Essential Elements of Best Practice for Cochlear Implant Fitting in Children: Considerations for Behavioral Methods of Verification and Validation

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Introduction

The main objective of this document is to provide clinicians with a description of essential components to consider for best practices for cochlear implant (CI) programming (fitting) in children using behavioral methods. We believe that the objectives of fitting for audibility and comfort are best achieved through a systematic process of verification prior to validation using various outcome measurements (see Figure 1). Following a systematic approach provides the clinician with an opportunity to cycle back to previous processes when measured outcomes are not consistent with clinical expectations. In this document we will concentrate on the verification of audibility and comfort steps in this process.

Figure 1: The sequential aspects of the cochlear implant fitting process.

The clinician providing services for pediatric CI recipients should fit the sound processor so that audibility for all levels of speech is achieved across the broadest frequency range possible and that loud sounds are not uncomfortably loud. In addition, the distribution of electrical levels across the individual's perceptual dynamic range (threshold to comfort limit) should be maximized on each electrode. This enables the CI to most effectively convert acoustic information into useable electric information for the CI recipient (Geers et al., 2003; Shapiro and Bradham, 2012; Skinner et al., 1999). Finally, access to other auditory stimuli (e.g., music) should be provided, and low-level adverse distortion (hum) and signals that are counterproductive to speech perception should be minimized.

In subsequent sections of this document we use the terms fitting and programming interchangeably, with both referring to the process of adjusting the CI for optimal audibility and comfort. There is some debate related to differentiating between verification vs. validation in the device fitting process (Ricketts, Bentler & Mueller, 2019). For traditional hearing aid fittings, verification typically relates to the process of ensuring that hearing aid functioning or output meets specific criteria such as manufacturer standards or prescriptive fitting targets. Validation is the process of ensuring that the device settings allow the communication goals of the patient to be met (Ricketts, Bentler & Mueller, 2019). Applied to the hearing aid fitting process for pediatric patients, real-ear probe microphone measures and aided speech perception may be considered as verification and validation procedures respectively.

Unlike hearing aids, there are no validated prescriptive fitting formulae for CIs, nor are there standardized procedures for verifying frequency-specific gain and electroacoustic output characteristics of the system (real-ear or test box measures used for hearing aids). Recent survey data suggest a lack of consensus regarding the definition of verification in the CI fitting process (Gordey, Davidson & Moodie, 2016). In this document, we use the term “verification” to describe the process of determining optimal audibility of the CI fitting by obtaining behavioral aided detection thresholds for either frequency-specific stimuli or speech stimuli. In subsequent sections of this document, we reference relevant literature suggesting audibility targets for speech or frequency-specific stimuli. We use the term “validation” to refer to speech perception tests or questionnaires that assess overall hearing function in daily listening environments. We refer the reader to the Pediatric Minimum Speech Test Battery (PMSTB) developed by the PMSTB working group (Uhler et al., 2017) for recommendations regarding assessment of speech perception abilities in children with hearing loss.

This document does not provide recommendations for CI assessment/candidacy, and selection of CIs for children. It also does not provide recommendations for specific outcome measures to be used for further validation of CI fitting for children. The interested reader is directed to the American Academy of Audiology Cochlear Implant Practice Guidelines (Messermith et al., 2019), Wolfe & Schafer (2015) as well as Carlson et al. (2017) for information about these topics.

Currently available CIs included in this document

This document is prepared for clinicians who are selecting and fitting a CI system commercially available in 2020 from: (1) Advanced Bionics Corporation; (2) Cochlear Corporation; (3) MED-EL; or (4) Oticon Medical.

CI fitting and verification for audibility

The goals of the fitting are provision of optimal audibility for all speech levels across the broadest frequency range possible while maintaining comfort for loud sounds. The fitting strategies recommended for setting electrical current levels (threshold and comfort levels) can differ across age and device manufacturers (Shapiro & Bradham, 2012; Wolfe & Schafer, 2015). Threshold level (T-level or THR) and upper comfort levels (C-level, M-level, or MCL-level) specific to each manufacturer will be discussed in more detail below.

Behavioral methods for CI fitting <u>and</u> verification

Similar behavioral procedures are used to help assess the electrical dynamic range of individual electrodes (fitting) and to verify the programming. Behavioral methods used with the youngest children may only involve simple detection tasks. Older children may be able to complete detection, loudness scaling, and balancing tasks. **The age-brackets listed in this document are only suggestions as developmental readiness should be considered for each individual child**. The clinician should employ the most thorough and advanced tasks that the child is able to complete when measuring behavioral programming levels. Behavioral methods (in order of complexity) include visual reinforcement, conditioned play or conventional audiometry, and loudness scaling and balancing procedures.

Basic procedures for verifying audibility include detection/identification of both speech (e.g., recorded/calibrated Ling 6 sounds) and frequency-specific stimuli [(e.g., Frequency Modulated (FM) tones, Pediatric Noise™, FRESH Noise™), Glista et al., 2014]. If standard narrowband noise stimuli are used, one must consider the wider bandwidth (versus pure tone) and convert values from effective masking level to estimated dB HL (Davidson et al., 2009). Research in both pediatric and adult CI recipients has shown that better (lower) aided soundfield thresholds are associated with improved speech perception scores (Baudhuin et al., 2012; Davidson, Geers, & Nicholas, 2014; Davidson et al., 2010; Davidson et al., 2009; Donaldson & Allen, 2003; Firszt et al., 2004; Holden et al., 2013; Holden et al., 2007; James et al., 2003). Aided thresholds of 20–30 dB HL from 250–6000 Hz typically provide adequate audibility for hearing soft speech sounds (Davidson, 2006; Firszt et al., 2004).

The use of monitored live or calibrated recorded speech and other environmental sounds may be used to assess comfort. Formal speech perception testing using materials that are developmentally and linguistically appropriate for each child should accompany these measures as soon as possible (see age appropriate PMSTB referenced above).

