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Evidence-based practice: What evidence is missing?

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Background: Evidence-based practice (EBP) is defined as “an approach in which current, high-quality research evidence is integrated with practitioner expertise and client preferences and values into the process of making clinical decisions” (ASHA, 2005). Evidence-based practice has gained significant momentum around the world. Many professional healthcare organisations, including those associated with speech-language pathology, have recommended that clinicians incorporate EBP into everyday clinical practice.

Aims: An approach such as EBP relies on the practitioner being able to locate high-quality research in order to provide data that informs his/her clinical decision making. The present paper lists at least five possible sources of bias that serve to reduce available evidence within EPB: funding bias, publication bias, consumer/researcher mismatch, reduced clinical applicability, and over-reliance on randomised controlled trials.

Main Contribution: Possible sources of bias within the EPB process, resulting in “missing” evidence are outlined and illustrated. Specific examples are provided from various healthcare fields.

Conclusions: It is suggested that discussion of sources of bias within EBP may help to maximise its potential. Audience suggestions provided at the 2005 Clinical Aphasiology Conference regarding possible directions for future work in this are appended.

Over the past decade, the term “evidence-based medicine” has gained considerable favour. It is based on the notion that clinicians should be able to identify published medical literature that is scientifically sound and ready for clinical application. Sackett, Rosenberg, Gray, Haynes, and Richardson (1996, p. 71) state:

Good doctors use both individual clinical expertise and the best available external evidence, and neither alone is enough. Without clinical expertise, practice risks becoming tyrannized by evidence, for even excellent external evidence may be inapplicable to or inappropriate for an individual patient. Without current best evidence, practice risks becoming rapidly out of date, to the detriment of patients.

“Evidence-based practice” (EBP) is the name of this concept when applied to the field of Communication Disorders. EBP is defined as “an approach in which current, high-quality research evidence is integrated with practitioner expertise and client preferences and values into the process of making clinical decisions” (ASHA, 2005).

The American Speech-Language-Hearing Association (ASHA) has recently adopted the position that speech-language pathologists and audiologists

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“incorporate the principles of evidence-based practice in clinical decision making to provide high quality clinical care” (ASHA, 2004a, 2005). In addition, the ASHA Joint Coordinating Committee on Evidence-Based Practice has issued its report with a recommended action plan over the next 10–15 years regarding EBP within the Association, the clinical professions, and the membership (ASHA, 2004b).

ASHA is not the only professional speech-language organisation in the United States to focus on EBP. The Academy of Neurologic Communication Disorders and Sciences (ANCDS) is currently developing and disseminating evidence-based practice guidelines for a range of neurological conditions. Frattali, Bayles, Beeson, Kennedy, Wambaugh, and Yorkston (2003, p. x) state that the primary goal of the guidelines is “to improve the quality of services rendered by assisting clinicians in decision making about the management of specific populations through guidelines based on research evidence”. ANCDS has established writing committees in order to develop the guidelines. It has received funding support from ASHA and the US Department of Veterans Affairs.

Evidence-based practice has gained significant momentum around the world. In fact, EBP has its roots in the United Kingdom, as Dr Archie Cochrane was one of the earliest proponents of evidence-based medicine (Walker, 2003). Named for him, the Cochrane Collaboration has worldwide centres and networks that focus on collection and dissemination of research evidence. In addition, *The Cochrane Library* comprises thousands of systematic reviews on health disorders.

Professional speech-language associations outside the United States are focusing on EBP. For example, The Royal College of Speech & Language Therapists in the United Kingdom has established evidence-based clinical policies, written papers related to “getting the evidence into practice”, and published national clinical guidelines. The Canadian Association of Speech-Language Pathologists and Audiologists (CASLPA) was an early affiliate organisation of the Canadian Cochrane Network and Centre, and is “helping to advance the cause and use of evidence-based practice among its members and students” (Orange, 2004, p. 265). In Australia, Speech Pathology Australia has developed an evidenced-based practice network for special-interest group members who are interested in the topic.

Integrating research evidence with practitioner expertise and client preferences into clinical decision making, in order to provide high-quality care, is laudable. However, the potential for bias is present from several sources. The present paper attempts to articulate some of the areas of potential bias in order to encourage discussion and problem solving.

