *quasi-experimental* studies are often encountered. A quasi-experimental design is one that looks a bit like an RCT except for one main difference: There is no random assignment of subjects to the control and experimental groups (RCT) nor to the experimental groups (cohort studies). Sometimes referred to as "queasy" experiments, they are considered to be less robust in terms of research design. With respect to internal validity, they often appear to be inferior to randomized experiments. But there is something compelling about these designs; taken as a group, they are more frequently implemented than their randomized cousins.

Advantages to meta-analysis include the following:

- Offers greater statistical power
- Provides confirmatory data analysis
- Has greater ability to extrapolate to the general population affected
- Considered an evidence-based resource

Disadvantages to meta-analysis include the following:

- Difficult and time consuming to identify appropriate studies
- Not all studies provide adequate data for inclusion and analysis
- Requires advanced statistical techniques

A meta-analysis published in 2015 by Akeroyd and Whitmer looked at the effects of hearing impairment and hearing aids on sound localization. Their findings indicated that hearing impaired listeners show poorer abilities than listeners with normal hearing in determining the spatial direction of sound from all directions, and especially so from the side. They also conclude that there is no experimental evidence that hearing aids improve the situation.

Levels of Evidence

Now that you are familiar with the designs in research, the levels shown in Figure 1–1 are more meaningful. Many clinicians, professors, and supervisors like to assign level-coding to the research design. You can see two different approaches in Tables 1–3 and 1–4. What is not always clear to students and clinicians when they first begin to study EBP is that levels and quality must go hand in hand. Even though a research team may decide to carry out an RCT, if they fail to meet certain quality markers, the research might not be included in a systematic review or a meta-analysis due to its poor quality, and in spite of its great design.

Table 1–3. Assignment of Level Coding to the Different Research Designs

Level	Description
Ia	Well-designed meta-analysis of more than one randomized controlled trial (RCT)
Ib	Well-designed RCT
IIa	Well-designed controlled study without randomization
IIb	Well-designed quasi-experimental study
III	Well-designed nonexperimental studies, i.e., correlational and case studies
IV	Expert committee report, consensus conference, clinical experience of respected authorities

Source: Robey (2004). Adapted with permission of the Agency for Healthcare Research and Quality.