Behavioral methods for programming upper levels of comfort ensure that conversational level speech and loud sounds are not uncomfortable. Categorical loudness scaling procedures have been used to define the range between threshold and optimal comfort for individual electrodes across the electrode array for pediatric and adult CI recipients. It is generally recommended that loudness scaling be completed on a minimum of 5 electrodes distributed across the electrode array (Baudhuin et al., 2012; Blamey et al., 1992; Davidson et al., 2000, Holden, et al., 2011; Skinner, 2003; Skinner et al., 1997). Categorical loudness scaling involves having listeners assign specific categories to a range of stimulus levels (Serpanos and Gravel, 2000). Loudness categories ranging from soft to loud may be used with as few as two choices (e.g., soft and loud) to as many as 7 choices (e.g., no sound, very soft, soft, medium soft, medium loud/comfortable, loud, too loud). Serpanos and Gravel (2000) examined the clinical utility, reliability, and feasibility of using a cross modality loudness matching task to assess loudness growth for children who may have difficulty performing traditional categorical loudness scaling procedures. Sixteen children aged 4- 12 years, with normal hearing sensitivity or moderate to severe sensorineural hearing loss were asked to match loudness level to line length. The authors concluded that a cross modality task of line length and loudness may be feasible for assessing loudness growth and fitting hearing aids for children as young as 6 years. Visual analog scales depicting loudness growth in increasing size from little to big have been used to measure loudness in pediatric CI recipients (Wolfe & Schafer, 2015). For these tasks, the child may be asked to rate loudness growth using progressively larger objects and an appropriate instruction set (see Figure 2 and Appendix A). Due to developmental level, not all children can complete categorical loudness measures. In these cases, objective measures may be used to establish the upper range of comfort levels across electrodes.

Figure 2: Categorical loudness rating scale

Loudness balancing tasks can be used to determine equal loudness levels across electrodes. Programs balanced for equal loudness are associated with better speech perception scores and overall comfort (Dawson et al., 1997; Sainz, de la Torre et al., 2003; Wolfe & Schafer, 2015). Loudness balancing is typically conducted once children acquire the necessary cognitive and vocabulary skills to complete the task while ignoring pitch differences. Loudness balancing requires children to report if electrical stimulation levels at the upper range of comfort are perceived as equal in loudness across the electrode array. This is achieved by asking the child to indicate whether one electrode is louder or softer than another electrode, with the clinician adjusting electrical levels accordingly. This is more easily accomplished for two adjacent electrodes, but may also be done for multiple pairs of electrodes or even between ears (see Appendix A).

Physiologic methods for CI fitting and verification

We believe that behavioral measures are essential for both fitting and verification of CIs for children. For children who are unable to provide reliable behavioral responses, physiologic measures including electrical stapedial reflex thresholds (ESRTs) and/or electrical compound action potentials (ECAP[1]) should be used in conjunction with behavioral techniques. The reliability of physiologic measures in this population has been assessed and general guidelines for using these measures when setting electrical levels during mapping are available (AAA,

[1] ECAP may be referred to as NRI (Neural Response Imaging), NRT (Neural Response Telemetry) or ART (Auditory nerve Response Telemetry) or Neuro-ECAP.

2019; Gordon et al., 2004a; Gordon et al., 2004b; Hodges et al., 1997; Hodges et al., 1999; Holstad et al., 2009; Overstreet, 2004; Pedley et al., 2007; Shapiro and Bradham, 2012; Smoorenburg, 2004; Walkowiak et al., 2010; Wolfe and Schafer, 2015). The interested reader is directed to these references for additional detail as this document focuses on behavioral methods.

General recommendations specific to manufacturer for CI fitting across different age groups using behavioral methods

Manufacturer: Advanced Bionics®

Setting T-levels for Advanced Bionics for all age groups:

Two different programming philosophies may be considered for T-level stimulation: (1) T-levels not measured but set based on most comfortable stimulation levels (i.e. by default, the manufacturer software sets the T-level to 10% of M-Level), or (2) T-levels are measured and actual stimulation levels are set at a point just below audibility. T- levels may be measured on individual electrodes using tone bursts, or on groups of electrodes using speech bursts. If measuring T-levels, it may be advisable to set the T-level just below the level that elicits a response for at least a low-, mid- and high-frequency electrode. Visual reinforcement or conditioned play techniques are appropriate for determining T-levels for younger children. Levels for the remaining electrodes may be estimated/interpolated based on the measured values. For younger children, it may not be possible to set T-levels for all electrodes and the use of speech bursts may be advisable until more refined programming can be conducted. Some clinical evidence supports setting the T-level at 10-15 Clinical Units (CU) below the measured 50% detection threshold or ~50% of the measured 100% detection threshold (Holden et al., 2011; Baudhuin et al., 2012). If the clinician determines that responses are minimal response levels, not detection thresholds, levels should be decreased to just below the level that elicits a response to avoid extraneous noise when no input is present. When detection measures are unreliable, one may consider using the first method listed above to avoid extraneous noise (such as humming).

Consider using ECAP (Neural Response Imaging -NRI) responses to guide conditioning for behavioral testing in challenging cases. While measuring NRI, the clinician may be able to observe the child for a behavioral reaction to the stimulus administered by the software. The behavioral reaction is a point at which the child hears on that electrode and can be used as a reference point for training. The tNRI (threshold NRI) can be used to guide conditioning for behavioral testing and to train awareness to stimulation. It is not equivalent to a behavioral T- or M-level (see references cited in Physiologic methods for CI fitting and verification above).

