New MED-EL Pediatric Candidacy Criteria

Aimee Gross :: MED-EL Corporation :: US Clinical Research

This Is Why

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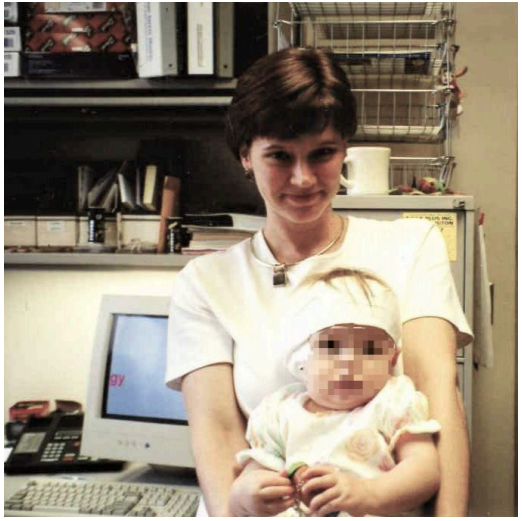
– Senior Manager, Regulated Research



Why cochlear implants?

- **What**: a cochlear implant (CI) is a device that is surgically placed under the skin behind the ear and inside the inner ear to stimulate the hearing nerve
- **Who**: candidacy criteria (indications) describe FDA guidelines for getting a cochlear implant
- **Why:** to provide more access to sound when hearing aids aren't enough
- **When:** within critical (sensitive) periods of development, or the time when our brain is most sensitive to developing certain skills

Why expand indications?

- To remove barriers and improves access
  - Insurance coverage
  - Referral rates

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- To remove barriers and improves access
  - Insurance coverage
  - Referral rates
- To improve outcomes and reduce burden
  - Developmental delays
  - Listening effort/fatigue

Why expand indications?

- Spoon Theory
  - Metaphor for energy
    - Used to describe energy-limiting conditions
    - Like listening effort/fatigue with hearing loss

Why expand indications?

- Spoon Theory
  - Metaphor for energy
    - Used to describe energy-limiting conditions
    - Like listening effort/fatigue with hearing loss
  - Spoons = energy
    - Every daily activity uses spoons
    - Goal = budget our energy, so we don’t run out of spoons

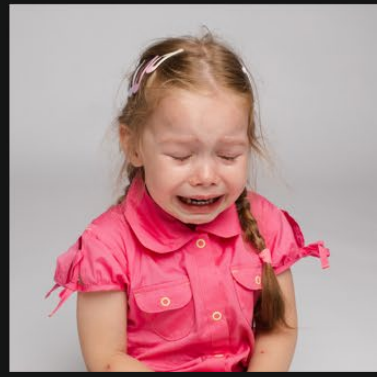
Why expand indications?

- Spoon Theory
  - What happens if we run out of spoons?

NO MORE SPOONS



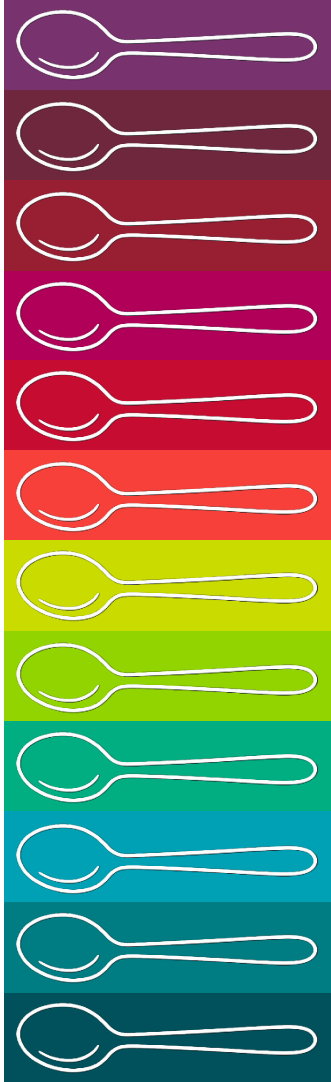







Why expand indications?