WHAT EVIDENCE IS MISSING?

An approach such as EBP relies on the practitioner being able to locate high-quality research in order to provide data that inform his/her clinical decision making. What does it mean when such evidence is not found? The practitioner may misinterpret a lack of evidence to mean that the clinical treatment is ineffective. In addition, third-party payers and other stakeholders are likely to begin linking treatment reimbursement to published evidence (Adams & Gilbody, 2001; Walker, 2003). However, there are many reasons why evidence may be lacking.

Funding bias

Lack of research in a particular area might be due to insufficient research funding. There are limited research funds available and priorities must be made. However, in research funding, there may be additional sources of bias. For example, Stanley Prusiner had difficulty receiving federal funding for his early work on the prion theory because his ideas were considered heretical. In order to continue his studies, Prusiner was forced to convince private individuals and companies to fund his research. His persistence and determination paid off—he was awarded the Nobel Prize in 1997.

We all know that there are limited resources. There is now a trend to allocate healthcare resources—clinical and research—on the basis of evidence. Kerridge, Lowe, and Henry (1998) suggest that “allocating resources on the basis of evidence may therefore involve implicit valued judgments” (p. 1150). Bradley and Field (1995) state, “It may only be a short step from the notion that a therapy is ‘without substantial evidence’ to it being thought to be ‘without substantial value’” (p. 838).

Publication bias

Another reason for a lack of evidence could be due to a publication bias. One investigation showed that only 60% of medical studies with non-significant results were reported (Stern & Simes, 1997). If 40% of studies with non-significant results are unreported, how can a practitioner learn what treatments are ineffective? As Naylor (1997) indicates, meta-analyses based only on published trials may generate an inflated estimate of a treatment’s effectiveness. A possible solution would be for editors to remind authors that they welcome submission of non-significant result studies for possible publication. The flip side of non-significant result bias is the tendency for positive trials to be published more than once. This may also result in inflated effect size estimates in a meta-analysis.

In addition, there is potential for bias within the publication process itself. A relatively small number of individuals are in the editor and associate editor positions at our professional journals. Typically the associate editor is responsible for selecting two or three reviewers for a submitted manuscript. These reviewers could be “friendly” or “unfriendly” to the topic and methodology of the submission. Publication decisions are not purely objective—it is impossible for personal beliefs and preferences to be eliminated.

Consumer/researcher mismatch

In addition to the potential for funding or publication bias, there may be a mismatch between the interventions that are researched and those that are desired or prioritised by consumers. Tallon, Chard, and Deippe (2000) compared published and unpublished studies to consumer opinions regarding desired interventions for osteoarthritis treatment. They found that the intervention areas that most interested consumers were not the areas that dominated the published research. A similar empirical study has not yet been conducted regarding aphasia treatment. However, people with aphasia reported, via in-depth interviews, that quality of life and psychosocial issues related to their language loss were typically not

adequately addressed within the therapeutic process (Parr, Byng, Gilpin, & Ireland, 1997). Approaches such as “evidence-based patient choice”, “patient-centred medicine”, and “shared decision making” offer several ways to incorporate consumer priorities into research and clinical care (Bensing, 2000; Edwards & Elwyn, 2001).

Reduced clinical applicability

At the Clinical Aphasiology Conference (CAC), discussion has often included debate about criteria for internal and external validity. There is often a trade-off between subject selection criteria and clinical applicability. Certain populations of patients, including those with severe problems or co-morbidities, may be under-represented in clinical trials that have homogeneous subject selection criteria. For example, in aphasia research it is not unusual for individuals with severe aphasia to be excluded because of difficulty in comprehending verbal instructions. This provides a challenge for the clinician to generalise results to the more severe or complex patient that is often seen in clinical practice. Cayley (2003, p. 381) states:

If solid evidence-based medicine was readily available to answer every possible clinical question, medical practice would be straightforward. But for now, we are faced with a wide array of medical practices and patient problems and a relative paucity of evidence. When we cannot find the information that directly answers a particular clinical question, patient and clinician values become a factor.