Advanced Bionics M-Levels: 0 to 4 years of age

M-levels are set by observing the child's responses while gradually increasing the electrical stimulation from first response levels. The goal is to determine a level where responses are consistent and relatively fast. Visual reinforcement, or conditioned play techniques can facilitate child engagement. The aim is to achieve audibility and comfort, ensuring loud sounds are not uncomfortable. Comfort for M-levels should be confirmed by sequentially stimulating across individual electrodes (sweeping). In cases where limited responses on individual electrodes are problematic due to the child's age or abilities, then incremental global increases in M-levels could be used in live-speech mode using threshold level responses (T-profile) as a starting point. More precision can be achieved over time as the child develops the ability to participate in the process. In situations where behavioral measures cannot be reliably obtained, clinicians should consider using ESRT responses to guide setting M-levels. If ESRT responses are used to map audibility and comfort, clinicians should confirm that this has been achieved by observing the child's responses in live-speech mode via behavioral methods.

Advanced Bionics M-Levels: 5 to 8 years of age

M-levels are set by gradually increasing the electrical stimulation from first response levels. The goal is to determine a most comfortable stimulation level. This process is facilitated by using visual analog scales to indicate when a change in loudness is perceived. The number of rating categories can be increased from two (e.g., soft/small or loud/big) to as many as three - five (e.g., no sound, soft/small, medium/just right, loud/big) as the child improves in abilities. The M-level is set at a level that the child rates as medium/just right (see examples 1-3 in appendix). The aim is to achieve audibility and comfort, ensuring loud sounds are not uncomfortable. Comfort for M-levels should be confirmed by sequentially stimulating across individual electrodes (sweeping) and asking the child if each electrode is perceived as most comfortable. Live-speech mode should be activated to confirm that speech is audible and comfortable.

Advanced Bionics M-Levels: 8 years and above

M-levels are set by gradually increasing the electrical stimulation from first response levels. The goal is to determine a most comfortable stimulation level. This process is facilitated by using visual scales to indicate when a change in loudness is perceived. The number of rating categories can be increased to five or more (e.g., no sound, soft, medium, loud, too loud) as the child improves in abilities. The M-level is set at a level that the child rates as medium (see examples 1-3 in appendix). The aim is to achieve audibility and comfort, ensuring loud sounds are not uncomfortable. Comfort for M-levels should be confirmed by sequentially stimulating across individual electrodes (sweeping) and asking the child if each electrode is perceived as most comfortable. Loudness balancing across electrodes can be attempted. Live-speech mode should be activated to confirm that speech is audible and comfortable.

Manufacturer: Cochlear®

Setting T-levels for Cochlear for all age groups:

Set T-levels at behavioral threshold (100% response) for at least 5 electrodes equally spaced across the array with the goal of checking all electrodes during subsequent visits (Plant et al., 2005). Levels for the remaining electrodes may be estimated/interpolated based on the measured electrodes. If the clinician determines that responses are minimal response levels (not detection thresholds), T-levels may be set slightly below the minimal response levels. Visual reinforcement or conditioned play techniques are appropriate for determining T-levels for younger children. T-levels can also be set using a "count the beeps" method. Using this method, the T-levels are set at the softest Clinical Unit (CU) level at which the child can accurately count how many beeps are presented (typically the number of presentations vary from 1-6). Generally, this will result in T-levels that are ~3–10 CUs above the detection threshold.

Consider using ECAP (Neural Response Telemetry –NRT) responses to guide conditioning for behavioral testing in challenging cases. While measuring NRT, the clinician may be able to observe the child for a behavioral reaction to the stimulus administered by the software. The behavioral reaction is a point at which the child hears on that channel and can be used as a reference point for training. The NRT can be used to guide conditioning for behavioral testing and to train awareness to stimulation. It is not equivalent to a behavioral T- or C-level (see references cited in Physiologic methods for CI fitting and verification above).

Cochlear Corporation C-Levels: 0 to 4 years of age:

C-levels are set by observing the child's responses while gradually increasing the electrical stimulation from T-levels / first response levels. The goal is to determine a level where responses are consistent and relatively fast. Visual reinforcement or conditioned play techniques can facilitate child engagement. The aim is to achieve audibility and comfort, ensuring loud sounds are not uncomfortable. Clinicians may choose to set C-levels at some predetermined initial level (generally 10 to 15 Clinical Units [CUs] above threshold) to obtain a minimum dynamic range and observe response for detection and discomfort while stimulating the electrodes sequentially across the array (sweeping). A wider dynamic range should be achieved over time until plateauing at loud but comfortable levels. In cases where limited responses on individual electrodes are problematic due to the child's age or abilities, then incremental global increases in C-levels could be used in live-speech mode. More precision can be achieved over time as the child develops the ability to participate in the process. Consider using NRT responses to guide conditioning for behavioral testing in challenging cases. In situations where behavioral measures cannot be reliably obtained then clinicians should consider using ESRT responses to set C-levels. If ESRT responses are used, these levels should be confirmed by observing the child's responses in live-speech mode and by sweeping at C-level.

Cochlear C-Levels: 5- to 8-year-olds:

After setting T-levels, C-levels are set by gradually increasing the electrical stimulation from T-levels / first response levels. The goal is to determine a level that the child indicates is “loud but okay”. This process is facilitated by using visual analog scales to indicate when a change in loudness is perceived. The number of rating categories can be increased from two (e.g., soft/small or loud/big) to as many as three - five (e.g., no sound, soft/small, medium/just right, loud/big) as the child improves in abilities. The C-level is set at a level that the child rates as loud/big but not too loud (see examples 1-3 in appendix). The aim is to achieve audibility and comfort, ensuring loud sounds are not uncomfortable. Comfort for C-levels should be assessed by sequentially stimulating across individual electrodes (sweeping) and confirming if the stimulation on each electrode is perceived as “loud but okay”. Live-speech mode should be activated to confirm that speech is audible and comfortable.