– Spoon Budget	12 Spoons
• Getting dressed	1 spoon
• Daycare/school activities	3 spoons
• Hobbies/sports	2 spoons
• Therapy services	1 spoon
• Listening effort	3 spoons
• Homework	1 spoon
• Family time	1 spoon
• Bath	1 spoon



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• Homework	1 spoon
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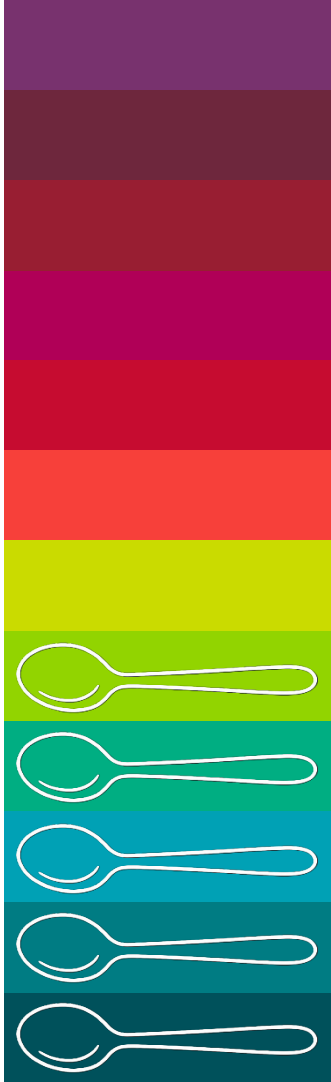
• Bath	1 spoon



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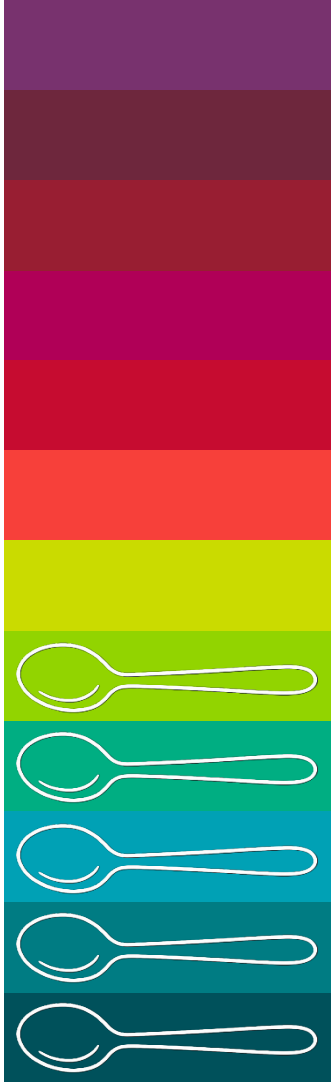
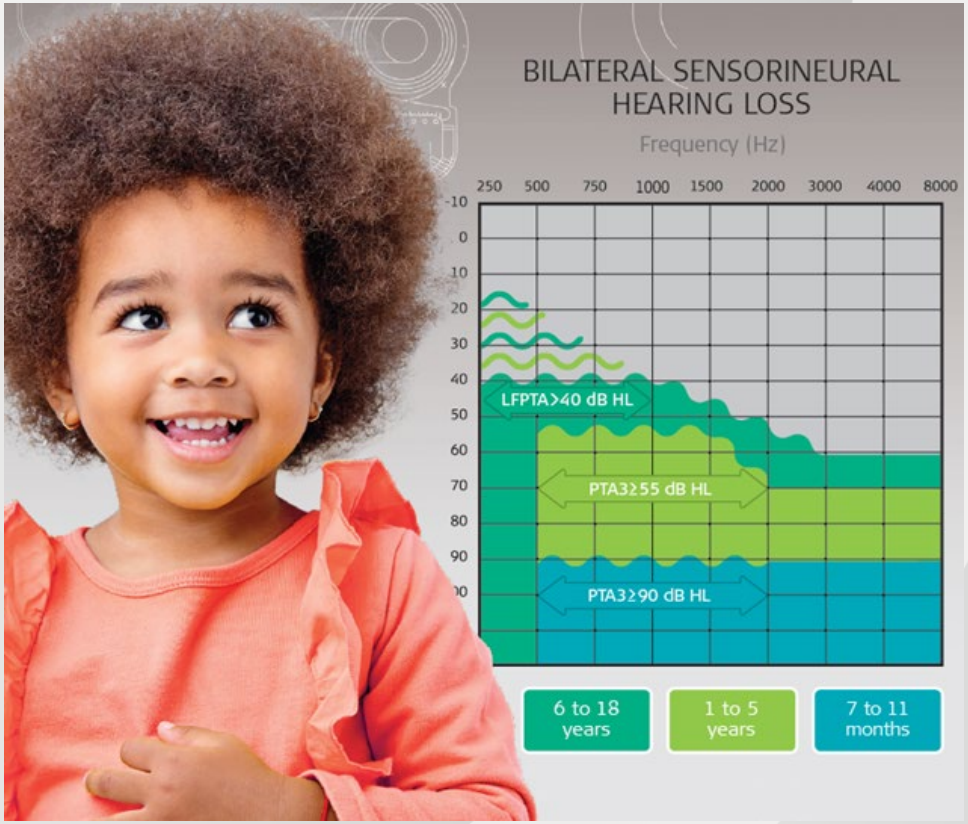


