

# A prospective study evaluating cochlear implant management skills: development and validation of the Cochlear Implant Management Skills survey

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**Key Words:** cochlear implant, handling skills, management skills, survey, patient benefit, patient outcomes.

**Abbreviations:** CI: cochlear implant; CIMS: Cochlear Implant Management Skills; ICC: intraclass correlation; SD: standard deviation.

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## ABSTRACT

**Objective:** To investigate the ability of cochlear implant recipients to physically handle and care for their hearing implant device(s) and to identify factors that may influence skills. In

order to assess device management skills a clinical survey was developed and validated on a clinical cohort of cochlear implant recipients.

**Design:** Survey development and validation. A prospective convenience cohort design study.

**Setting:** Specialist hearing implant clinic.

**Participants:** Forty-nine postlingually deafened, adult cochlear implant recipients, at least 12 months post-operative.

**Main Outcome Measures:** Survey test-retest reliability, inter-observer reliability and responsiveness. Correlations between management skills and participant demographic, audiometric, clinical outcomes and device factors.

**Results:** The Cochlear Implant Management Skills survey was developed, demonstrating high test-retest reliability (0.878), inter-observer reliability (0.972) and responsiveness to intervention (skills training) [ $t(20) = -3.913, p=0.001$ ]. Cochlear Implant Management Skills survey scores range from 54.69% to 100% (mean: 83.45%, SD: 12.47). No associations were found between handling skills and participant factors.

**Conclusions:** This is the first study to demonstrate a range in processor handling skills in cochlear implant recipients and offers clinicians and researchers a tool to systematically and objectively identify shortcomings in cochlear implant recipients' device handling skills.

## INTRODUCTION

As part of the cochlear implant (CI) rehabilitation program clinicians provide information, training and user manuals on the daily care and maintenance of the external

components of the hearing implant system, including the speech processor, battery compartment, transmitter coil, transmitter coil cable and coil magnet, and associated accessories, and described hereafter as the “CI device”<sup>1,2</sup>. However, little is known regarding the effectiveness of these techniques and the prevalence of CI device handling difficulties in populations of hearing implant users.

The importance of hearing aid handling skills are evidenced in their positive association with hearing aid outcomes such as hearing aid use<sup>3,4</sup> and satisfaction<sup>3,5</sup>. Studies have described handling problems experienced by hearing aid users to include difficulties with insertion, cleaning, volume and program control, and hearing on the telephone<sup>6-9</sup>. Given that the CI device has many functional similarities to a hearing aid, it can be expected that CI recipients may experience similar problems to hearing aid users. However, there is currently no reports available describing CI device handling skills.

The primary purpose of this study was to investigate the ability of cochlear implant recipients to physically handle and care for their hearing implant device(s) and to identify factors that may influence skills. In order to assess management skills a clinical survey was developed and validated on a clinical cohort of cochlear implant recipients.

## **METHODS**

### **Ethical Considerations**

Ethics clearance for this study was granted by the Human Research Ethics Office of The University of Western Australia, and all participants provided informed consent to participate.

## **Survey development**

The Cochlear Implant Management Skills (CIMS) survey was developed by a team of eleven clinical and research hearing care professionals. In order to ensure content validity the team reviewed existing surveys evaluating device handling skills<sup>10</sup>, studies describing hearing aid handling and associated factors<sup>3,8,9</sup>, and Cochlear® user manuals for commercially available speech processors<sup>11,12</sup>. The draft version of the survey was then pilot tested on five cochlear implant recipients each with a different implant audiologist, resulting in some refinements to language to produce the final version.

The CIMS survey is a ten question survey with six questions having two parts. A three point Likert scale is used to record the performance of participants, grading them as 'performs task accurately and with no difficulty' (zero points), 'performs task with some difficulty and would benefit from retraining' (one point) or 'performs inaccurately, unable or does not perform' (two points), and includes a 'not applicable' option (zero points). The scores were summed, subtracted from 30 and multiplied by -3.33 to produce the final score representing percentage of competency, increasing to 100% as competency increases.

