The Evolution of Pediatric Candidacy for Cochlear Implants: A New Indication

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Agenda

Introduction	5 min
History of Pediatric Candidacy for Cochlear Implantation	10 min
Industry Data Supporting Cochlear Implantation at 9 months of age	15 min
Stanford Children's Health Experience with Early Implantation in Children 9-12 months of Age	15 min
Current Technology for Pediatric Cochlear Implant Recipients	10 min
Conclusions and Q & A	5 min

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Poll Question

Who is in our audience today?

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Poll Question

What is your experience with cochlear implant recipients?

4

Poll Question

How many years of experience do you have working with cochlear implant recipients?

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Learning Outcomes

History of Pediatric CI Candidacy

- Describe the history of pediatric cochlear implant candidacy

Evidence that supports early implantation

- Describe the data that supports earlier implantation in children with bilateral severe to profound sensorineural hearing loss

New candidacy indications

- List Cochlear's new indications for pediatric cochlear implantation according to the FDA

Considerations for the pediatric population

- List features in modern cochlear implant systems which contribute to success in pediatric recipients

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The History of Pediatric Cochlear Implant Candidacy

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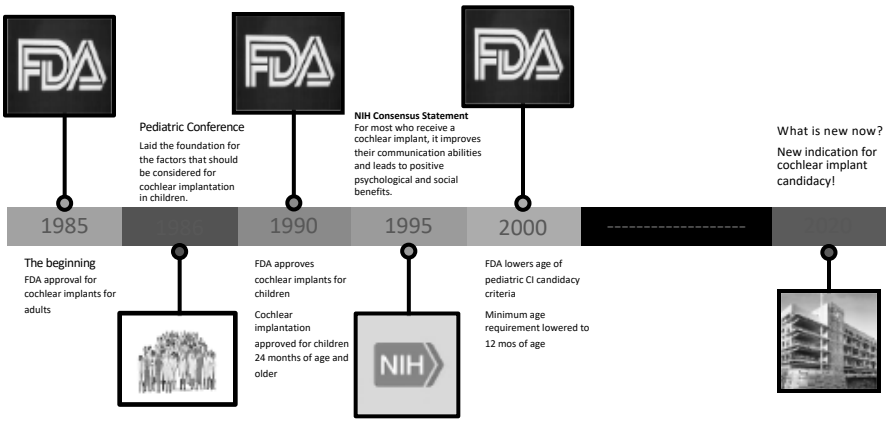
History of Pediatric Cochlear Implantation Candidacy in the United States

Significant movement with the FDA between 1985 and 2000



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How does that timeline compare to the experience of patients and providers?

What was occurring in the meantime?

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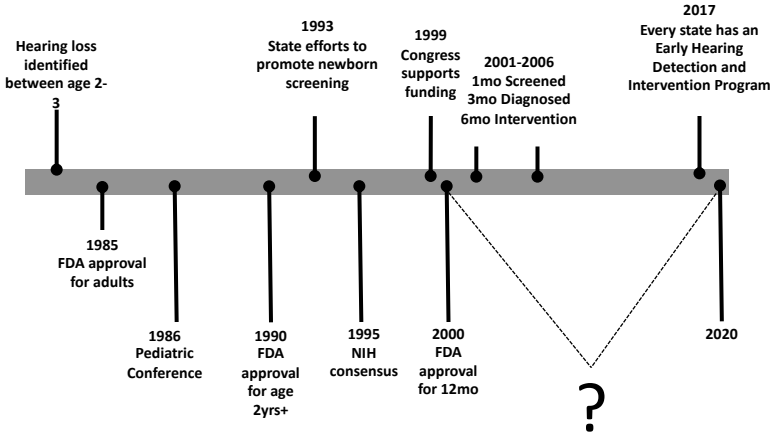
History of Pediatric Candidacy in the US in Relation to Evolution of Early Identification and Early Intervention



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Poll Question

Do you have experience working with children who were implanted prior to 12 months of age?

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What happened during that gap?

- More awareness of the importance of early identification and early intervention outside of our immediate circles of audiology and speech pathology.
- Infants under 12 months were being implanted at various practices and implant centers.
- Changes in implant electrode arrays and surgical approaches as well as advancements in external components of implant systems.
- Research studying the impact of these advances on cochlear implant recipients overall as well as those under 12 months of age.