New indications:

Removing barriers

and expanding access



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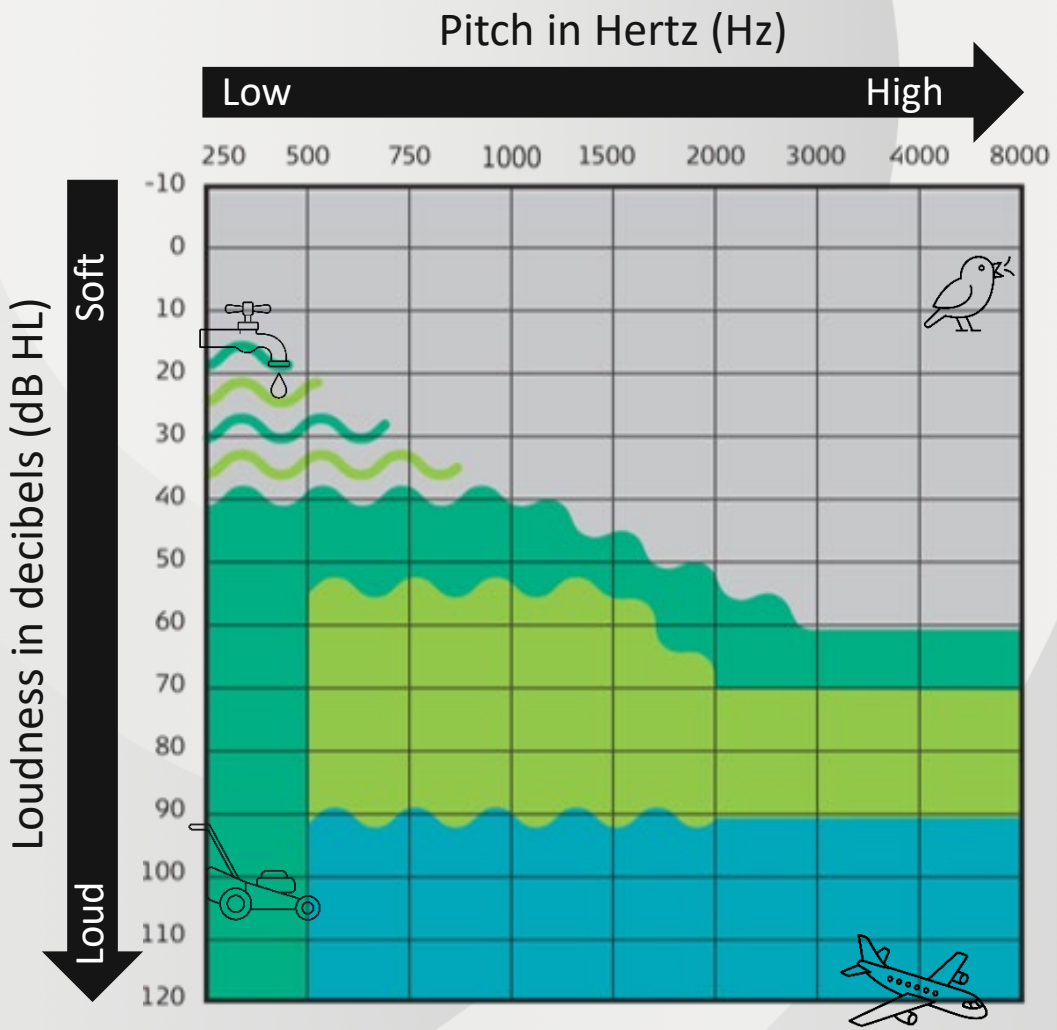
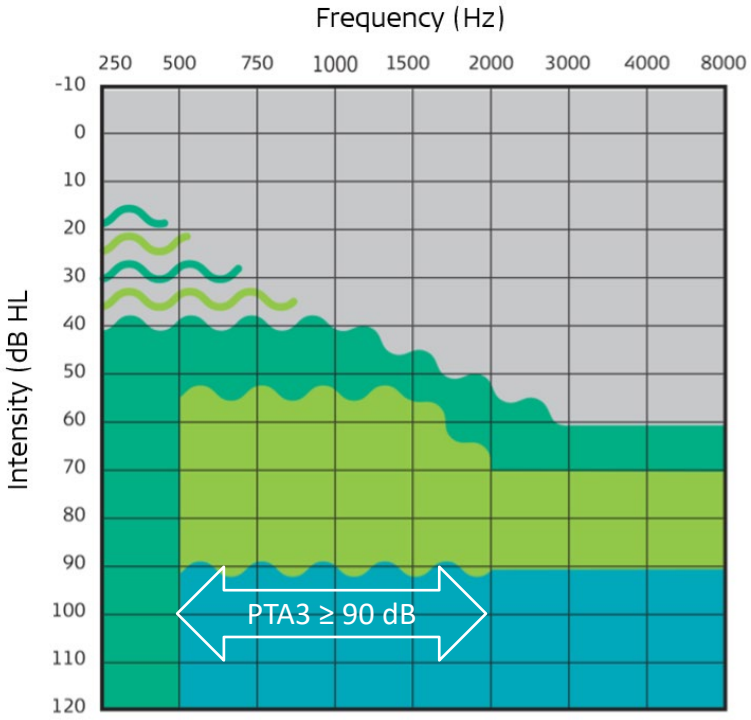