The CIMS survey is designed to be administered aurally. However, as participants are required to remove their CI device to perform some of the tasks, the survey comes with flash cards with each question written in a large font. Eight of the 49 participants relied on the flash cards during data collection.

## **Participants**

All adult cochlear implant recipients who received rehabilitation services from the Ear Science Institute Australia Hearing Implant Centre and had been implanted with a

Cochlear® device at least twelve months prior to February 2014 were invited to participate. Of the 300 potential participants, 49 participated (response rate 16.3%).

Participants were required to attend two 30-minute data collection sessions approximately two weeks apart. The first 46 participants were randomly assigned to two groups: Group One, the intervention group, to evaluate responsiveness of the survey; and Group Two, the delayed intervention group, to evaluate test-retest reliability of the survey. The last three participants who responded were reassigned to Group One as it had become apparent that not all of Group One participants were returning for the second session. Five participants from Group One (aged  $75.23 \pm 12.57$  years; four males and one female) did not attend the second session due to personal reasons.

Two audiologists (aged  $34 \pm 2.8$  years; both female) participated as observers, administering the surveys, both with postgraduate degrees in audiology and each with over ten years' experience in clinical audiology.

### **Data collection**

During session one, participants first completed a short clinical history form, which included a single question regarding their overall perception of their ability to manage their CI device(s) and a question regarding their overall satisfaction with their CI device(s), both on a 5-point Likert scale. They then joined two clinicians in a private consultation room to complete the CIMS survey. Both clinicians evaluated each participant on the CIMS survey simultaneously: one clinician administered the survey, reading with the exact wording of each question, and both clinicians scored independently of each other. The flash card with

the relevant question was also provided if required. The clinicians did not compare their scores whilst the study was underway.

Participants in Group One (intervention group) received retraining on hearing implant handling skills listed in the CIMS survey immediately following the first data collection session, if required. Training was delivered in line with recommendations outlined in the user manual that accompanied their cochlear implant processor. Participants in Group Two (delayed intervention) were informed that any questions they may have would be answered at the second session. All participants were asked not to discuss or seek help for device handling between the first and second sessions. Client records were checked to ensure participants had not attended a clinical appointment between the two data collection sessions.

During the second session participants again completed the short clinical history form, this time also asking them to confirm that they had not sought advice or assistance for their CI device since the last session; none had. The CIMS survey was readministered as per the procedure in the first session. Where indicated by CIMS survey scores, participants received retraining on hearing implant handling skills as per the first session.

Participant demographic, audiometric, clinical outcomes and CI device data was extracted from client files including: aided four frequency average hearing loss (4FAHL) for the implanted ear (at least 12 months post implantation); aided binaural City University of New York (CUNY) sentence perception test<sup>13</sup> scores (at least 12 months post implantation) and Abbreviated Profile of Hearing Aid Benefit (APHAB)<sup>14</sup> survey scores (at least 12 months post implantation); processor model; and years since implantation and most recent processor upgrade.

## Data Analysis

When completing the CIMS survey each participant was scored independently by two clinicians and thus received two CIMS survey scores at each appointment. For evaluation of inter-observer reliability the two CIMS survey scores were compared and for all other analyses the two scores generated by the two clinicians were averaged.

Data were not normally distributed, and as transformation did not result in normally distributed data nonparametric tests were used. Four outliers were excluded as indicated by z-scores. Sampling distribution was investigated using independent sample t-tests and Chi-Square tests for between group differences (intervention versus delayed intervention).

**Survey validity.** Construct validity was assessed using Spearman's rank-order correlations for the following hypotheses: 1. CIMS survey scores will be positively correlated with overall satisfaction with CI device; 2. CIMS survey scores will be positively correlated with perceived overall ability to manage CI device; 3. CIMS survey scores will be negatively correlated with age; 4. CIMS survey scores will not be associated with gender; 5. CIMS survey scores will not be associated with hearing sensitivity (aided 4FAHL).

