Evidence Based Practice: Implications for SGD Funding

Lewis Golinker, Esq.
Director, Assistive Technology Law Center
401 East State Street, Suite 401
Ithaca, New York 14850
607-277-7286 (v)
607-277-5239 (fax)
Lgolinker@aol.com (e-mail)
EBP in AAC: What Is It?

- Definition of EBP in AAC: “the integration of best and current research evidence with clinical/educational expertise and relevant stakeholder perspectives to facilitate decisions for assessment and intervention that are deemed effective and efficient for a given direct stakeholder.”

Let’s Ask Again: EBP, What Is It?

• EBP Definition: “the integration of best and current research evidence with clinical/educational expertise and relevant stakeholder perspectives to facilitate decisions for assessment and intervention that are deemed effective and efficient for a given direct stakeholder.”
EBP: Simplifying the Definition

$\text{BCRE} + \text{C/E E} + \text{RSP} = \gg \text{O}$

BCRE = Best and current research evidence
C/E E = Clinical/educational expertise
RSP = Relevant stakeholder perspectives
$\gg \text{O} = \text{Better approaches to assessment and treatment and better results (outcomes)}$
C/E E: What is Clinical/Educational Expertise?

C/E E = Clinical/Educational Expertise

is clinical reasoning, intuition, knowledge and skills, based on an SLP’s education, experience and professional judgment.

Key Practitioner Questions:

How can this be explained to a funding source?
RSP: What Are Relevant Stakeholder Perspectives?

RSP = Relevant Stakeholder Perspectives are factors related to the client, his or her closest communication partners, and all other communication partners that will affect decision making regarding the appropriateness of a particular treatment intervention, such as use of an SGD.

Key Practitioner Questions:

How can this be explained to a funding source?
BCRE + C/E E + RSP = >> O

BCRE = Best and current research evidence

Key Practitioner Questions:
What Evidence?
How to find it?
How to apply it in clinical decision making?
BCRE: What Is Evidence?

- Evidence is information
- Where is evidence to be found? For EBP includes published, professional literature
- Sources of EBP:
  - articles in peer-reviewed journals?
  - textbooks and treatises???
  - Internet information?
BCRE: What Is Research?

• According to Schlosser, research includes:
  – Meta-analyses (studies about studies)
  – Group experimental design studies (small or large groups)
  – Single subject experimental design studies
  – Quantitative reviews
  – Single case studies
Quality of Evidence: “Hierarchies”

• Discussion of EBP always includes reference to
  – the quality of evidence
  – Evidence hierarchies
  – “gold standard” of research
  – double-blind studies
  – controlled studies
Limitations on Research Designs for AAC Interventions

- Limits on research design for AAC interventions include:
  - Very low incidence population
  - Widely geographically dispersed
  - “Controls” are difficult to identify (Very heterogeneous mix of physical, cognitive and communicative abilities and needs)
  - “Single factor” variables are difficult to identify (Communication “functioning” can only be measured by its effectiveness, which involves an infinite range of communicative acts and communication partners)
Hierarchy of Evidence for AAC

- Meta-analysis of single subject designs or quasi-experimental group designs
- One well-designed non-RCT or one single subject experimental design study of one intervention or of multiple interventions
- Quantitative reviews that are non-meta-analytic
- Narrative reviews
- Pre-experimental group designs (case studies of groups) or single subject case studies
- Respectable opinion (e.g., Aug. Comm. News; ASHA DAAC Perspectives; ISAAC Bulletin; opinions of expert presenters; textbook authors)
Synthesizing EBP in AAC

The purpose of EBP is to find objective support for clinical practice that will maximize the potential for positive outcomes.

• Objective support is not the primary or the only consideration: clinical experience and stakeholder perspectives also must be considered.

• Objective support must come from specific sources. Acceptable evidence sources include professional journals, as well as “respected opinion” from texts and treatises.

• Among research literature, the types of studies most commonly conducted for AAC are accepted as reliable. All are listed on the hierarchy of evidence for AAC.

• The absence of some research designs for AAC reflects the nature of the population in need rather than a research “flaw”.