Cochlear C-Levels: 8 years and above:

After setting T-levels, C-levels are set by gradually increasing the electrical stimulation from T-levels / first response levels. The goal is to determine a level that the child indicates is “loud but okay”. This process is facilitated by using visual analog scales to indicate when a change in loudness is perceived. The number of rating categories can be increased to five or more (e.g., no sound, soft, medium, loud, too loud) as the child improves in abilities. The C level is set at a level that the child rates as loud but not too loud (see examples 1-3 in appendix). The aim is to achieve audibility and comfort, ensuring loud sounds are not uncomfortable. Comfort for C-levels should be confirmed by sequentially stimulating across individual electrodes (sweeping) and confirming if the stimulation on each electrode is perceived as “loud but okay”. Loudness balancing across electrodes can be attempted. Live-speech mode should be activated to confirm that speech is audible and comfortable.

Manufacturer: MED-EL®

Setting T (THR)-levels for MED-EL for all age groups:

Two different programming philosophies may be considered for THR-level stimulation: (1) THR-levels are not measured but set based on most comfortable stimulation levels (i.e., by default, the manufacturer software sets the T-level to 10% of maximum comfortable level (MCL)), or (2) THR-levels are measured and actual stimulation levels are set at a point just below audibility. If measuring THR-levels, it may be advisable to set the T-level just below the level that elicits a response for at least a low-, mid- and high-frequency electrode. Visual reinforcement or conditioned play techniques are appropriate for determining THR-levels for younger children. Levels for the remaining electrodes may be estimated/interpolated based on the measured electrodes. For younger children, it may not be possible to set THR-levels for all electrodes. Two studies on adult Med-El CI recipients reveal no differences in speech perception abilities for individuals using maps derived with measured threshold levels vs. levels based on most comfortable level or by adjusting the Maplaw setting (Boyd, 2006; Spahr & Dorman, 2005). Results from a pediatric study, however, revealed better aided detection and speech perception abilities for maps using measured minimum stimulation levels (Payne & Horlbeck, 2014). When detection measures are unreliable, one may consider using the first method listed above or adjustments to the Maplaw settings to avoid extraneous noise (such as humming).

Consider using ECAP (Auditory nerve Response Telemetry –ART) responses to guide conditioning for behavioral testing in challenging cases. While measuring ART, the clinician may be able to observe the child for a behavioral reaction to the stimulus administered by the software. The behavioral reaction is a point at which the child hears on that particular channel and can be used as a reference point for training. The ART can be used to guide conditioning for behavioral testing and to train awareness to stimulation. It is not equivalent to a behavioral THR- or MCL-level (see references cited in Physiologic methods for CI fitting and verification above).

MED-EL MCL-Levels: 0 to 4 years of age:

MCL-levels are set by gradually increasing the electrical stimulation from first response levels. The goal is to determine a level where responses are consistent and relatively fast. Visual reinforcement or conditioned play techniques can facilitate child engagement. The aim is to achieve audibility and comfort, ensuring loud sounds are not uncomfortable. Comfort for MCL-levels should be confirmed by sequentially stimulating across individual electrodes (sweeping). In cases where limited responses on individual electrodes are problematic due to the child's age or abilities, then incremental global increases in MCL-levels could be used in live-speech mode. More precision can be achieved over time as the child develops the ability to participate in the process. In situations where behavioral measures cannot be reliably obtained then clinicians should consider using ESRT responses to set MCL-levels. If ESRT responses are used to map audibility and comfort, these levels should be confirmed by observing the child's responses in live-speech mode and by sweeping at MCL-level.

MED-EL MCL-Levels: 5- to 8-year-olds:

MCL-levels are set by gradually increasing the electrical stimulation from first response level. The goal is to determine a level that the child indicates most comfortable. This process is facilitated by using visual analog scales to indicate when a change in loudness is perceived. The number of rating categories can be increased from two (e.g., soft/small or loud/big) to as many as three - five (e.g., no sound, soft/small, medium/just right, loud/big) as the child improves in abilities. The MCL-level is set at a level that the child rates as loud/big but not too loud (see examples 1-3 in appendix). The aim is to achieve audibility and comfort, ensuring loud sounds are not uncomfortable. Comfort for MCL-levels should be confirmed by sequentially stimulating across individual electrodes (sweeping) and asking the child if each electrode is not perceived as "too loud". Activate live-speech mode and confirm that speech is audible and comfortable.

MED-EL MCL-Levels: 8 years and above:

MCL-levels are set by gradually increasing the electrical stimulation from first response levels. The goal is to determine a level that the child indicates most comfortable. This process is facilitated by using visual analog scales to indicate when a change in loudness is perceived. The number of rating categories can be increased to five or more (e.g., no sound, soft, medium, loud, too loud) as the child improves in abilities. The MCL-level is set at a level that the child as loud but not too loud (see examples 1-3 in appendix). The aim is to achieve audibility and comfort, ensuring loud sounds are not uncomfortable. Comfort for MCL-levels should be confirmed by sequentially stimulating across individual electrodes (sweeping) and asking the child if each electrode is not perceived as "too loud". Loudness balancing across electrodes can be attempted. Activate live-speech mode and confirm that speech is audible and comfortable.

Manufacturer: Oticon Medical®

Setting T-levels for Oticon Medical for all age groups:

Set T-levels at behavioral threshold (100% detection) for at least 5 electrodes or groups of electrodes equally spaced across the array with the goal of checking all electrodes during subsequent visits. Visual reinforcement or conditioned play techniques are appropriate for determining T-levels for younger children. As the child develops the ability to complete more complex tasks, T-levels may be set at "soft" if using groups of 2-5 electrodes, or "very soft" if using single electrode measurements: using a developmentally appropriate loudness scale. Levels can also be set using a "count the beeps method". Using this method, the T-levels are set at the softest level at which the child can accurately count how many beeps are presented (typically the number of presentations vary from 1–6). Intraoperative ECAP responses (NEURO-ECAP) can be used in conjunction with careful observation of behavioral responses to aide in creating a starting profile of T-levels.