Test-retest reliability was assessed using intraclass correlation (ICC) for individuals CIMS survey scores in the delayed intervention group (Group Two), with a minimum of two and a maximum of three weeks between test and retest. Inter-observer reliability was assessed using intraclass correlation between clinician scores for each individual hearing implant recipient, and analysing both data collection sessions separately. ICC values were interpreted as per Landis & Koch <sup>15</sup>.

Responsiveness, the instruments ability to detect clinically important changes over time <sup>16</sup>, was evaluated using paired sample t-test to compare mean CIMS survey scores pre

and post intervention for Group One (intervention group), excluding the five participants who did not attend the second session.

Internal consistency is a commonly used psychometric evaluation of survey validity. It is used to examine the extent to which survey items correlate and thus measure the same concept<sup>17</sup>. However, internal consistency is not appropriate for surveys such as the CIMS, where all items evaluate different aspects of CI handling, and thus individual items are not likely to correlate. For example, it cannot be assumed that a participant who demonstrates difficulty cleaning their CI device would also demonstrate difficulty inserting their device.

***Factors associated with CI device management.*** Associations between CIMS survey scores and participant demographic, audiometric, clinical outcomes and CI device factors were investigated using Spearman's Rho or AOVNA.

## RESULTS

There were no significant differences between demographic and audiometric factors between the groups (intervention and delayed intervention), with the exception of length of time since implantation [ $t(37.15) = 3.058, p = 0.004$ ]; however, this was found not to be associated with other variables in this study.



**Table 1.** Cohort description

	Group One (intervention) (n = 26)	Group Two (delayed intervention) (n = 23)
Age (mean years $\pm$ SD)	65.49 $\pm$ 17.21	64.34 $\pm$ 16.85
Gender	Male (n=12), Female (n=14)	Male (n=10), Female (n=13)
Aetiology	Congenital (n=8), Meniere's (n=6), Hereditary (n=4), Otosclerosis (n=3), Noise exposure (n=1), Meningitis (n=1), Unknown (n=4)	Congenital (n=1), Meniere's disease (n=1), Hereditary (n=9), Otosclerosis (n=3), Noise exposure (n=2), Neurofibromatosis (n=1), Nerve Damage (n=1), Osteogenesis Imperfecta (n=1), Unknown (n=4)
Implant models	N22 (n=1), CI24RE(CA) (n=25), CI24RE(ST) (n=1), CI24R(CS) (n=4), CI24R(ST) (n=3), CI422 (n=1), CI512 (n=2)	CI24RE (CA) (n=17), CI24RE (ST) (n=1), CI422 (n=5), CI512 (n=7), CI513 (n=1)
Processor Models	ESPr3G (n=1), Freedom (n=4), CP810 (n=25), CP910 (n=6)	Freedom (n=8), CP810 (n=23), CP910 (n=4)
Time since initial implantation (mean years $\pm$ SD)	6.47 $\pm$ 4.52	3.42 $\pm$ 2.20
Time since most recent processor upgrade (mean years $\pm$ SD)	2.71 $\pm$ 2.47	2.39 $\pm$ 1.82
Aided 4FAHL (for the implanted ear) (mean decibels $\pm$ SD)	28.27 $\pm$ 4.51	26.56 $\pm$ 6.96
Bilateral CUNY speech scores (mean $\pm$ SD)	93.25 $\pm$ 2.47	94.17 $\pm$ 10.05
Post-op APHAB scores (mean $\pm$ SD)	37.96 $\pm$ 16.07	35.42 $\pm$ 13.49

### Survey validation

Three of the five hypotheses tested for construct validity were met (Table 2).

