An Evidence-Based Approach to Applying Hearing Instrument Technology in Pediatrics

Catherine V. Palmer

Introduction

According to the Centre for Evidence-Based Medicine in Oxford, UK, evidence-based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. Evidence-based practice is the integration of (a) clinical expertise, (b) current best evidence, and (c) patient values to provide high-quality services reflecting the interests, values, needs, and choices of the individuals served. As can be seen from the definition, clinical expertise is listed first and is essential to evidence-based practice. In order to apply the evidence base to the individual, the clinician must continually exercise clinical expertise. The inclusion of patient interests, values, needs and choices is particularly important in the pediatric population, where the values of a variety of family members, teachers, and other individuals with whom the child interacts may come into play. In order to pursue evidence-based practice, the clinician must be familiar with key research terminology and definitions and use this information to be a critical consumer of research.

Terminology and Definitions

Hearing aids are considered a health care intervention, and many studies in the area of amplification (e.g., examining hearing aid features or the latest signal processing technique) are consistent with how epidemiologists view health care interventions. Health care intervention studies generally can be categorized into one of three areas (Haynes 1999). Efficacy (can it work?) is the extent to which an intervention does more good than harm. The testing is conducted under ideal circumstances (e.g., fixed directional microphone in a sound booth with fixed noise sources at the nulls with the child positioned ideally). Effectiveness (does it work in the real world?) assesses whether an intervention does more good than harm when used in typical practice (e.g., fixed directional microphone compared to an omnidirectional response in real-world listening conditions with the child interacting in the environment naturally). Efficiency (is it worth it?) is the effect of an intervention worth the additional cost that may be related to its use (cost effectiveness). For example, automatic, adaptive feedback control may be shown to be effective, but if hearing aids with this feature cost more, is the additional cost to the family worth the benefit obtained? There is a high expectation that a manufacturer will not release a feature or signal-processing scheme without efficacy data. The clinician is most concerned with effectiveness and efficiency. One expects effectiveness data to come from independent laboratories (rather from a manufacturer). Efficiency may be largely based on the clinician’s expertise in interpreting the effectiveness data in light of the child’s abilities and needs, as well as the family’s priorities.

Table 1 provides a list of definitions that will be useful to the clinician when trying to evaluate original research articles. Table 2 provides sources of other definitions and examples that may be of interest to the reader. The clinician will be most confident when data come from randomized controlled trials, systematic reviews, and meta analyses (see the ranking of levels of evidence in table 3). When a clinician plans to search the research literature for the answer to a clinical question, it is criti-
Table 1. Definitions that will aid in interpreting original research articles.

- Case series
  - An uncontrolled description of events and outcomes for a sequence of individual cases (e.g., patients)
- Case study
  - An uncontrolled observational (descriptive) report of events and outcomes of a single case
- Case-control study
  - A retrospective, observational study comparing a group of people with a disorder (cases) and a group of people free of the disorder (controls) to determine whether differences in the groups’ previous exposures, experiences, risk factors, etc. could explain their different outcomes
- Cohort study
  - An observational study in which a sample of participants is followed over time in an effort to determine the factors leading to different outcomes
- Cross-sectional study
  - A study of a single sample at one point in time in an effort to understand the relationships among variables in the sample
- Cross-over trial
  - A study in which participants first receive one type of treatment and then are switched to a different type of treatment
- Observational study
  - A study in which events are observed as they unfold, without any experimental manipulation
- Experimental study
  - A study in which the investigator actively manipulates (alters) one or more variables in order to contrast the experimental and control conditions
- Randomized controlled trial (RCT)
  - A study in which people are assigned at random (by chance alone) to receive one of several treatment conditions, including the experimental treatment and either a different type of treatment or no treatment
- Systematic Review
  - A summary of the scientific literature in which explicit methods are used to perform a comprehensive search and critical appraisal of individual studies.
- Meta-analysis
  - A specialized form of systematic review in which the results from several studies are summarized using a statistical technique to yield a single weighted estimate of their findings.