Oticon Medical C-Levels: 0 to 4 years of age:

C-levels are set by observing the child's responses while gradually increasing the electrical stimulation from T-levels / first response levels. The goal is to determine a level where responses are consistent and relatively fast. Set C-levels across 5 individual electrodes or groups of electrodes equally spaced across the array with the goal of checking all electrodes at subsequent visits. Comfort for C-levels should be confirmed by sequentially stimulating across individual electrodes (sweeping). A sweep of the T-levels across the electrodes may be initiated prior to sweeping C-levels to control for a potential reaction at low levels. In cases where limited responses on individual electrodes are problematic due to the child's age or abilities, then incremental global increases in C-levels could be used in the software "live mode". More precision can be achieved over time as the child develops the ability to participate in the process. To have a sufficient Electrical Dynamic Range (EDR) T-levels can be defined as 40% of C-levels.

Oticon Medical C-Levels: 5- to 8-year-olds:

After setting T-levels, C-levels are set by gradually increasing the electrical stimulation from T-levels / first response levels on an increasing number of electrodes. The goal is to determine a level that the child indicates as comfortably loud. This process is facilitated by using visual analog scales to indicate when a change in loudness is perceived. The number of rating categories can be increased from two (e.g., soft/small or loud/big) to as many as three- five (e.g., no sound, soft/small, medium/just right, loud/big) as the child improves in abilities. The C level is set at a level that the child rates as loud/big but not too loud (see examples 1-3 in appendix). The aim is to achieve audibility and comfort, ensuring loud sounds are not uncomfortable. Before going into "live mode", the potential summation effect should be accounted for by globally reducing C levels 4-5 steps before turning stimulation on for live speech. Activate "live mode" and ensure that speech is audible and not uncomfortable.

Oticon Medical C-Levels: 8 years and above:

After setting T-levels, C-levels are set by gradually increasing the electrical stimulation from T-levels / first response levels on an increasing number of electrodes. The goal is to determine a level that the child indicates as comfortably loud. This process is facilitated by using visual analog scales to indicate when a change in loudness is perceived. The number of rating categories can be increased to five or more (e.g., no sound, soft, medium, loud, too loud) as the child improves at the task. The C level is set at a level that the child rates as loud but not too loud (see examples 1-3 in appendix). The aim is to achieve audibility and comfort, ensuring loud sounds are not uncomfortable. Loudness balancing across electrodes can be attempted. Before going into "live mode", the potential summation effect should be accounted for by globally reducing C levels 4-5 steps before turning stimulation on for live speech.

Behavioral verification for audibility of the CI fitting

For all CI fittings, regardless of manufacturer, audibility and comfort of the map/program should be confirmed in calibrated soundfield conditions. It is generally recommended that soundfield detection responses quieter than 20 dB HL and louder than 30 dB HL may indicate that CI re-programming should be considered. The following measures could be used:

1. Detection of frequency specific sounds at 20–30 dB HL for 250 through 6000 Hz (8000 Hz if possible). FM tones and narrowband noise have both been used for obtaining aided detection responses. Davidson et al. (2009) found that narrowband noise stimuli were approximately 8 dB higher in output (dB SPL) than FM stimuli when presented at the same dB HL dial level for 250-6000 Hz. Thus, narrowband noise thresholds are slightly poorer (~8 dB) than the dial reading indicates.
2. Detection of Ling 6 sounds (monitored live voice or calibrated recorded version) at 20–30 dB HL. If responses are inconsistent (e.g., younger patients or those recently implanted) detection of conversational speech (average 60 dB SPL/45 dB HL) should be assessed.
3. Identification of calibrated recorded Ling 6 sounds at soft levels 50 dB SPL/35 dB HL, once developmentally able.
4. Assessment of comfort for loud environmental sounds (e.g., clapping of hands, noise makers) and loud speech (75 dB SPL/60 dB HL).

General recommendations for addressing audibility

Recommendations may vary across manufacturers if the goals of audibility are not achieved. Specific recommendations may also change as programming software, speech coding strategies and processor technology are updated. Clinicians should consult representatives

from specific manufacturers to determine the current default values and recommendations for altering map/program and processor parameters.

Advanced Bionics®

1. Reassess the T- and M-levels. Set T-levels just below detection.
2. Consider activating software that enhances soft speech levels.
3. Increase the input dynamic range (IDR) from the default.
4. Adjust filter gains on electrodes globally or at electrodes covering frequency ranges where audibility goals are not met.
5. Increase sensitivity setting, knowing that this may impact speech perception in the presence of background noise.

Cochlear Corporation®

1. Reassess the T- and C-levels.
2. Confirm that sensitivity is at the recommended default setting.
3. Adjust filter gains on electrodes globally or at electrodes covering frequency ranges where audibility goals are not met.

MED-EL Corporation®

1. Reassess the THR- and MCL-levels. Set THR-levels just below detection.
2. Consider changes to the Maplaw setting.

Oticon Medical®

1. Reassess the T- and C-levels, making sure that T-levels are set to just audible/detectable/very soft.
2. Audibility for specific sounds or frequencies can be validated during a fitting session by visualizing the input to the microphones being mapped into the patient's electrical dynamic range from within the fitting software while in "live mode". T-levels can then be adjusted during this live mode stimulation until the patient detects the input.

Recommendations for addressing comfort issues

If comfort issues occur consider sweeping across upper programming levels to identify areas of potential discomfort, re-measuring individual upper programming levels as needed and activating programming for live-speech. See manufacturer-specific instructions provided above.

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Appendix: Suggested protocols for loudness scaling and loudness balancing procedures with children

Loudness Scaling

The audiologist assesses the electrical dynamic range (EDR) for individual electrodes using the cochlear implant (CI) programming software. The EDR is defined as the range between minimum and maximum electrical stimulation levels. Beginning at a level slightly below first detection, the electrical current is gradually increased in clinical unit steps (clinical units vary depending on manufacturer) while the child rates perceived changes in loudness. Generally, a five to eight-point categorical rating scale is used for this task (no sound, soft, comfortable, loud, and too loud). The upper limits of the dynamic range are set at the clinical stimulation unit rated as “most comfortable” or “loud but comfortable”. The upper range of comfort will vary based on the manufacturer (see sections in document); some will denote setting the upper limit at maximum loudness while others designate most comfortable.