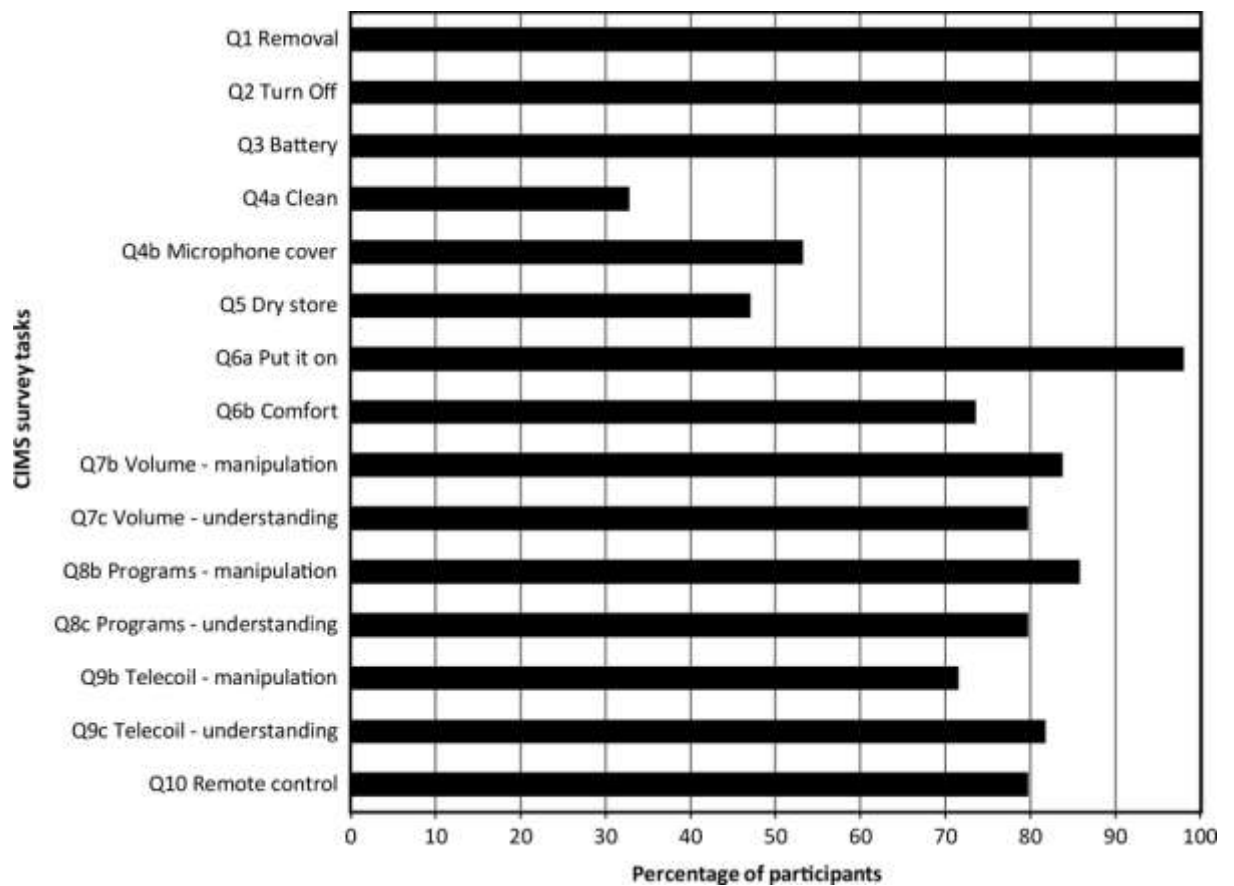
**Table 2.** Associations between CIMS survey scores and participant demographic and self-report outcome factors to establish construct validity of the CIMS survey

Spearman's rank-order correlations	
1. Overall satisfaction with CI device(s)	$r_s = 0.360$ $p = 0.016^*$
2. Single question on perceived ability to manage CI device(s)	$r_s = -0.268$ $p = 0.074$
3. Age	$r_s = -0.105$ $p = 0.499$
4. Gender	$r_s = -0.132$ $p = 0.394$
5. 4FAHL for the implanted ear	$r_s = 0.029$ $p = 0.855$

\* Correlation is significant at the 0.05 level (2-tailed)