Children 7-11 Months of Age

7-11 Months Old

Bilateral SNHL



Lack of progress or plateau in auditory skill development

7-11 Months Old

Why 7 months?

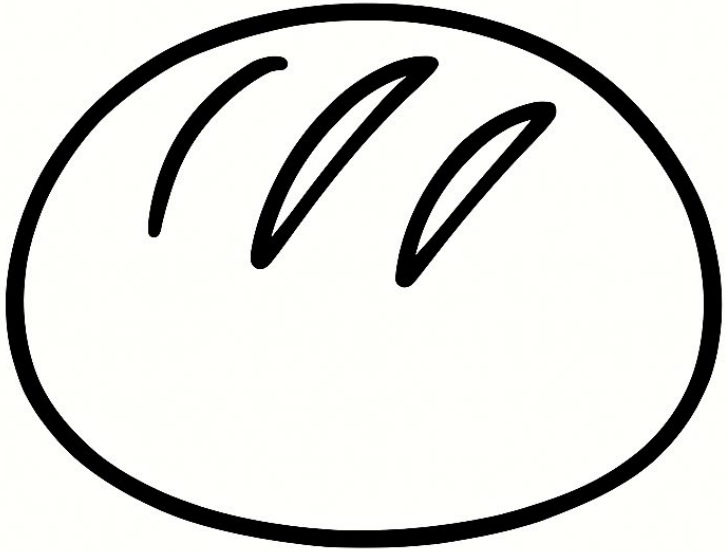
- EHDI guidelines recommend “timely and appropriate intervention services before **6 months** of age…to achieve optimal language, cognition, and socioemotional outcomes.” (EDHI_FAQ11.pdf)

- If we learn that hearing aids are not an “appropriate” intervention by 6 months old, then we can aim to implant at 7 months old

7-11 Months Old

Why 7 months?

- Like ingredients in a recipe, the motor and sensory systems rely on one another for normal brain development in early infancy.



7-11 Months Old

Why 7 months?

- Like ingredients in a recipe, the motor and sensory systems rely on one another for normal brain development in early infancy.

FLOUR

Motor

WATER

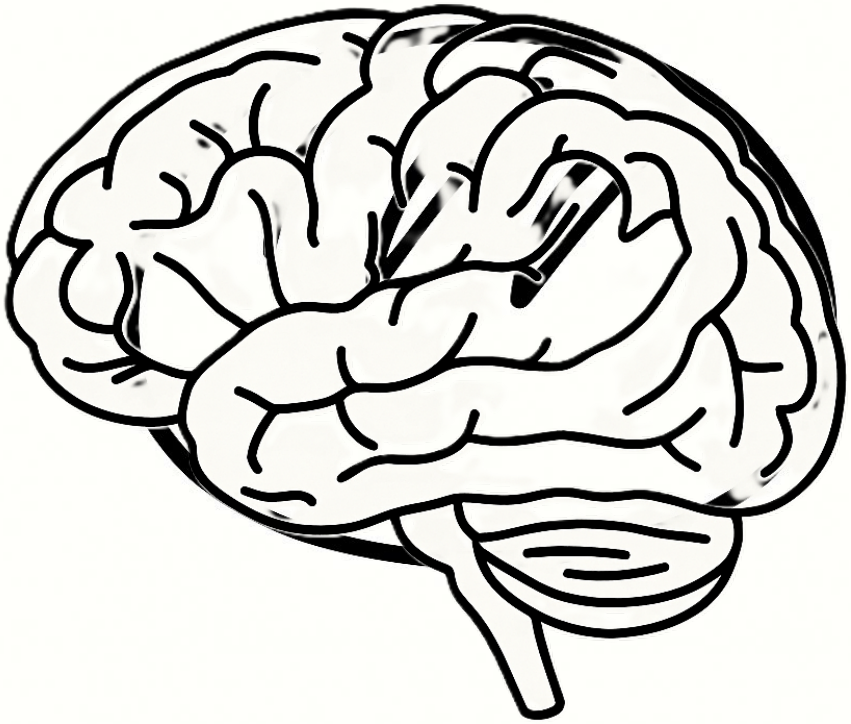
Hearing

YEAST

Sight

SALT

Touch



7-11 Months Old

Why 7 months?