Once familiar with the above information, the clinician can be a critical consumer of research. When reviewing original research the clinician should look for biases, confounds, blinding (double-blind), use of a control group, experimental control, and effect size. Clinicians are particularly suited to identify biases and confounds in studies because of their day-to-day familiarity with the patient population. The clinician quickly identifies experimental designs that may bias the results or potential confounds that have been unknowingly added to the study. Blinding is particularly important in comparison studies. Ideally neither the research participant nor the researcher responsible for outcome measures will be knowledgeable about the condition being tested. The use of a control group (a similar population not receiving the treatment) is particularly important in pediatric research because the study participants (children) mature during the course of a treatment (e.g., use of a particular signal processing strategy). If no change is seen in the control group, then it will be more likely to attribute the change to the treatment and not maturation. Effect size is an important detail that allows the clinician to evaluate poten-
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When critically reviewing the literature, the clinician must be realistic. For instance, randomized controlled trials are not always ethical or feasible: the clinician will not see a randomized controlled trial comparing a group of moderately to severely hearing-impaired children fitted with hearing aids and a group not fitted with hearing aids, because it would not be considered ethical to withhold amplification from a group of hearing-impaired children. Blinding also can be difficult in certain studies. For instance, you cannot blind the participant to the comparison of a unilateral versus a unilateral fitting.

Table 3. Levels of evidence and corresponding grades.

<table>
<thead>
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<th>Levels of Evidence</th>
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<tr>
<td>1. Systematic reviews and meta-analyses of randomized controlled trials</td>
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<td>2. Randomized controlled trials</td>
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<td>3. Non-randomized intervention studies</td>
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<td>4. Descriptive studies (cross-sectional surveys, cohort studies, case-control designs)</td>
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<td>5. Case studies</td>
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<td>6. Expert opinion</td>
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<th>Corresponding Grades</th>
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<tr>
<td>A. Consistent level 1 or 2 studies</td>
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<tr>
<td>B. Consistent level 3 or 4 studies or extrapolations (data are being used in a clinically different situation) from level 1 or 2 studies</td>
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<tr>
<td>C. Level 5 studies or extrapolations from level 3 and 4 studies</td>
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<tr>
<td>D. Level 6 evidence or troubling inconsistencies or inconclusive studies at any level</td>
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When presented with the phrase “literature review”, many clinicians think back to graduate school when the goal was to find everything ever written about a topic (the more references the better). An evidence-based search is meant to be very efficient and should only produce papers directly relevant to answering the clinical question. The search should produce one to four directly related articles. The clinician will first review the titles and/or abstracts to eliminate articles that do not critically review the literature regarding a specific clinical question and provided the answer to the question. The clinician will want to keep an eye out for systematic reviews either in publication or presentation form throughout the year. Recently, an entire edition of the Journal of the American Academy of Audiology was devoted to a systematic review of questions related to amplification. One of the publications (Palmer and Grimes 2005) focused on questions related to amplification and children. This entry indicated that there was strong evidence (Grade A, see table 3) for: (1) increased audibility (~13.5 dB) over what is considered adequate for adults for low-input levels in order for pediatric patients to achieve adult performance, and (2) ensuring audibility through using WDRC with children with a compression threshold of 45–55 dB, a compression ratio of 1.7 to 2.3, and a fast attack time (10 msec). This does not mean that other compression thresholds or ratios would not be appropriate, but these were the values tested in the current literature. The pediatric clinician can see these data applied in a day-to-day manner through the use of the Desired Sensation Level fitting algorithm (v5.0; Scollie et al. 2005).

Answering Clinical Questions

Cox (2004, 2005) provides a detailed review of the process for answering clinical questions. The material in this section is a summary of Dr. Cox’s suggestions. In addition, an example of a clinical question and the actual process used is provided. There are five steps to perform in answering a clinical question: 1) ask an answerable question (the question should be very specific); 2) conduct an efficient search of the literature to locate the available evidence relevant to the question (search using “entrez pubmed” and/or CINAHL); 3) evaluate the quality of evidence (using table 3); 4) decide how the evidence applies to this particular child and generate recommendations for treatment (use your clinical expertise); and 5) evaluate the outcome of the treatment and seek ways to improve next time (this is a step that often is overlooked).

What Can the Clinician Do?

The clinician can integrate evidence-based practice into their day-to-day clinical services using three mechanisms: 1) put systematic reviews into practice, 2) answer clinical questions, and 3) use published clinical guidelines and protocols.

Putting Systematic Reviews into Practice

The Systematic Review or Meta Analysis is the clinician’s best friend. These are publications that have critically reviewed the literature regarding a specific clinical relevance. If there is a very small effect size (very small difference between the treatments) then the difference may or may not be clinically relevant even though the difference was statistically significant.