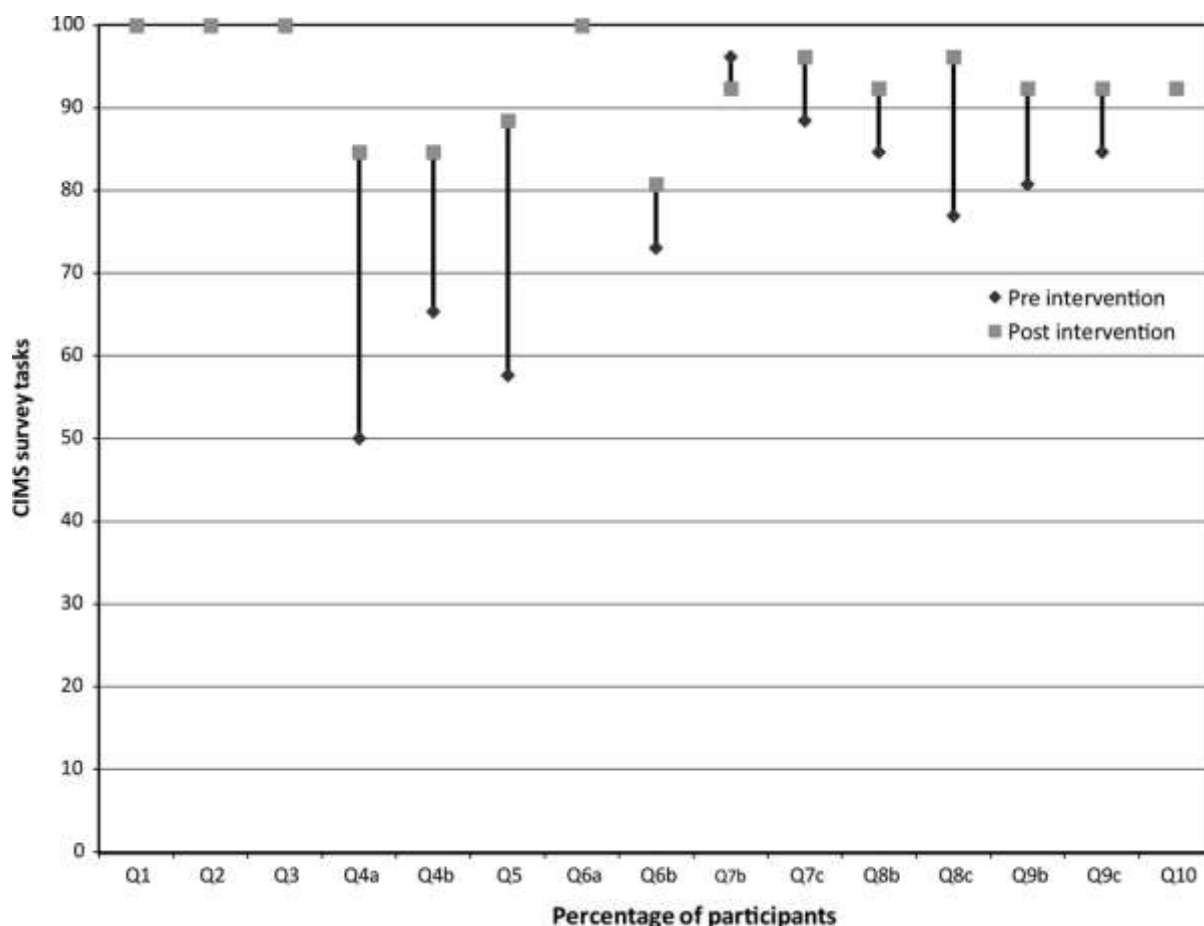
The test-retest reliability of the CIMS survey was almost perfect (ICC = 0.878; CI 95%: 0.735 to 0.947). The inter-observer reliability of the CIMS survey was almost perfect when administered during the first (ICC = 0.972; CI 95%: 0.950 to 0.984) and second (ICC = 0.982; CI 95%: 0.966 to 0.990) data collection sessions. Evaluation of the responsiveness of the CIMS survey demonstrated a significant improvement when comparing pre intervention ( $83.63 \pm 12.45$ ) to post intervention ( $94.12 \pm 8.64$ ) scores, [ $t(20) = -3.913$ ,  $p=0.001$ ].