FLOUR

WATER

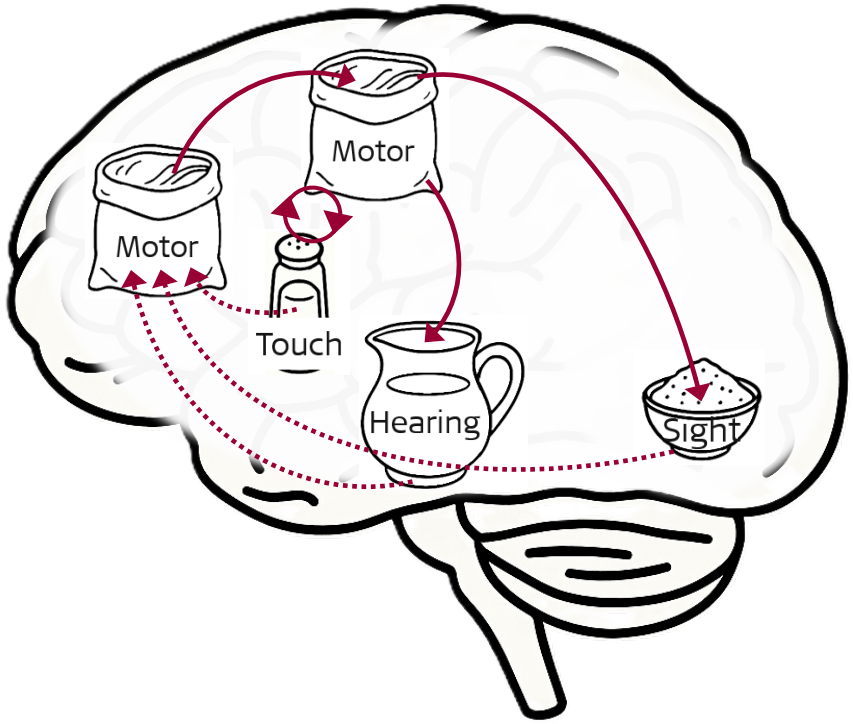
YEAST

SALT

7-11 Months Old

Why 7 months?

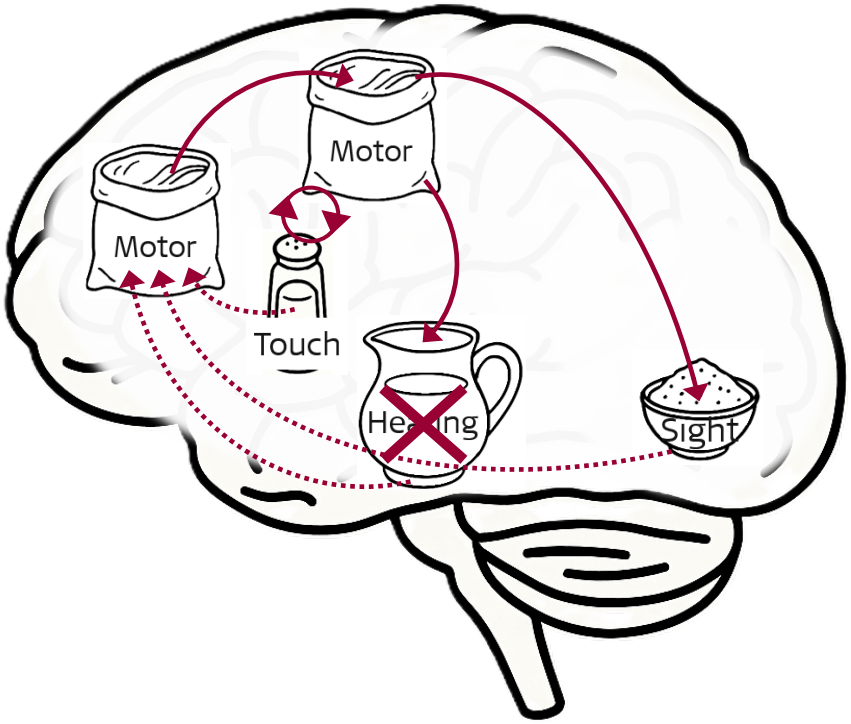
- The ingredients mix after birth
- The motor and all sensory systems form critical connections during early infancy
- Kral and colleagues (2025) call this multimodal interactions or brain connectivity



7-11 Months Old

Why 7 months?

- What happens if we mix our dough without water (hearing) or add it after the bread is already baked
- According to Kral and colleagues, delayed access to hearing during the critical period for brain connectivity can have “irreversible consequences” into adulthood
  - They identify 9 months as a key milestone and recommend access to hearing by 9 months old



7-11 Months Old

Why it Matters

Not all critical periods are created equal (Leigh et al., 2013)

- Speech perception skills: beyond 1 year of age
- Language development skills: before 1 year of age

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Why it Matters

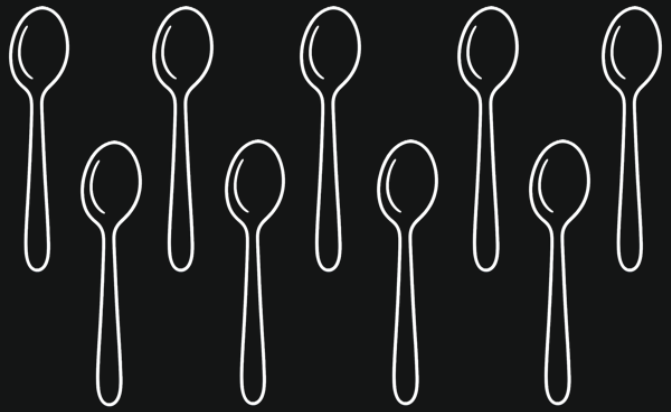
Not all critical periods are created equal

- Studies show that children implanted before 9 months outperformed children implanted at ≥ 9 months old on functional listening skills, language, and speech production (Culbertson et al., 2022; Leigh et al., 2013; Karltorp et al., 2020)

7-11 Months Old

Why it Matters

More of These…

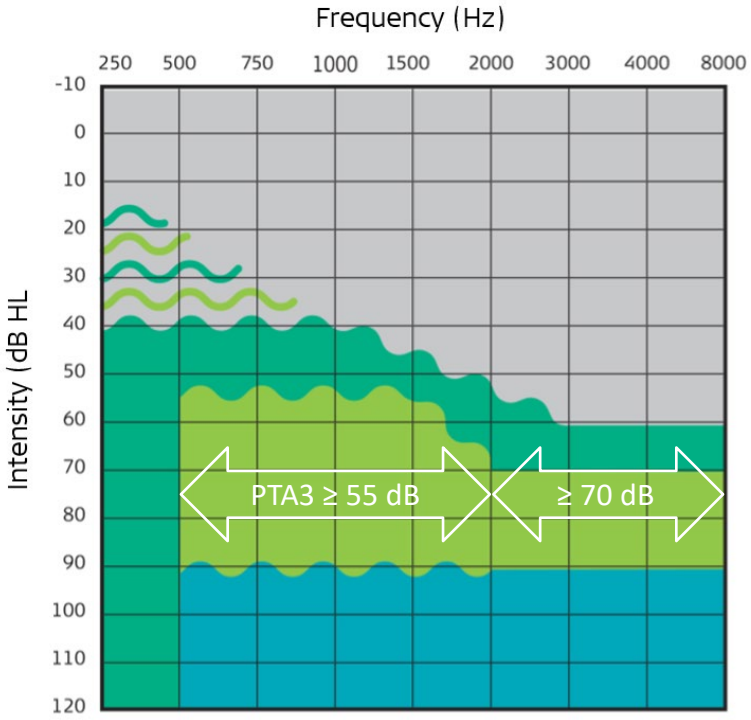


Less of These…

Children 1-5 Years Old

1-5 Years Old

Bilateral SNHL



Lack of progress or plateau on auditory skill development or ≤ 40% on a developmentally-appropriate test of word recognition (e.g., ESP, MLNT, LNT, PBK, CNC)

1-5 Years Old

Why it Matters

- "Children need better audibility, bandwidth, and signal-to-noise ratios than adults to reach age-appropriate speech understanding" (Leal et al., 2016)
  - Access to more sound
  - Access to more frequencies
  - Speech louder than noise

1-5 Years Old

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1-5 Years Old

Why it Matters

- Hearing aids are not always “appropriate”
  - May not provide enough access to high-frequency speech sounds for age-appropriate speech understanding with severe to profound hearing loss
  - Amount of gain needed distorts the speech signal
- What can the child **DO** with hearing aids?