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What have we learned?

Safety

- Cochlear implantation is a safe procedure (Birman, 2009; Colletti, 2012 and others)

Stability of the electrode array

- Electrode array remains stable (Hoffman, 1997; Roland, 1998 and others)

Impact on Development

- Auditory deprivation negatively impacts development (Hoffman 1997, Halpin 2010, and others)
- Earlier implantation prevents gaps in development (Moeller 2000, Yoshinaga- Itano, 2003 and others)

Early Access to Sound and Early intervention are a dynamic duo

- Improved spoken language skills when implanted early (Cuda D, 2014 and others)

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Chang, Kay. (2019). Safety of Cochlear Implantation in Children Under 12 Months of Age. [PowerPoint slides]. Retrieved from https://cdn.ymaws.com/www.acialliance.org/resource/resmgr/c2019_ppt/7_chang_thursday_july_11_111.pdf

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Industry Data Supporting Cochlear Implantation in Children 9 months of age

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Pediatric Study

Study sponsored by Cochlear Americas

Sites, leaders, and teams who participated in data collection:

- Susan Waltzman, PhD and the CI team at NYU
- Karen Gordon, PhD and the CI team at SickKids
- Jennifer Woodard, AuD and the CI team at UNC
- Jace Wolf, PhD and the CI team at Hearts for Hearing
- Matthew Fitzgerald, PhD and the Pediatric Audiology and CI Team at Stanford Children's Health

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Pediatric Study

Purpose: Gather safety information on children implanted <12 months of age

Method: Retrospective chart review

Sites: 5 investigational sites across the US and Canada

Metrics Gathered:

Demographics

Surgical variables

Anesthesia variables

Post-operative complications

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Results: Demographics (N=136)

Most common comorbidities

- Developmental delay
- Genetic syndrome
- Congenital malformations
- CMV
- Meningitis
- Seizures

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Preliminary Results: Surgical Variables

	UNI (N=20)	BILAT (N=101)
Weight	9.19kg	8.62kg
(Range)	6.1-11.8kg	6.1-11.7kg
	UNI (N=21)	BILAT (N=56)
EBL	11.29cc	14.7cc
(Range)	2-25cc	1-100cc
	UNI (N=26)	BILAT (N=106)
Anesth Duration	2:28	3:47
(Range)	1:22-4:48	2:14-6:19
	UNI (N=24)	BILAT (N=104)
Recov Duration	2:30	2:35
(Range)	0:26-9:10	0:35-10:28

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Preliminary Data:

Reportable Events encountered during study

39 of 136

Subjects experienced an event that was reported in the study. These events ranged from cold symptoms through to hospital readmittance.

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Events related to temperature regulation during or immediately after surgery.

5

Met **Medical Device Reporting** criteria due to their relationship to the device/procedure and requirement of surgical or antibiotic intervention.

3.7%

Medical Device Reportable Event rate within this study, similar rates to manufacturer's database of 2.5 % of those implanted <12 months and about 3.1% for those implanted between 12 – 24 months with same electrodes as study.

Safety

To reduce the risk of anesthetic-related adverse events, a pediatric anesthesiologist should be present during surgery for infants implanted under 12 months of age.

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Preliminary Data: Events involving Device/Procedure

RWE (US+CA)					
Months at Implant Surgery	Registered Surgeries	Reportable Complaints (MDR)	All Complaints	Reportable Complaints Rate	All Complaints Rate
9m	52	1	10	1.9%	19.2%
10m	35	1	4	2.9%	11.4%
11m	58	1	14	1.7%	24.1%
9-11m	145	3	28	2.1%	19.3%
Predicted 12-24m	706	17	162	2.4%	22.9%

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Conclusions of the pediatric study

For infants implanted under 12 months

Substantial difference is not seen within:

- Demographics
- Surgical complications
- Post-operative complications

The communication outcomes demonstrated in the literature show an undeniable benefit of early implantation

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Poll Question

In your experience, do you feel that the process for a pediatric candidate to be implanted early is smooth?

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Poll Question

How long do you feel it takes a pediatric patient to complete the process (from referral to surgery)?