The mean CIMS survey score (pre intervention) was 83.45% (SD 12.47, Range 54.69% to 100%). 89.80% of participants scored below 100% and therefore had difficulty with at least one aspect of CI device handling. All participants were able to remove their device, turn it off and change/charge the battery satisfactorily (Figure 1), indicating a ceiling effect for these questions. Participants had the most difficulty with the questions on the CIMS survey relating to cleaning, changing the microphone cover and using the dry store unit (Figure 1).



**Figure 1.** Percentage of participants able to complete questions on the CIMS survey (n = 49).

Of the participants from Group One (intervention group), 80% were unable to complete all tasks on the CIMS survey and thus required and received retraining on at least one aspect of CI device handling. Two to three weeks following intervention, 83% of these participants demonstrated a significant improvement in CIMS survey scores [ $t(20) = -3.913$ ,  $p = 0.001$ ]. Improvements in handling skill were greatest for CIMS survey items 4a, 4b and 5 (Figure 2).



**Figure 2.** Comparing percentage of participants unable to complete items on the CIMS survey pre and post intervention (Group Two; n = 23). Improvement in cochlear implant management skills.

Notes: Questions on the CIMS survey: Q1 Removal; Q2 Turn Off ; Q3 Battery; Q4a Cleaning; Q4b Changing microphone cover; Q5 Using dry store; Q6a Put it on; Q6b Comfort; Q7b Volume – manipulation; Q7c Volume – understanding; Q8b Programs – manipulation; Q8c Programs – understanding; Q9b Telecoil – manipulation; Q9c Telecoil – understanding; Q10 Remote control.

**Factors associated with CI device management**

No associations were found between handling skills (CIMS survey scores) and participant demographic, audiometric, clinical outcomes and CI device factors, with the exception of self-reported overall satisfaction with CI device (Table 3).

**Table 3.** Associations between CI device management skills (CIMS survey scores) and participant demographic, audiometric, clinical outcomes and device factors.

	Spearman's rank-order correlations	ANOVA
Age	$r_s = -0.105$ $p = 0.499$	
Gender		$F(1, 42) = 1.225$ $p = 0.275$
Processor Models		$F(2, 42) = 0.834$ $p = 0.442$
Time since initial implantation (years)	$r_s = -0.065$ $p = 0.673$	
Time since most recent processor upgrade (years)	$r_s = -0.053$ $p = 0.733$	
Aided 4FAHL (for the implanted ear)	$r_s = 0.029$ $p = 0.855$	
CUNY speech scores (bilateral; at least 12 months post implantation)	$r_s = -0.058$ $p = 0.711$	
Post-op APHAB scores (at least 12 months post implantation)	$r_s = -0.025$ $p = 0.884$	
Self-report satisfaction with CI device(s)	$r_s = 0.360$ $p = 0.016^*$	

\* Correlation is significant at the 0.05 level (2-tailed)

## DISCUSSION

To date there have been no tools available to assist clinicians in systematically evaluating CI recipients level of skill with regard to CI device handling and management. This study has developed and validated such a tool, and reports the handling skills of a cohort of CI recipients.

Given that patient care may rely on survey scores, in that CI recipients will or will not receive additional retraining based on their performance, it is paramount that scores reflect participant skills and not population variance or clinician bias. CIMS survey test-retest reliability was high demonstrating that CIMS survey scores represent participant individual

ability and not variation in the population<sup>17</sup>. Inter-observer reliability of the CIMS survey was 'almost perfect', indicating low susceptibility to clinician bias<sup>18</sup> and high reliability for clinical application<sup>19</sup>.

Participants showed a significant improvement in CIMS survey scores following intervention, demonstrating that the CIMS survey is sensitive enough to detect changes in CI device handling skills following retraining<sup>16</sup>. However, despite receiving retraining and demonstrating full competency only two weeks prior, 18% of participants still could not complete all tasks on the CIMS survey when reassessed at the second data collection session. Although determining the reasons for participants' inability to demonstrate handling skills two weeks following retraining were beyond the scope of this study, it may be possible that CIMS survey scores were affected by cognitive function<sup>20</sup>, or participant personal investment in learning the new skills<sup>21, 22</sup>. Future studies could investigate the correlation between these factors and patients' capacity to learn as it may inform clinicians how to improve delivery models and enhance patient care.