4. Comprehend
3. Identify
2. Discriminate
1. Detect

1-5 Years Old

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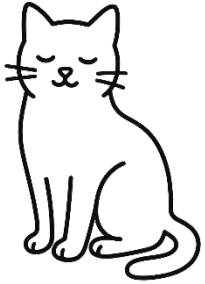
- Can detect “cat”
- Can hear a difference between “cat” and “hat”
- Knows that this is a cat



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1-5 Years Old

Why it Matters

- Can detect “cat”
- Can hear a difference between “cat” and “hat”
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- And this is a hat

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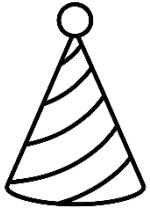

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1-5 Years Old

Why it Matters

- Can detect “cat”
- Can hear a difference between “cat” and “hat”
- Knows that this is a cat
- And this is a hat
- Understands that most cats don’t like hats

4. Comprehend

1-5 Years Old

Why it Matters

- Speech Intelligibility Index (SII): describes the proportion of speech cues available to the listener on a scale from 0 to 1
  - Children with an aided **SII < 0.61** are at risk for spoken language delays (Wiseman et al., 2023)
  - Children need an aided **SII ≥ 0.65** for optimal language development with hearing aids (Leal et al., 2016)

1-5 Years Old

Why it Matters

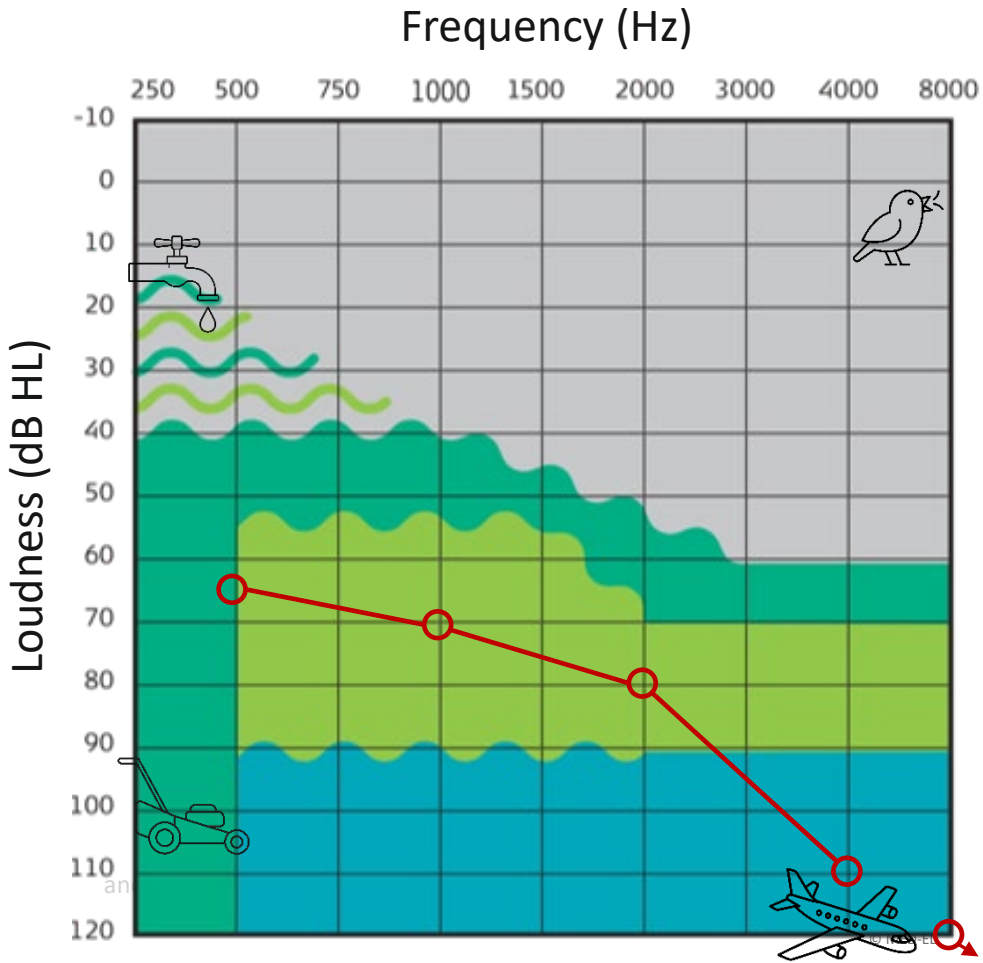
- Studies show that children with some (residual) hearing before surgery do better with cochlear implants than hearing aids, whether they keep their residual hearing or not (Park et al., 2025; Meredith et al., 2017; Gratacap et al., 2015)