Over-reliance on randomised controlled trials

Another source of potential bias is the tendency for EBP to rely on randomised controlled trials (RCT) as the “gold standard”. Various systems exist for classifying studies into “levels of evidence”. In the United States, the Agency for Healthcare Research and Quality (AHRQ) is considered to be the authority regarding the assessment of research (ASHA, 2004b). In the AHRQ classification system, well-designed RCTs are considered to provide more support for procedures or treatment compared to observational studies. However, direct comparisons of observational studies to RCTs for the same treatments showed that both types of research had extremely similar effect sizes (Benson & Hartz, 2000; Concato, Shah, & Horwitz, 2000). Concato and colleagues (2000) state, “The popular belief that only randomised, controlled trials produce trustworthy results and that all observational studies are misleading does a disservice to patient care, clinical investigation, and the education of health care professionals” (p. 1892). As Sackett et al. (1996) state, “Evidence based medicine is not restricted to randomised trials and meta-analyses. It involves tracking down the best external evidence with which to answer our clinical questions” (p. 72). Bensing (2000, p. 19) combines the issues of randomised clinical trials and clinical applicability:

Randomised clinical trials are performed on homogenous patient groups, that are artificially constructed by banning many patients, while the consultation room is filled with patients that show a wide diversity in related symptom patterns and an even wider diversity in the way they evaluate and cope with these symptoms ...

Questions regarding over-reliance of RCTs in EBP are not unique to aphasiology or the field of communication disorders. Fields as diverse as psychiatry (Williams & Garner, 2002), emergency room medicine (Kerridge & Saul, 2003), surgery (von Segesser, 2003), and nursing (Walker, 2003) have all voiced similar concerns.

Randomised controlled trials and observational studies can have complementary roles. Investigators should strive to find the “best fit” research design depending on the experimental question (Elman, 1995; Green & Britten, 1998; Haynes, 2002). In addition to different “levels of evidence” provided among the quantitative research designs, it is difficult to determine how, or if, single subject designs or qualitative research studies are currently incorporated into many EBP classification systems.

SOME CONCLUDING THOUGHTS

Cayley (2003, p. 381) concludes:

Whatever the clinical scenario, we must bear in mind that applying evidence-based medicine to patient care involves a complex interplay of evidence and values ... we must be precise in framing clinical questions, diligent in searching for precise answers, honest in understanding the role of our own values as we assess evidence, and faithful to our patients in translating evidence into information they can use to form decisions.

What can aphasiologists do in order to reduce the likelihood of potential bias in EBP? The present paper argues that the first step is to identify potential sources of bias. Funding bias, publication bias, consumer/researcher mismatch, reduced clinical applicability, and RCT over-reliance are five areas that have been identified as possible sources of bias in the EPB process. This is not an exhaustive list. By articulating problems and discussing possible ways of addressing them, we can help EBP realise a fuller potential for both practitioner and consumer. Let the discussions begin!

Audience members provided comments and questions following this paper’s presentation at the 2005 CAC in Ft. Myers, Florida. They are included in Appendix 1 in order to offer possible directions for future work in this area.

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APPENDIX

Audience comments and questions raised at the 2005 Clinical Aphasiology Conference (CAC) in Ft. Myers, Florida.

- Single subject designs are not considered by many classifications systems to be strong evidence. This is a problem for the field of aphasiology.
- There are people in the United Kingdom who are beginning to create meta-analyses for qualitative research. This may be one way to incorporate qualitative research into EBP.
- We need people who will organise speech-language clinics so that every client becomes an experiment. This will help us amass more evidence.
- We must be sure to use appropriate methodology for our research questions. Observational studies must use rigorous methods that are available.
- Part of CAC should be for “out of the drawer” papers; papers that are not quite ready to be presented but that would benefit from constructive feedback.
- CAC should create guidelines that equate single subject designs or other research designs with RCTs.
- We need to be careful about taking our discipline out of the mainstream and being “different”.
- Robey (1998) has performed meta-analysis on the effect sizes from single subject designs and has found strong evidence.
- Clinicians are busy and many professional journals are too expensive. We need to create bulletins or other types of publications that are more accessible to clinicians.
- There are many sources of tension for clinicians given the realities of health care. How can we use EBP with patients who will be gone before our treatment is known to be effective? What should the clinician do? Truncate the treatment? Apply something else that might work in a shorter period of time but without evidence? Should researchers continue to develop treatment that takes longer to be effective or should they focus on treatments that can be accomplished in a shorter time-span given the realities of health care today?