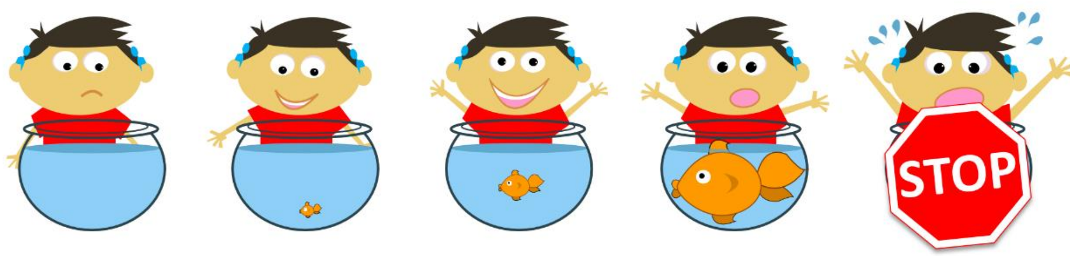
The examples below serve to illustrate how loudness scaling may be accomplished with pediatric CI recipients. As noted in the **Essential Elements of Best Practice for Cochlear Implant Fitting in Children: Considerations for Behavioral Methods of Verification and Validation**[1] document, the task will need to be adapted to be appropriate for the age-, developmental- and language-level of the child.

A categorical loudness-rating task is shown in example 1. The child is instructed to point to picture cards and accompanying vocabulary depicting increased loudness from no sound to sound that is too loud. The following terms are used: *I can’t hear*, *soft*, *just right*, *loud* and *too loud*. Clinicians may also use the term *medium* (between soft and loud) to denote *comfortable* or *just right*. The clinician should use the term that is most easily understood by the child. Note that facial expressions are also paired with the pictures and text: for example, *I can’t hear* shown with a questioning/sad face, *just right* shown with a happy face and *too loud* with a frown/sad face.

Example 1

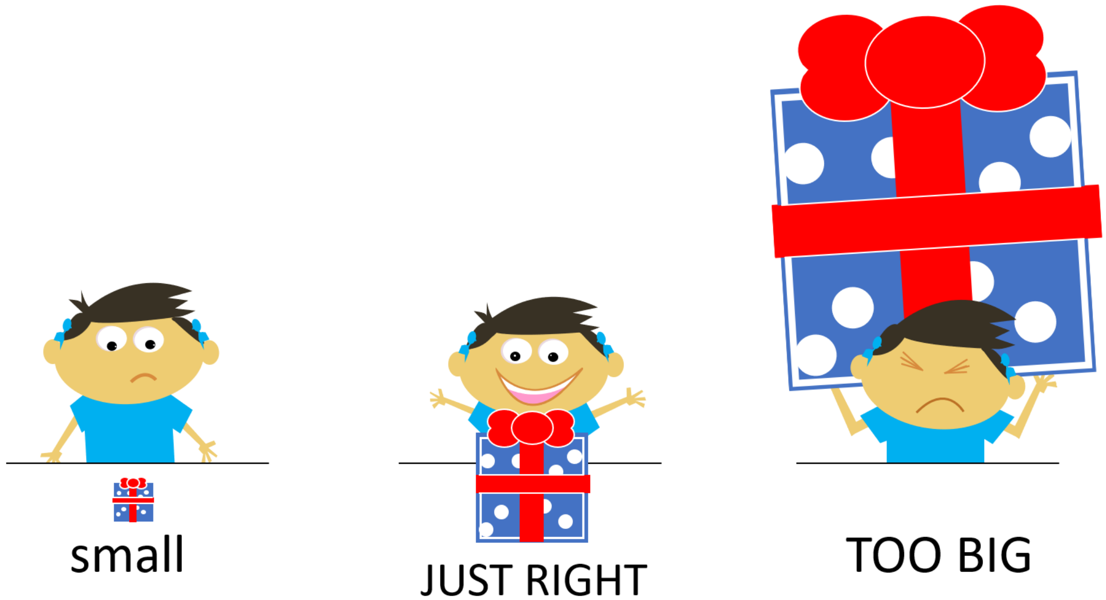
For children who do not have the vocabulary knowledge to report loudness percepts, the concept of size may be used (e.g. *small/little* for ***soft**, just right* for ***comfortable*** and *big* for ***loud***) as shown in example 2. Note that *medium* or *perfect* may also be used for *just right*. The clinician should determine the term that is most relevant for the child. The stimulus is increased from below the first response (shown here as an empty fish bowl accompanied with a sad/questioning face on the boy) to higher/louder levels (shown by increasing size of the fish in the fish bowl and changing expressions on the boy's face) that can ultimately be reported as *too big* or *stop*. The child is instructed to choose the *nothing* card (empty fish bowl) for no sound and point to the increasingly larger fish until a stop sign for *too big* (too loud). Most comfortable levels may be set at the stimulation level that elicits a response just below *big* (the terms *medium*, *just right*, *OK* or *perfect* may be used). When obtaining maximum comfort levels, the stimulation level that elicits a *big* rating should be used. Maximum stimulation levels should be set below the level that elicits *too big* or *stop*.