- Delays ≥ 3 years between meeting candidacy and implantation can cause poorer outcomes (Park et al., 2021)

Case Study

- Age at ID: 4 months
- Age at first HA: 5 months
- Age at CI: 50 months

- Average thresholds: 72 dB HL
- PBK score, implant ear: 40% (word recognition)




I NG HO
O CO LA
BY E IRE

Case Study

- 12 months after CI activation
  - PBK Words, implant ear: 84%

SIPPING HOT
CHOCOLATE
BY THE FIRE

US Multicenter Clinical Trial

Safety (Risks)

- All complications were known risks of cochlear implantation
- Number and rate of major complications were similar to the literature (< 6%)
- **Children implanted < 12 months old did not have more device-related complications than children 12 months and older**

Efficacy (Benefits)

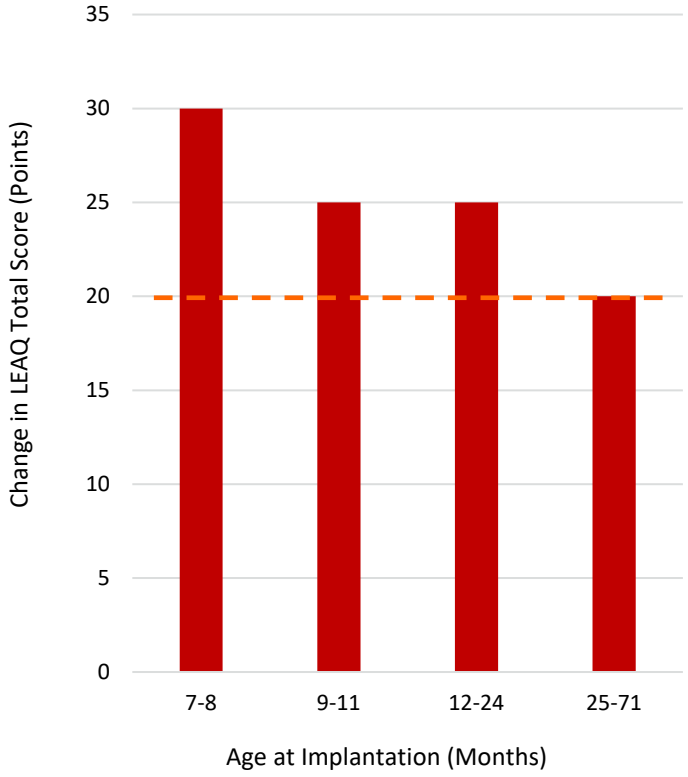
- Children showed high rates of clinical success on speech understanding and auditory skill development

- Over 86% of children met strict performance goals by 12 months after activating the implant
  - 91% of children implanted < 9 months old and 85% of children implanted ≥ 9 months old
  - 93% of children with better than profound HL and 86% of children with a profound HL

Improvement at 12 Months

LittlEARS Auditory Questionnaire (LEAQ)

- Change in LEAQ Total Score from 0 to 12 months (maximum possible = 35 points)
  - Change expected in children with normal hearing (birth to 12 months) = 20 points (Coninx et al., 2009)
  - Change in study participants (before surgery to 12 months after activating the implant) by age group
    - Participants implanted at 7-8 months old showed largest improvement



MED-EL cochlear implants are safe and effective for children as young as **7 months old** and offer the **broadest** speech criteria in children

Children aged 1 year and older with more residual hearing now qualify for a MED-EL cochlear implant

MED-EL candidacy criteria in children aged 6 years and older now match our adult expanded indications

FDA Approval

7-11 Months Old

Why it Matters

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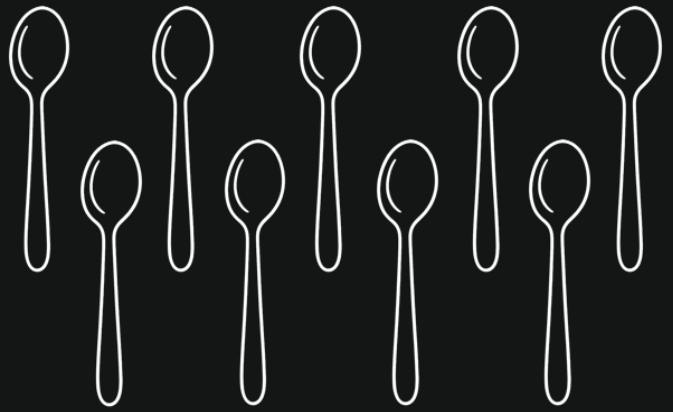

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MED EL

hearLIFE