### **Factors associated with CI device management**

Although one may assume that CI device handling skills might be affected by factors such as participant age, years of experience with CIs or process model, this study found no such associations. These findings have significant clinical implications in that clinicians should not assume that younger or experienced CI recipients already have the skills necessary to use and manage their CI devices appropriately. Instead, comprehensive training and systematic evaluation of handling skills should be part of the rehabilitation process for all CI recipients.

A significant finding of this study was the association between CIMS survey scores and self-reported satisfaction. That is, participants who demonstrated greater difficulties in completing CI device daily management tasks reported being less satisfied with their CI devices. These findings suggest that clinicians may be able to improve client satisfaction by improving CI device handling skills.

### **Clinical considerations**

Handling problems were greatest for questions regarding device maintenance such as cleaning, changing the microphone covers and use of the dry store, suggesting that CI recipients may benefit from increased focus on the training of these skills. CI device maintenance is an important aspect of CI device use as devices that are not appropriately cared for may be more prone to repair and malfunction<sup>2, 23</sup>, and thus reduce the cost effectiveness of cochlear implantation as an intervention option<sup>24</sup>.

Although the majority of participants demonstrated full competency in cleaning their device following intervention, changing microphone covers remained a challenge. This difficulty was likely due to the microphone cover for the CP810, CP910 & CP920 processors being very small and difficult to manipulate. This may have been particularly problematic for participants with poor manual dexterity, reduced tactile sensitivity or vision impairment<sup>3, 9, 25</sup>, and exacerbated in older populations<sup>6, 9</sup>. As such, clinicians need to be cognisant of the impact that reduced vision, dexterity and cognition may have on CI recipients' ability to acquire CI device handling skills<sup>9, 20, 25</sup>.

Although studies with hearing aid users report an association between objectively measured handling skills and self-reported overall ability to manage devices<sup>7</sup>, this

association was not supported by the findings of this study. This finding highlights a potential flaw in current clinical protocols, as during CI rehabilitation appointments CI recipients are routinely asked by their clinicians if they are competent in using their CI device and accessories. If the patient says “yes”, then the clinician generally assumes that the patient has learned the skills they require to use and maintain their device effectively<sup>6</sup>. However, results from this study suggest that CI recipients are generally poor at recognising CI device handling deficiencies. As such, clinicians should not rely on a simple client report of their handling skills; rather clinicians should use tools to assess patient skills and knowledge regarding device management and use.

Clinical uptake of survey, to evaluate CI device handling skills, such as the CIMS, assists: 1) clinicians by providing an easy to use checklist for training and evaluation purposes; 2) CI recipients by ensuring they have developed the skills required to optimally use and maintain their device, and prevent unnecessary breakdowns and repairs; 3) clinic managers to demonstrate to third party payers the provision of sufficient training and support; and 4) CI device manufacturers to support improvement in device design and user education tools.

### **Limitations and future research**

A limitation of this study was that although the CIMS survey was developed for use with all brands of CI devices, to date it has only been validated on participants using Cochlear® brand devices. Furthermore, validation was performed on a cohort recruited from a single clinic. As such, a large multicentre study is needed to include participants with a wider range of CI device brands and models to further validate the CIMS survey.



## CONCLUSION

This is the first study to demonstrate a range in processor handling skills in CI recipients, and offers clinicians and researchers a tool to systematically and objectively identify shortcomings in CI recipients' device handling skills. A significant finding of this study was that CI recipients are generally poor at recognising CI device handling deficiencies. As such, clinicians should not rely on a simple client report of their handling skills; rather clinicians should incorporate tools, such as the CIMS survey, into clinical practices to assess patient skills and knowledge regarding device management and use.

The CIMS survey is available on line at [esia.org.au](http://esia.org.au)

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## Declaration of interest

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