When critically reviewing the literature, the clinician must be realistic. For instance, randomized controlled trials are not always ethical or feasible: the clinician will not see a randomized controlled trial comparing a group of moderately to severely hearing-impaired children fitted with hearing aids and a group not fitted with hearing aids, because it would not be considered ethical to withhold amplification from a group of hearing-impaired children. Blinding also can be difficult in certain studies. For instance, you cannot blind the participant to the comparison of a bilateral versus a unilateral fitting.
directly answer the question being asked. Therefore, the clinician will only spend time with the articles that will directly impact the care of this particular patient. This entire process should take approximately 20 minutes. It is well worth seeking some continuing education in literature searching, because an efficient search strategy generally will dictate how long this process takes. The following is an example of a question that was asked in our clinic recently.

- Will a 9-year-old patient with a moderate-to-severe sensorineural hearing loss benefit from using directional microphones as compared with omnidirectional microphones?

Table 4 provides a breakdown of the elements of the question. These elements are required in order to create an efficient search strategy. The person is an active 9-year-old child. The problem is a moderate-to-severe sensorineural hearing loss. The current treatment is omnidirectional microphones, and we would like to compare that to the use of directional microphones. In the case of pediatric patients, there may not be a “current” treatment. If that is the case, two comparison treatments are chosen. The data represent what type of information you are interested in. In this case we were interested in speech intelligibility in noise in the real world. We decided to accept studies that used either objective or subjective measures. We decided not to accept laboratory studies. The data selection is completely up to the clinician and should reflect the measurements of interest for the particular question being asked. In addition, the clinician should consider what level of evidence will be acceptable. In this case, we decided to accept evidence that had grades of A or B.

We used search words hearing aid$ AND directional microphone$ and searched in PubMed and CINAHL. We put limits on the search, which included “English, Humans, Abstracts, Not Implants, and Child.” When we used “Pediatric” as a limit, no articles were found. This reminds us that searches are highly dependent on titles and keywords that have been used in articles. The “$” sign allows for variations in the word (s, ing, etc.) during a search. Limits are very helpful in reducing the number of titles and/or abstracts that the clinician must review to get to the studies that actually will answer the question being asked. Four articles were found in this search (Davidson, 2006; Gravel, Fausel, Liskow and Chobot 1999; Kuk, Kollofski, Brown, Melum and Rosenthal 1999; Littman, Blankenship and Koenig 2002). One article was eliminated because it was a review article (not systematic). One article was eliminated because the testing was not done in the real world (laboratory only). One article was eliminated because it did not test directional compared to omnidirectional microphones. Kuk et al. (1999) was the article that was accepted.

Kuk et al. (1999) had an evidence level of 3 with a grade of B. This really only speaks to the research design and, as mentioned previously, the clinician must be a critical evaluator of the literature. In reading this study, it is evident that there was a strong possibility of bias (individuals were provided with “new” hearing aids to compare to their “old” hearing aids), and subjects and the researcher were not blinded. Results of the Listening Inventory for Education (LIFE) questionnaire and parental impression showed improved speech recognition in noise with the “new” directional hearing aids compared to the users’ current (old) omnidirectional hearing aids. The data from the study indicate that the answer to the question “Will a 9-year-old patient with a moderate-to-severe sensorineural hearing loss benefit from using directional microphones as compared with omnidirectional microphones?” would be “yes” with a high level of uncertainty. Another way to say this would be that there is weak evidence that would support using a directional microphone for a child as compared with an omnidirectional setting.

Now that the evidence has been reviewed, it is time to apply clinical expertise to the final recommendation. In this child’s case, parent and teacher reports indicate that this child benefits from incidental learning (overhearing). This child is currently a successful FM system user in the classroom. Given the weak level of evidence, the ability to use overhearing which would be compromised with a directional setting, and the current appropriate use of an FM system in order to overcome noise problems in the classroom, directional microphones were ordered on the new hearing aids, but were disabled for the time being. Finally, we must have an out-

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<th>Person</th>
<th>Active 9-year-old child</th>
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<td>Problem</td>
<td>Moderate-to-severe SNHL</td>
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<tr>
<td>Treatment</td>
<td>Directional microphone (any configuration)</td>
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<tr>
<td>Comparison</td>
<td>Omnidirectional microphone</td>
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<tr>
<td>Data</td>
<td>Objective or subjective speech intelligibility in noise in the real world</td>
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come assessment plan. In this case, observations of parents and teachers may be appropriate.