Poll Question

What are common challenges patients and referring providers face to complete the process in a timely way?

Stanford Children's Health Experience with Children 9-12 months of Age

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Our experience (likely similar to other pediatric CI centers) and what this means for those referring to pediatric CI centers

Our process for workup and evaluation and how we strive to expedite the process

Our patient data and case examples

How our team works to navigate care and rehabilitation post activation

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Children's Hearing Center

Pediatric Audiologists
(including those with CI specialization)


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Rachael Jocewicz, Au.D


Claire Umeda, Au.D


Lauren Bloom, Au.D


Sonia Rehagen, Au.D


Veronica Koo, Au.D


Casey Heidohrn, Au.D


Alice Kuang, Au.D


Logan Faust, Au.D

Speech Language Pathologist


Kayla Kolhede, CCC-SLP, LSLS Cert AVT

Otologists


Alan Cheng, MD


Kay Chang, MD


Iram Ahmad, MD


Nikolas Blevins, MD

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Our medical work-up for cochlear implant candidates

Audiologic workup

Typically includes

- Diagnostic ABR +ASSR
- Behavioral hearing evaluation
- Fitting with amplification

Otologic workup

Typically includes

- Lab work-up
- Imaging

Speech and language evaluation and developmental assessment

Goal is to

- Establish baseline to monitor outcomes and growth
- Possibly identify anything that could have a role in adjusting expectations

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How our team works to expedite the process

Striving to have everyone on our team be knowledgeable in CI candidacy and evaluation

- It's important that we all have the knowledge to recognize a potential candidate.
- This helps us all be an advocate in educating a family as this is key to getting patients and families on the right path.

Receiving as much information a possible at the time of referral

- Receiving reports and waveforms within the referral is pertinent to timely scheduling

Telehealth visits as a form of intake

- Newly incorporated but this can be helpful to get the ball rolling on counseling, expectation settings, physicians placing lab orders, etc.

Consolidation of visits

- We do quite a few appointments with coordination of otologist with audiologist and speech pathologist on the same day.

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Stanford Children's Health's Experience with Early Implantation (Patients implanted <12 months): Demographics

23 Number of surgeries for patients under 12 months

57% Percentage of our patients who receive a cochlear implant prior to 12 months have Connexin 26 mutation.

69.5% Percentage of patients implanted under 12 months of age who are auditory oral

*17% we do not have information on as they are no longer followed in our clinic

21 Number of cases that received **bilateral simultaneous** cochlear implants

6.34 months Average number of months between entering our CI evaluation process and time of surgery

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How our team navigates rehabilitation post activation

Co-treatment sessions

- Collaboration between speech pathologist and audiologist during the visit as patient is scheduled to see both on the same day.

Collaboration with early interventionists and local DHH programs

- Insuring good communication with early interventionists and DHH programs
- Release of information- Key to timely communication and receiving reports
- Bay Area specific programs:
  - BabyTalk
  - Listen To Me

Staying in tune with overall development

- When developmental concerns arise, prompt discussion with family to have child seen for developmental assessment.

Tele-Health visits and collaboration with our CI manufacturers' patient support teams

- Offering Tele-health visits for counseling and check in
- Access to tele-therapy with our Speech Pathologist
- Working with patient support teams for the 3 CI companies

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Case Examples

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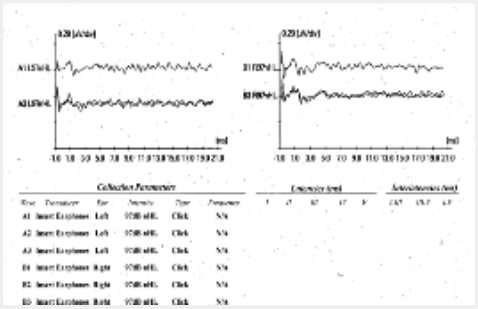
Case Example #1

The case with the multiple opinions

Patient History

- Born to normal pregnancy and delivery
- Failed NBHS
- Received outpatient NBHS at 5 weeks
- Had 3 ABRs (2 at 1 location, 1 at another location) with between 2-3 mos of age with various interpretations
- 4th ABR (3rd opinion) with our clinic: bilateral severe to profound SNHL (4 mos of age).
- 5th ABR + ASSR with our clinic at 7 mos of age: sedated confirmed severe to profound SNHL (done as a form of monitoring hearing)



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Case Example #1

Cochlear implant evaluation and surgery

- Fit with HAs at 4 mos after obtaining medical clearance
- Counseled regarding all communication options
- Family expressed desire to have their communication option be listening and spoken language, so we connected them to local auditory oral program in addition to the county early intervention program
- Medical workup: CT scan negative, Connexin 26 positive
- Underwent speech evaluation and developmental assessment
- Between 7-8 mos performed behavioral hearing evaluations
- Implanted at 10 mos of age bilaterally

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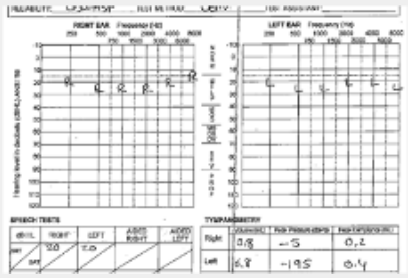
Case Example #1



Pediatric Az-Bio (+5 SNR)- recorded	
Right	94.60%
Left	88.70%

CNC Words (recorded)		
Right	Word score: 94%	Phoneme Score: 86%
Left	Word score: 83%	Phoneme score: 86%

Post Cochlear Implantation

Rehabilitation:

- Received early intervention and was also enrolled in local auditory oral DHH school since infancy.
- Received intensive therapy focused on listening and spoken language
- Family participated in Listen To Me camp
- Family very invested and dedicated in aural rehab plan

TODAY:

- 6-year-old in mainstream classroom with continued speech therapy and DHH support at school.

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Case Example #2

The importance of timely referral and the benefit of developmental assessments

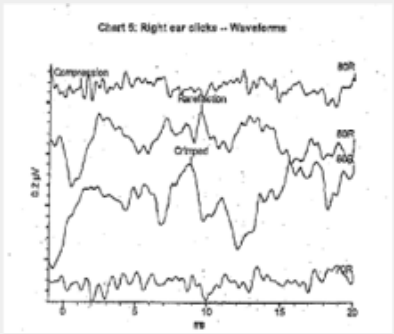
Patient History

- Uncomplicated pregnancy and delivery
- Failed NBHS
- Diagnostic ABR at 2 mos of age
- Referral to our clinic was received when patient was 5 mos of age, but records not received until 6 mos of age.
- Patient seen in our clinic from outside referral for first time at 8 mos of age

	Right Ear	Left Ear
Tone Burst 500 Hz	94 dB+	94 dB+
Tone Burst 2000 Hz	100 dB+	100 dB+
Tone Burst 4000 Hz	95 dB+	95 dB+
Bone conduction clicks	DNT	30 dB+

IMPRESSIONS

Today's test results were consistent with profound bilateral sensorineural hearing loss. An auditory neuropathy can be ruled out at this time.



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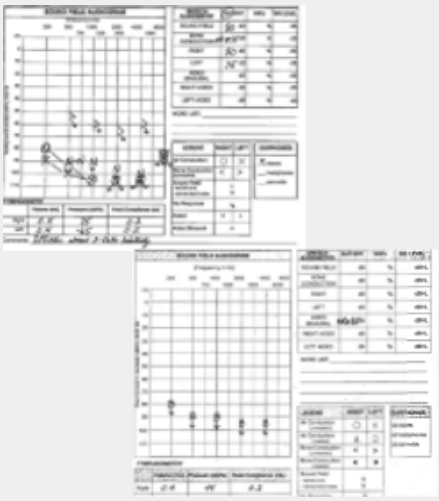
Case Example #2

Cochlear implant evaluation and surgery

- CI evaluation at 8 mos of age
- Speech eval at 8 mos of age: noting delayed language development
- Developmental assessment at 9 mos of age: noted delays across all domains not just expressive and receptive language. Early learning skills were noted to be delayed.
- Genetic testing was negative, CT scan was normal
- Underwent bilateral cochlear implant surgery at 11 mos of age.



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Case Example #2

Post Cochlear Implantation

- Concerns regarding aggressive behavior and limited social interaction resulted in referral for follow-up developmental assessment.
- Diagnosed with autism at 3 years of age

TODAY:

- Fatigues quickly with testing but shows aided detection to be in the 25-30 dB HL range
- Receives ABA therapy with great benefit
- In SDC classroom in lieu of DHH program
- Receives speech therapy 2x week.
- Working to determine an appropriate AAC device for communication needs
- He is a full-timer user of his cochlear implant
- When coil falls off patient will place it back on.

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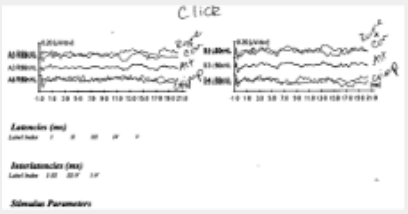
Case Example #3

The Ideal Case: When everything goes as expected

Patient History

- Born to an uncomplicated pregnancy and delivery
- Failed NBHS (outpatient screen at 4 weeks)
- Diagnostic ABR and ASSR at 2 mos of age at our clinic: severe to profound SNHL
- Able to see ENT on same day who gave medical clearance for HA and initiated workup.



AUDITORY STEADY STATE RESPONSE (ASSR) EVALUATION:

The Biologic Master II system was used to perform today's ASSR. Estimation of hearing sensitivity is as follows:

Right ear Air Conduction (Manufacturer default correction factor of 10 dB was applied):
500 Hz: 85 dB eHL
1000 Hz: 95 dB eHL
2000 Hz: 95 dB eHL
4000 Hz: 95 dB eHL

Left ear Air Conduction (Manufacturer default correction factor of 10 dB was applied):
500 Hz: 85 dB eHL
1000 Hz: 95 dB eHL
2000 Hz: 95 dB eHL
4000 Hz: 95 dB eHL

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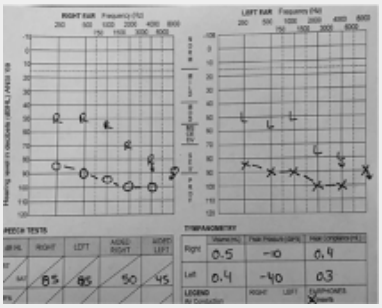
Case Example #3

Cochlear implant evaluation and surgery

- Fit with HAs at 2 mos of age
- Counseled regarding all communication options
- Family expressed desire to have their communication option be listening and spoken language, so we connected them to local auditory oral program in addition to the county early intervention program
- Medical workup: CT scan negative, Connexin 26 positive
- Underwent speech evaluation and developmental assessment
- Between 6 mos performed behavioral hearing evaluation (just before surgery which was already scheduled)
- Implanted at 7 mos of age bilaterally (done off-label)



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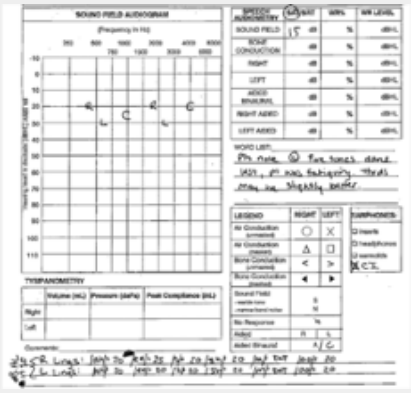
Case Example #3



Post Cochlear Implantation

Rehabilitation:

- Receives early intervention and is also enrolled in local auditory oral DHH school since infancy.
- Receives intensive therapy focused on listening and spoken language
- Family participated in Listen To Me camp
- Family very invested and dedicated in aural rehab plan

TODAY:

Patient is 23 mos old, beginning to speak in 2-3 word phrases, started successfully doing CPA for her evals at 18 mos

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Current technology and considerations for the pediatric population

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Current technology and considerations for the pediatric population

FDA approved cochlear implant candidacy indications

Current technology considerations for the pediatric population

Other considerations

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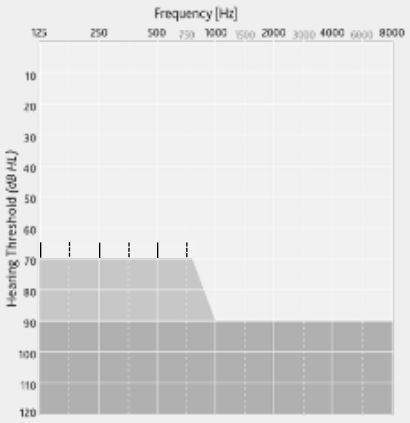
Nucleus® Cochlear Implant Indications: 2000 FDA Candidacy Criteria



12 to 24 months of age

- Bilateral profound sensorineural deafness and demonstrate limited benefit from appropriate binaural hearing aids.

