Emerging Issues #2: CI Candidacy in 2018

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Disclosures

• Terry Zwolan
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• Craig Buchman
  • Ownership – Advanced Cochlear Diagnostics, LLC
  • Consultant – Advanced Bionics and Cochlear Corp.
CI Candidacy

• CI Candidacy decisions are influenced by FDA and insurer indications
• These indications typically include statements about unaided hearing and benefit from hearing aids (speech recognition scores)
• Today, patients who are receiving CIs demonstrate high levels of pre-operative open-set speech recognition, and many clinics are providing implants outside the FDA-approved indications
Professional responsibility

• Making a decision about CI candidacy carries great responsibility
• Decisions must be made thoughtfully and evidence-based

• Dr. Oliver Adunka and Dr. Maura Cosetti will discuss medical aspects that should be considered when implanting children, adults, and the elderly.
• Unfortunately, elderly patients with Medicare are currently required to meet stricter requirements than patients with other insurance...
ACIA is trying to change that...

- ACIA is sponsoring a Coverage with Evidence Determination (CED) study approved by the Center for Medicare and Medicaid Services (CMS) to examine expansion of CMS indications for a CI from:
  - Bilateral moderate to profound SNHL with limited benefit from amplification defined by test scores of < 40% in the best aided listening condition on open-set sentence recognition
  - To include patients with bilateral moderate to profound SNHL who demonstrate test scores between 40 and 60% on open-set sentences

- We are hopeful the results of this study will bring CMS indications more in line with those of FDA-approved indications
20 CMS CED ERID Study Sites across the US

- 19/20 sites have IRB approval and are actively recruiting
Summary of results to date best aided

![Graph showing best aided results for different time periods and institutions, with error bars representing +/- 1 SD.]

- **Pre Op (N=28)**
- **6 months (N=18)**
- **12 months (N=15)**

Institutions:
- CNC
- AzBio
- CUNY
Summary of results to date, implanted ear
What about other indications?

• Current indications often leave room for clinical judgement in regards to test materials, presentation level, and mode of presentation, such as presenting stimuli in quiet or in noise. This has led to great variability in how we are testing patients to determine candidacy.

• Dr. Sandy Prentiss will provide us with an update today regarding the procedures being used by most clinics to evaluate candidacy for a CI.
What about patients who do not meet traditional indications?

• The FDA tells us that “good medical practice and the best interests of the patient require that physicians use legally available drugs, biologics and devices to their best knowledge and judgement....
  - Responsibility to be well informed
  - Base its use on scientific rationale and sound medical evidence
  - Maintain records of its use and effects

• Patients being considered for implantation outside the traditional indications include those with SSD and asymmetric hearing loss, to name a few. Dr. Jill Firszt will tell us about some recent findings regarding outcomes with such patients.
Audience involvement

• Some presenters have included audience polling in their talks so we can obtain an idea of where we are in regards CI candidacy. We encourage all of you to respond...

• The session will conclude with a panel discussion of our presenters and we’ll open the floor for questions and discussion and a few more opportunities to poll the audience.