The entire process (without the outcome measure) should take approximately 20 minutes. Once the clinician has an answer, this evidence can be applied to other patients as well. Using the evidence base to make clinical recommendations with assurance or with appropriate uncertainty can be very empowering for the clinician. We have found that more and more of our informed families come in asking about the evidence that surrounds various recommendations. It certainly is helpful in clinical interactions with these families if the clinician has a firm knowledge of the evidence behind various recommendations.

There will be times when there is a lack of evidence. As clinicians, we do not have the luxury of waiting to make a decision until there is adequate evidence. Lack of evidence is not the same as lack of benefit. This is a time when you have to apply your best clinical judgment to the situation and be committed to look continually for evidence as it may emerge. In addition, there are times when we have evidence that we cannot apply because of technological limitations. Currently, this is the case with needed bandwidth for hearing-impaired children. Stelmachowicz, Pittman, Hoover and Lewis (2002) provided compelling evidence for an increased bandwidth for pediatric patients extending up to 9000 Hz in order for these patients to adequately have access to /s/. Unfortunately, there are no commercial hearing aids available that produce this needed bandwidth. At a minimum, the clinician should be choosing technology with the widest bandwidth possible.

For the pediatric clinician it also is reasonable to ask when it is acceptable to apply adult data to pediatric questions (Christensen, Winfrey and Stelmachowicz 2007). In the case of automatic feedback management, would it be acceptable to use studies with adults to evaluate whether automatic feedback management improves hearing aid fitting? It certainly could be argued that feedback is generated by the same mechanism whether your patient is an adult or child, and the same mechanism is engaged in order to reduce it. Another use of adults to answer pediatric questions is illustrated in a study by Marcoux, Yathiraj, Cote and Logan (2006) that created what would be considered a pediatric condition in an adult population. The investigators measured the effect of a noise reduction algorithm on the acquisition of novel speech contrasts in hearing-impaired adults. They used speech contrasts from a language foreign to the test subjects. The task (learning novel speech contrasts) mimics what pediatric patients are doing every day. The clinician has to evaluate these types of studies and decide if the conditions closely mimic the pediatric condition and therefore can be used to motivate treatment in this population.

Using Published Clinical Guidelines and Protocols

Clinicians should review published clinical guidelines related to the work they are doing (e.g., hearing aid fitting protocols). These guidelines generally are written by a group of experts, but wherever possible evidence should be supplied to support the various recommendations. The adult amplification guideline recently published by the American Academy of Audiology provides the evidence base along with the ranking of the evidence level for every recommendation. The Pediatric Amplification Guideline (AAA 2003) provides evidence throughout the protocol, but does not comment on the levels of evidence. When this is revisited (generally about every five years) clinicians will expect it to follow the format of the newer adult guidelines with the evidence clearly presented and rated. The current Pediatric Amplification Guideline calls on the clinician to use evidence-based fitting techniques: “Target values for gain and output are determined through the use of a prescriptive formula (evidence-based independent or evidence-based device-related) by using hearing sensitivity data and the RECD.”

Although approaching clinical decisions with an evidence base is essential, it is also important to know when certain clinical activities are supported by acoustic facts. For instance, clinicians working with pediatric patients need to measure and incorporate real ear to coupler difference into the hearing aid fitting because it is an acoustic (and physical) fact that young ears are smaller than adult, average ears. It is not necessary to have a study comparing fitting hearing aids with and without RECD to know that this is an essential measurement. This same logic applies to verification techniques. If the goal of the fitting is to provide audibility for soft, moderate, and loud sounds then a measurement capable of producing output sound pressure level data from the eardrum is necessary to achieve this verification goal.

Conclusion

The clinician must be familiar with the terminology used in evidence-based practice in order to speak the language common to this practice. This language will empower the clinician to be a critical consumer of the lit-
erature surrounding various topics related to clinical practice. The clinician can implement evidence-based practice through the use of systematic reviews, carefully asked clinical questions answered through a systematic literature search, and by implementing published clinical guidelines based on current evidence.

References