Example 2



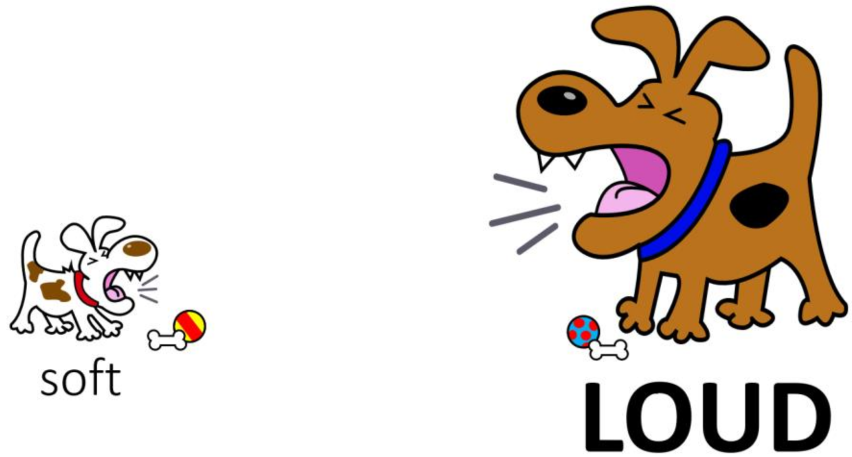
The number of loudness rating categories can be increased or decreased depending on the developmental level of the child. Example 3 shows fewer choices (e.g. *small, just right* and *big*). Here, *small, just right* and *too big* are shown with an increasing gift box size as well as changing facial expressions (questioning/frown for *small*, happy/smiling for *just right* and frown/uncomfortable for *too big*). The child is instructed to choose *small* and *too big* for soft and too loud, respectively. The middle picture can be labeled as *just right* to denote the target response level for most comfortable loudness percept. The terms *perfect* or *medium* may also be used for *just right*. The clinician should determine which term is most appropriate for the child.

Example 3

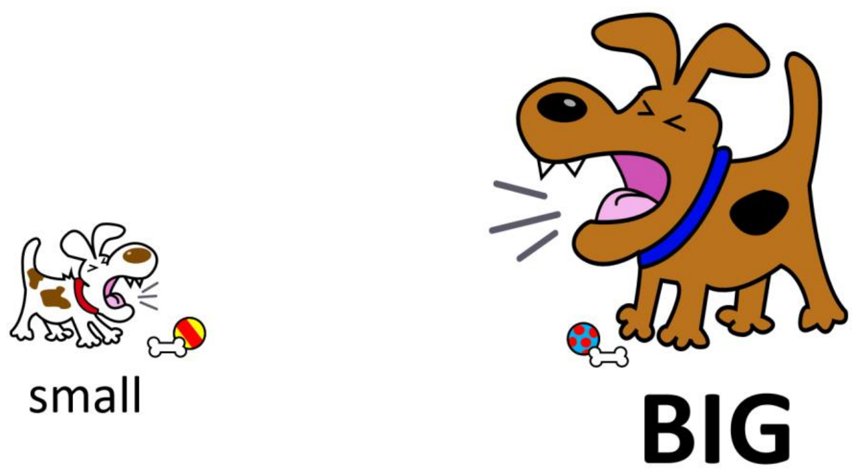


Loudness scaling may be introduced by using two broad categories such as *soft* vs *loud* shown in example 4a or using *small* vs *big* shown in example 4b (size is shown by a small vs. big dog, and small vs. big could also be further explained by contrasting loudness of the dogs' barking). Examples 4c and 4d use birds singing to illustrate the same task. For this task, a stimulus level presented at a soft level (i.e. previously measured threshold level) may be contrasted with increasingly higher stimulation levels.