• Finally, our default position is that enough reliable evidence exists to support everything SLPs will recommend.
EBP in SGD Funding Issues

<table>
<thead>
<tr>
<th>SGD in general</th>
<th>No evidence to support approval as treatment</th>
<th>SGD are experimental</th>
</tr>
</thead>
<tbody>
<tr>
<td>SGD for a particular condition</td>
<td>No evidence of a particular type</td>
<td>SGD are not medically necessary</td>
</tr>
<tr>
<td></td>
<td>Insufficient evidence</td>
<td></td>
</tr>
</tbody>
</table>

ASHA Conference 2006
EBP Example: Medicaid & Medicare

“In making such a decision [whether to provide payment for a particular service], a basic consideration is whether the service has come to be generally accepted by the professional medical community as an effective and proven treatment for the condition for which it is being used. If it is, Medicare may make payment. On the other hand, if the service is rarely used, novel or relatively unknown, then authoritative evidence must be obtained that it is safe and effective before Medicaid may make payment.”
SGDs are Generally Accepted by the Professional Medical Community

• _
• _
• _
• _
• _
• _
Proposed TennCare Definition of Medical Necessity

• It must not be experimental or investigational. A medical item or service is experimental or investigational if there is inadequate empirically based objective clinical scientific evidence of its safety and effectiveness for the particular use in question. This standard is not satisfied by a provider’s subjective clinical judgment on the safety and effectiveness of a medical item or service or by a reasonable medical or clinical hypothesis based on an extrapolation from use in another setting or from use in diagnosing or treating another condition.
EBP Example: Health Insurance

• “The use of [SGDs] as a strategy for speech and language training for persons with [CP] has not been proven efficacious by large scale studies using these devices.”
Insurance Denial Excuse for SGD for Child with DD

• Although this item is specifically excluded in your contract, I did have the documentation reviewed by our clinical staff…. Our physician reviewer indicated that this item does not meet our medical technology assessment protocol, in that it suffers from a lack of sound scientific evidence in the form of controlled clinical studies documenting its long-term efficacy and overall measurable impact on the net health outcomes. …
Medical Technology Assessment Guidelines

• 1. The technology must have final approval from the appropriate government regulatory bodies [FDA]
Medical Technology Assessment Guidelines

2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.

- The evidence should consist of well designed and well-controlled investigations published in peer reviewed English language journals. The qualities of the body of studies and the consistency of the results are considered in evaluating the evidence.

- Opinions and evaluations by national medical assoc., consensus panels or other technology evaluation bodies are evaluated according to the scientific quality of the supporting evidence on which they are based.
Medical Technology Assessment Guidelines

• 3. The technology must improve the net health outcomes.
  – The technology’s beneficial effects should outweigh any harmful effects on health outcomes.

• 4. The technology must be as beneficial as any established alternatives.
  – Should be as cost-effective as alternatives that achieve a similar health outcome.
Medical Technology Assessment Guidelines

• 5. The improvement must be attainable outside the investigational setting.
  – When used under usual conditions of medical practice, the technology should be reasonably expected to improve health outcomes to a degree comparable to that published in the medical literature.
EBP Example: Health Insurance

• “Any service that Premera Blue Cross determines is experimental or investigational on the date it’s furnished …. Our determination is based on the criteria stated in the definition of experimental/investigational services.

• If we determine that a service is experimental or investigational, and therefore not covered, you may appeal our decision.
Definition of Experimental

- A drug or device with no FDA approval
- The service is subject to oversight by an institutional review board
- No reliable evidence demonstrates the service is effective, in clinical diagnosis, evaluation, management or treatment of the condition
- The service is the subject of ongoing clinical trials
- Evaluation of reliable evidence indicates that additional research is necessary before the service can be classified as equally or more effective than conventional therapies
Reliable Evidence

- Reliable evidence includes but is not limited to reports and articles published in authoritative peer reviewed medical and scientific literature
Autism Exclusion

• “The available evidence in peer reviewed professional literature does not scientifically establish that SGD's are effective in the treatment of autistic disorders or other PDDs. The published literature about these devices [does not amount to] reliable evidence [because]:
  – There are no controlled research studies
  – Almost all studies are single subject or very small sample sizes, and are therefore anecdotal;
  – Almost all are set in school and provide no data about outcomes in home and community settings.”
Last Example: Health Insurance

• “We have determined an SGD is not considered a covered health service due to inadequate clinical evidence of safety and/or efficacy in published peer reviewed literature for the treatment of the documented diagnosis. As a result, the proposed SGD is considered unproven and is not eligible for benefits under the plan.”
Conclusion

• EBP has been and will be applied in the future to deny SGD funding requests. SLPs need to be alert to these denials.
  – They may well be internally inconsistent;
  – They may ask the wrong questions;
  – They may look at the only a subset of the available evidence;
  – They may not read the evidence correctly;
  – They may set up a standard for SGDs that isn’t and possibly can’t be met by other things they cover, such as wheelchairs