24 months to 17 years

- Severe to profound hearing loss bilaterally.
- Limited benefits from binaural hearing aid trial with WRS less than or equal to 30%

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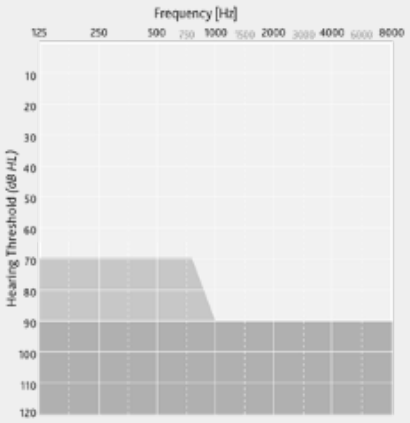
Nucleus Cochlear Implant Indications: US*

- **Children 9** to 24 months of age** who have bilateral profound sensorineural deafness and demonstrate limited benefit from appropriate binaural hearing aids.
- Children two years of age or older may demonstrate severe to profound hearing loss bilaterally.



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Poll Question

What features do you think are necessary for a pediatric cochlear implant processor?

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Considerations for CI processors in the pediatric population

Small processor size and wearing options

Tamper proof earhook

Snug Fit

Hug Fit

Ear mold used with designated ear mold earhook

Koala clip with long coil cable

Retention clip

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Considerations for CI processors in the pediatric population

LED Lights and tamper proofing battery doors

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Considerations for CI processors in the pediatric population

IP rating and waterproof option

- Water resistant (IP57) with rechargeable batteries
- Waterproof (IP68) when worn with Aqua+

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Considerations for CI processors in the pediatric population

Wireless connectivity and compatibility with FM/Roger classroom systems

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Considerations for CI processors in the pediatric population

Datalogging and keeping parents informed on processor status

In the clinic with Custom Sound

1. Establish time on air.
2. Highlights trends in listening environments.
3. Measure daily use of FM or DM system.

Between Visits with Nucleus® Smart App

1. Check processor battery life and function.
2. Track speech input with Hearing Tracker and receive notifications off air.
3. Find a lost Nucleus® 7 processor.

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Other Considerations for the pediatric population: Adjustments in the times of COVID-19

Development of an urgency scale

Used as a tool to assist with

- Rescheduling surgeries secondary to COVID-19
- Setting realistic expectations for surgery dates of those patients who have started the process during our stay at home orders
- Allows for us to be as equitable as possible for the needs of each individual case

Choose any criteria your team feels appropriate based on your patient population and resources available

- Our group used 4 criteria and rated each as being either urgent, moderate, or routine
- In the end we have a score of urgency that helps inform our decision
- Each provider uses this tool to justify their recommendation when we discuss at our team meeting

Cochlear implant surgery urgency scale (reschedules related to COVID-19)

# of Urgent	Recommendation for reschedule (from base scheduled date)	Score
Urgent meningitis or infection (this trumps every other category	Do not reschedule	5
4 Urgent (3 urgent and a 1 moderate)	Ok to reschedule 30 days	4
3 Urgent (2 urgent and a 1 moderate)	Ok to reschedule 60 days	3
2 Urgent (1 urgent and a 1 moderate)	Ok to reschedule 90 day	2
0-1 Urgent	Ok to recommend postponing scheduling	1

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Conclusion

What happened during that gap?

- Key goal of early identification and early intervention is early access to the technology that will aid in meeting the language and communication goals of a family
- Research supports the safety and benefits of early implantation (implantation as early as 9 months)
- Success takes a village!
- CI technology has many pediatric solutions that promote easy wear and empower recipients and their caregivers.

Conclusion

Various practices and implant centers.

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Questions and Answers

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Thank you

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