AAMI CI86 Cochlear Implant Systems – Requirements for Safety, Functional Verification, Labeling, and Reliability Reporting

AAMI CI-86 Standards Committee

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Disclosures

• Cochlear Americas Advisory Board Member
• Institute for Cochlear implant Training
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AAMI CI-86
Motivation for developing a US standard for CIs:
Establish uniform guidelines for reliability reporting

• Manufacturer’s device-reliability reports
  • European consensus statement on internal device failures and explantation (no authors listed, 2005)
  • International classification of reliability for implanted cochlear implant receiver stimulators (Battmer et al., 2010)
  • CI Soft Failures Consensus Development Conference Statement (Balkany et al., 2005)
  • ISO 5841-2:2000: Reporting clinical performance of cardiac pacemakers

• Limitations: Subjectivity was permitted in inclusion of data. For example, not all explanted devices were reported, such as those removed for medical reasons
Existing Standards

- BS EN 45502-2-3:2010 Active implantable medical devices. Particular requirements for cochlear and auditory brainstem implant systems

- ISO 14708-7:2013 Implants for surgery -- Active implantable medical devices -- Part 7: Particular requirements for cochlear implant systems

- Existing standards have limitations (i.e. they do not cover reliability reporting)

- These standards served as a useful reference for AAMI CI-86
**AAMI CI86: Development Timeline**

- **2010:** The FDA submitted a new work item proposal to AAMI for development of this standard
  - **Association for the Advancement of Medical Instrumentation (AAMI):** A healthcare technology nonprofit and standards developing organization

- **Between 2010 and 2017**
  - CI Committee was formed and met 15 times
  - Document was drafted and revised
    - 4 Committee Draft (CD) documents issued for ballot and some were submitted for public comment
      - 2014, 2015, **2015, 2016**

- **ANSI/AAMI CI86:2017 (Ed. 1)** published July 6, 2017
So what does a “standard” mean?

• **Standard**: Set of guidelines that a manufacturer can *voluntarily* comply to

• ANSI Essential Requirements for standard development state “The standards development process should have a balance of interests. Participants from diverse interest categories shall be sought with the objective of achieving balance.”
  
  • For AAMI/CI-86 those interest categories included
    • Regulatory and general interest/organizations
    • CI manufacturers
    • Clinicians
AAMI CI Committee Member Affiliations

• Four cochlear implant manufacturers
  • Advanced Bionics
  • Cochlear
  • MED-EL
  • Oticon/Neurelec

• FDA

• Clinicians/Academicians from a variety of settings
  • American Neurotology Society
  • Chattering Children
  • Gallaudet U.
  • Swedish Medical Center
  • U. California-Irvine
  • U. Iowa Hospital and Clinics
  • U. Maryland
  • U. Michigan
  • Arizona Ear Center
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AAMI Standards Directors: Jennifer Moyer & Colleen Elliott
How AAMI CI-86 will impact clinicians

• AAMI CI-86 will provide clinicians and recipients with improved information regarding device reliability
  • Impacts the information device manufacturers provide to the FDA about devices
  • Impacts the information we and our patients receive about cochlear implant products
  • Such information will enable clinicians and patients to make better, more informed decisions about cochlear implants
Not having a standard has impacted patient care

• Reliability is important
  • Reliability reports for contemporary internal devices vary among CI manufacturers. Clinicians and patients are confused.
  • Reliability of external components is important too, yet manufacturers rarely report on the reliability of externally-worn components

The Standard:

• Two levels of required, periodic reporting that includes detailed, proprietary reports for regulatory authorities and simplified reports for the public and clinical community.

• Each manufacturer will report their public data on their company website using a format and explanatory language that is common across all manufacturers, aiding patients and clinicians in interpreting reliability data.
Manufacturers will provide information about the percentage of implanted devices worldwide that have been removed following implantation. This number is the cumulative removal percentage (CRP).

- There are detailed procedures regarding device analysis and reporting of findings.
EXPLANTED DEVICE CATEGORIES

• In the reporting, explanted devices will be broken down into 4 categories:
  1) Medical reason for explant
  2) Non-medical reason for explant
  3) Inconclusive/no fault found (NFF): Failure analysis unable to identify the underlying cause
  4) Combined – the percentage of all medical, non-medical, and inconclusive (CRP)
• Devices are required to undergo a complete full destructive analysis before they are eligible for the inconclusive category
• Data will be stratified by patient population and reported both separately and combined for patients greater than or less than 10 years of age.
## Device Category Reporting

<table>
<thead>
<tr>
<th>Group</th>
<th>Adults</th>
<th>Children</th>
<th>Combined Adults and Children</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Medical Related</td>
<td>Device Failure</td>
<td>Inconclusive</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Total</td>
<td></td>
</tr>
<tr>
<td>Years</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Y1</td>
<td>0.20%</td>
<td>0.33%</td>
<td>0.08%</td>
</tr>
<tr>
<td>Y2</td>
<td>0.43%</td>
<td>0.64%</td>
<td>0.14%</td>
</tr>
<tr>
<td>Y3</td>
<td>0.58%</td>
<td>0.87%</td>
<td>0.19%</td>
</tr>
<tr>
<td>Y4</td>
<td>0.74%</td>
<td>1.16%</td>
<td>0.23%</td>
</tr>
<tr>
<td>Y5</td>
<td>0.91%</td>
<td>1.39%</td>
<td>0.27%</td>
</tr>
<tr>
<td>Y6</td>
<td>1.02%</td>
<td>1.69%</td>
<td>0.31%</td>
</tr>
<tr>
<td>Y7</td>
<td>1.08%</td>
<td>1.96%</td>
<td>0.36%</td>
</tr>
<tr>
<td>Y8</td>
<td>1.14%</td>
<td>2.32%</td>
<td>0.41%</td>
</tr>
<tr>
<td>Y9</td>
<td>1.21%</td>
<td>2.55%</td>
<td>0.43%</td>
</tr>
</tbody>
</table>

Note: CL_up and CL_low are 95% Confidence Limits
Manufacturer X, Device Model A
Failure Rates by Analysis Category for Adults
Manufacturer X, Device Model A
Failure Rates by Analysis Category for Children

Cumulative Failure Percentage

- Children All Categories
- Children Medical
- Children Device
- Children Inconclusive

Years of Use

Y1  Y2  Y3  Y4  Y5  Y6  Y7  Y8  Y9

0.96% 1.26% 1.78% 2.03% 2.37% 2.85% 3.21% 3.42% 3.84%
0.52% 0.63% 0.84% 1.05% 1.15% 1.27% 1.43% 1.57% 1.68%
0.12% 0.17% 0.26% 0.37% 0.44% 0.58% 0.63% 0.71% 0.88%
Manufacturer X, Device Model A
Failure Rates by Analysis Category for Adults and Children
Manufacturers will additionally report Failed Component Return Rate (FCCR), which describes sound processor reliability. FCCR = the percentage of the total number of failed processors received within the last month compared to the total number of the same processor sold in the US by the end of that month.
The Standard Includes Tools for Clinicians and the public

Several informative annexes have been included in the AAMI CI86 standard that provide clinicians with tools to understand device analysis, reporting, and aid patients in interpreting reliability data:

Annex A: Clinical identification & management of device failures
- Provides suggestions for pre-, peri-, and post-operative considerations when discussing and/or evaluating device failures

Annex B: Clinical checklist
- For completion by clinicians to ensure consideration of steps that should be taken to evaluate device function and also to note signs and symptoms that may be related to malfunction of a cochlear implant. This information is to be shared with the device manufacturer prior to device explant and an explant kit must be obtained from the manufacturer prior to explantation.

Annex C: Returned implant analysis report template
- Provides an example of how device manufacturers will report the results of the full device analysis

Annex D: Indications of performance decline
- Provides a list of symptoms clinicians can watch for that may indicate a device failure

Annex H: Reliability reporting template for the public and clinical community (previously described)
Other important regulatory features
Requirements for Device Labeling

• Information on use, warnings, and hazards

• **Specification sheets**: a **common** set of information to describe
  • Implant
  • Electrode
  • Sound-processing strategy(ies)
  • Sound processor(s)
  • Remote-control

• **Device reliability reports**: **uniformly** generated
  • Use **prescribed** failure-analysis steps to categorize explants
  • Report cumulative explant rates; stratify by explant category & pt. age
  • Make **publicly available** on mfgr’s website, update 2x/year

• Manufacturers will provide documentation to clinics to assist troubleshooting, explantation & return of devices
Describes How A Manufacturer Shall Characterize a CI Device System in a Regulatory Submission

- General description of device, intended uses, and model designations
- Inventory of system components
- Interconnection between implantable and non-implantable parts
- Wireless technology
- System hardware
- System software (including sound processing strategies)
- Electrode specification and characteristics
- Features of clinical fitting software
- Electrical Stimulation
  - Methodology/circuitry
  - Waveforms
  - Provisions for safe stimulation
A Device Shall Meet  
Design & Verification Requirements

- Electrical
  - Stimulation
  - Battery
- Thermal
- Mechanical
  - Safety of electrode array insertion
- Manufacturing
  - Hermeticity
  - Moisture levels
- Biocompatibility
- Sterility, packaging, and shipment
- Safe use in various intended environments (e.g., MRI)

- Test sample sizes may be risk-based
Manufacturer reliability reporting to regulatory bodies (Annex E)

• Contains examples of how reliability data are to be reported to regulatory bodies

• Such reports differ from those reported to the public (contain 3 and 12 month analysis intervals) will be proprietary to the manufacturer and not available to the public

Annex E
(Informative)

Reliability reporting to regulatory bodies

This Annex contains examples of how reliability data are to be reported to regulatory bodies in accordance with the requirements of Section 11.4.2. The examples include the following:

1) Other general observations (specify)

a) Acceptable graphical presentations of implant reliability data for 12-month analysis intervals. For brevity, the graphs shown only use 12-month analysis intervals and represent the limited publicly reported data. However, for compliance with this standard, data shall also be analyzed and graphed using three-month analysis intervals and 12-month analysis intervals, in accordance with the requirements of this standard.

b) Acceptable tabular presentations of implant reliability variables for three-month and 12-month analysis intervals.

Regulatory graphical and tabular reports will be proprietary to the manufacturer and not available to the public.
Conclusion

• ANSI/AAMI CI86 has been published and is available in the AAMI store: http://my.aami.org/store/SearchResults.aspx?searchterm=CI86&searchoption=ALL

• This is an important new CI standard that represents the collaborative effort of clinicians, device manufacturers, and regulatory personnel to improve reporting of device reliability

• The standard has several benefits, including provision of information to clinicians and recipients:
  • That will help determine if a device explant is warranted
  • That will educate clinicians regarding the root cause of internal device failures, including medical, device-related, and unknown for both children and adults
  • That will educate clinicians regarding the root cause of sound processor failures, including mechanical, electrical, moisture, or unknown
  • Provides uniformity in reporting reliability information by manufacturers, making it easier for existing and prospective patients, parents, clinicians, and researchers to interpret and compare reliability information across devices.