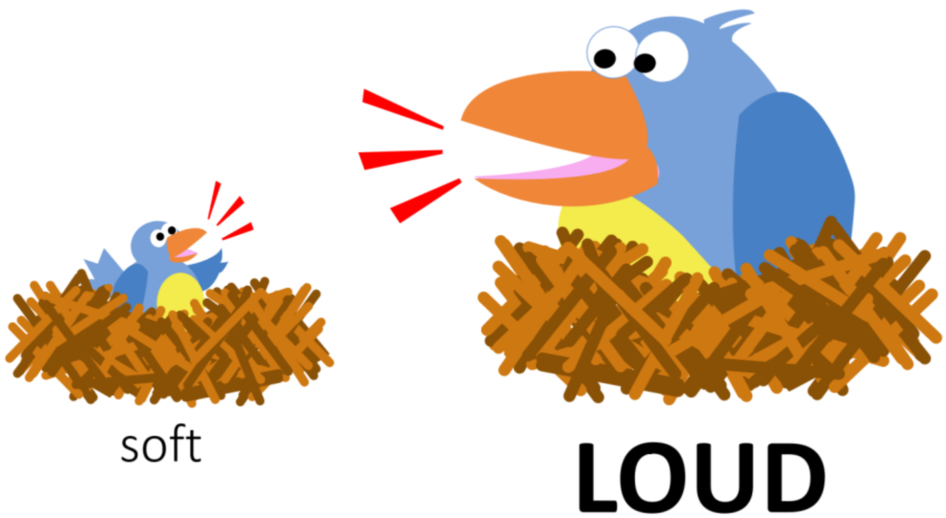
Example 4a



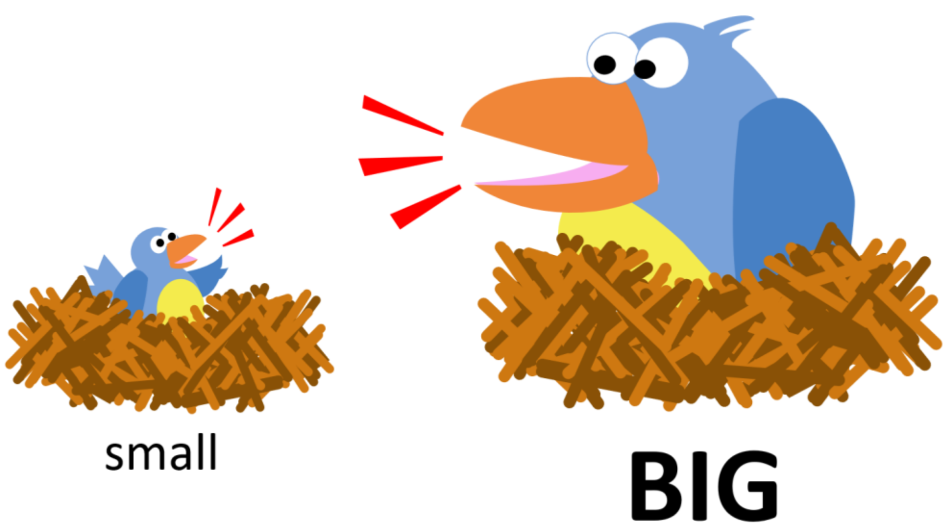
Example 4b



Example 4c



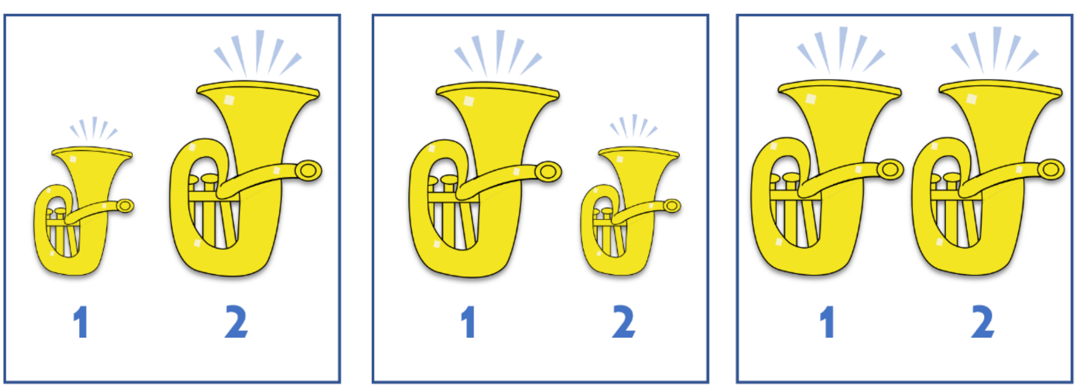
Example 4d



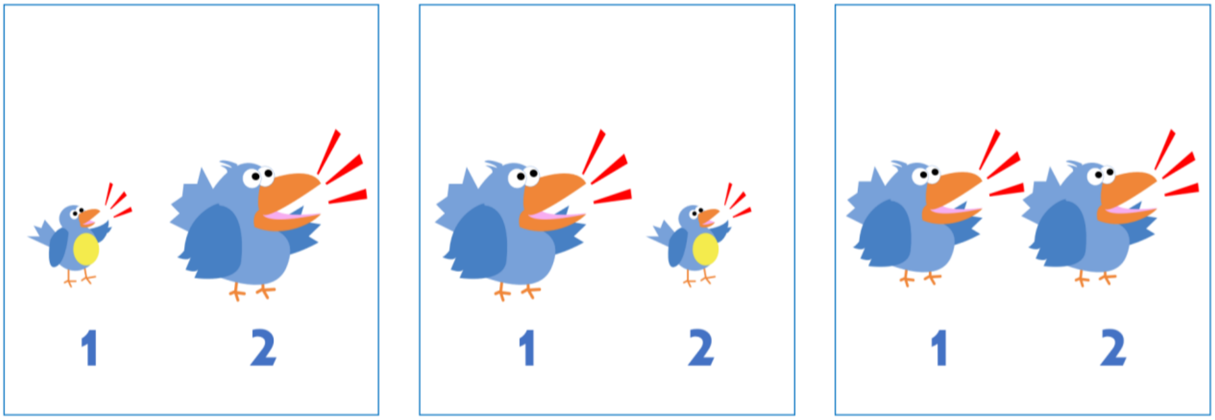
Loudness Balancing

After setting levels at most comfortable or the maximum comfort levels (depending on the manufacturer), loudness balancing is performed to ensure that stimulation levels on adjacent electrodes are perceived as equally loud. Beginning with the most apical electrode, stimulation at the most or maximum comfort level is presented followed by the presentation at the most/maximum stimulation level at the adjacent electrode. This process continues along the array with the electrical current levels on successive electrodes adjusted in pairs until each successive electrode is perceived to be equal in loudness to the preceding electrode. This task requires that the child be able to compare the loudness ratings of two electrodes using a same/different discrimination task. If the electrodes are judged to be different in loudness, the child must indicate whether the successive electrode is louder/softer or bigger/smaller than the preceding electrode. The current level at the adjacent (successive electrode) is increased or decreased until the loudness percepts are judged to be the same. Example 5a illustrates this task using size (small horn vs. big horn). The first electrode presented in the pair serves as the reference electrode and is usually the most apical electrode in the pair. The second electrode presented (usually the more basal electrode) is always adjusted in level until it is judged to be equally loud as the first (reference) electrode. Example 5a below would denote that the second electrode (horn labeled with a number 2) is *louder* (*bigger*) than the first electrode (horn labeled with a number 1). In this case, the clinician would decrease the electrical stimulation level on the second electrode in the pair until it is judged equally loud as the reference electrode (first electrode presented in the pair). In the second panel, the second electrode (horn labeled with a number 2) is judged as softer in loudness than the reference or first electrode (horn labeled with a number 1), therefore, the electrical stimulation level on the second electrode would be increased until it is judged equal in loudness to the first electrode. The third panel illustrates that electrodes 1 and 2 are judged to be equal (or for the child the *same*) in loudness. Example 5b uses birds singing to illustrate the same concept.

Example 5a



Example 5b



Use of visuals within this document:

The visuals within this document were created by **Mr. David Sindrey**. They can be used by clinicians for clinical use in their practice. If private businesses, hearing aid and/or cochlear implant companies, or other organizations wish to use them, they should first contact David Sindrey at dsindrey@uwo.ca or Sheila Moodie at sheila@nca.uwo.ca

All visuals are available for clinicians to download from uwo.ca/nca/fcei website or from the kipagroup.org website.

Two additional visual examples that could be used: