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Evidence-Based Adult Cochlear Implant Counseling Using the CIQOL Instruments, in partnership with American Auditory Society

Teddy McRackan, MD MSCR
Professor, Medical University of South Carolina
Medical Director, Cochlear Implant Program
Director, Skull Base Center

Teddy McRackan, MD, MSCR

Dr. Teddy McRackan, MD MSCR is a Professor in the Otolaryngology-Head and Neck Surgery Department at the Medical University of South Carolina. He is a fellowship trained neurotologist with a research career focused advancing our comprehensive understanding of the functional benefits of cochlear implantation in adults and developing interventions to enhance pre-cochlear implant (CI) patient counseling and post-CI outcomes. His research program has been supported by the National Institute on Deafness and Other Communication Disorders, National Center for Advancing Translational Sciences, American Cochlear Implant Alliance, and the Doris Duke Foundation. He has received the Triological Society's Harold Mosher Award for Outstanding Clinical Research and the American Auditory Society's Early Career Research Award. His research 2 v0921 interests have been informed by his experiences in basic, translational, and clinical outcomes research, and as a practicing neurotologist. He completed a Masters of Science in Clinical Research (MSCR) degree to provide formal training in epidemiology, clinical trial design and analysis, biostatistics and regression analysis, community engagement research, dissemination and implementation science, and team science. Through his K23 award, he also received formal and mentor-led training in mixed methods research, intervention mapping, and dissemination and implementation research. He also maintains an active clinical practice and serves as the Medical Director of the MUSC Cochlear Implant Program and Director of the MUSC Skull Base Center.

Disclosures

- **Presenter Disc**losure: Financial: Ted McRackan is employed by the Medical University of South Carolina. He received an honorarium for this presentation. Non-financial: Ted McRackan serves on the advisory board for Envoy Medical.
- **Content Disclosure**: This learning event does not focus exclusively on any specific product or service.
- **Sponsor Disclosure**: This course is presented by the American Auditory Society in partnership with AudiologyOnline.
- **Funding:**
  - NIH/NIDCD: R01DC020709
  - NIH/NIDCD: K23DC016911
  - American Cochlear Implant Alliance

Learning Outcomes

After this course, participants will be able to:

- Discuss how to apply a greater understanding of real-world adult cochlear implant functional outcomes in routine clinical care.
- Explain how to directly compare potential CI users' baseline abilities and expected outcomes to normative data.
- Identify how to better align their clinical practice with needs of adult CI users.

Personalized Evidence-Based Adult Cochlear Implant Care Using the CIQOL Instruments

https://education.musc.edu/ciqol

Personalized Evidence-Based Adult Cochlear Implant Care Using the CIQOL Instruments

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Personalized Evidence-Based Adult Cochlear Implant Care Using the CIQOL Instruments

- Pre-CI counseling
- Post-CI monitoring
- Personalizing auditory training

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Personalized Evidence-Based Adult Cochlear Implant Care Using the CIQOL Instruments

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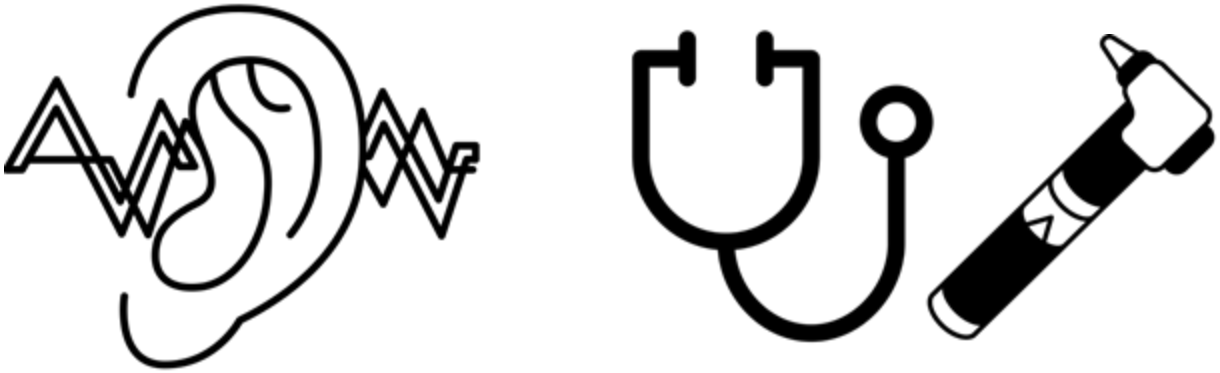
https://education.musc.edu/ciqol

Cochlear Implant Evaluation

https://education.musc.edu/ciqol

Cochlear Implant Evaluation



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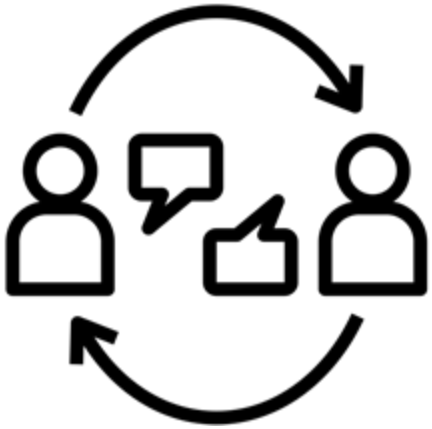
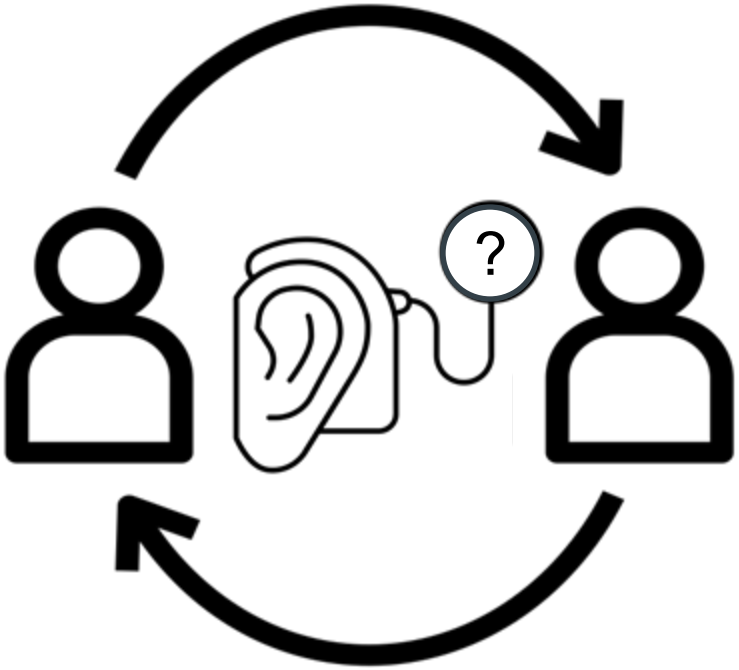
Cochlear Implant Evaluation



https://education.musc.edu/ciqol



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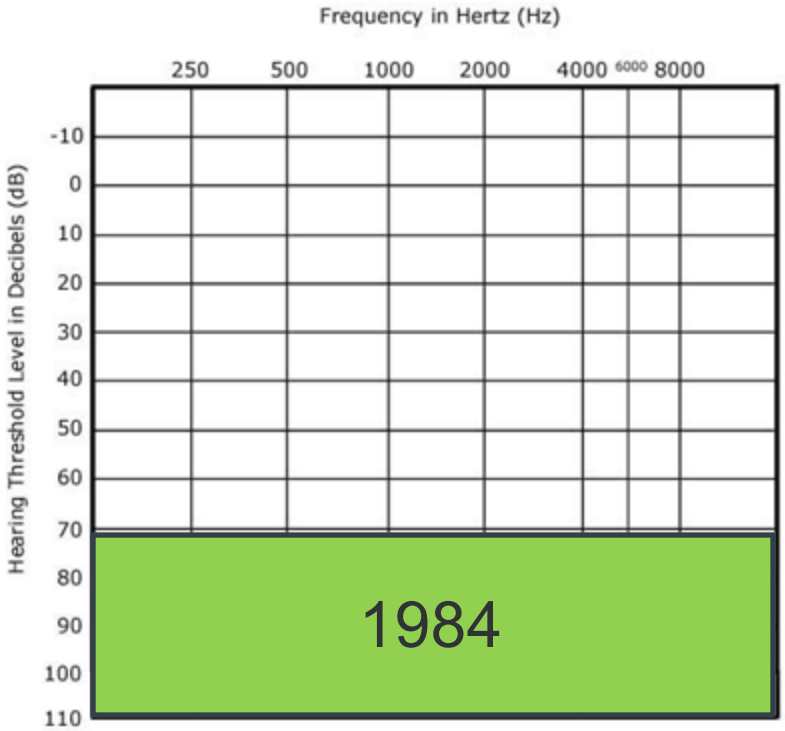
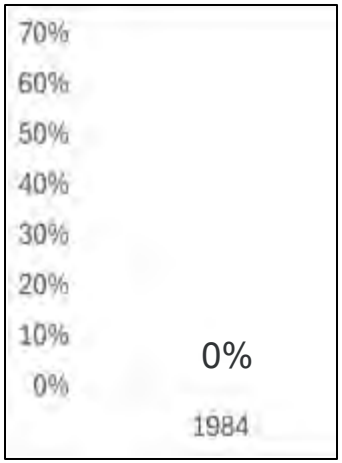
Prentiss et al. JAMA-oto. 2019
Zeitler DM et al. Laryngoscope 2024
Fabie JE et al. Ear Hear under rev





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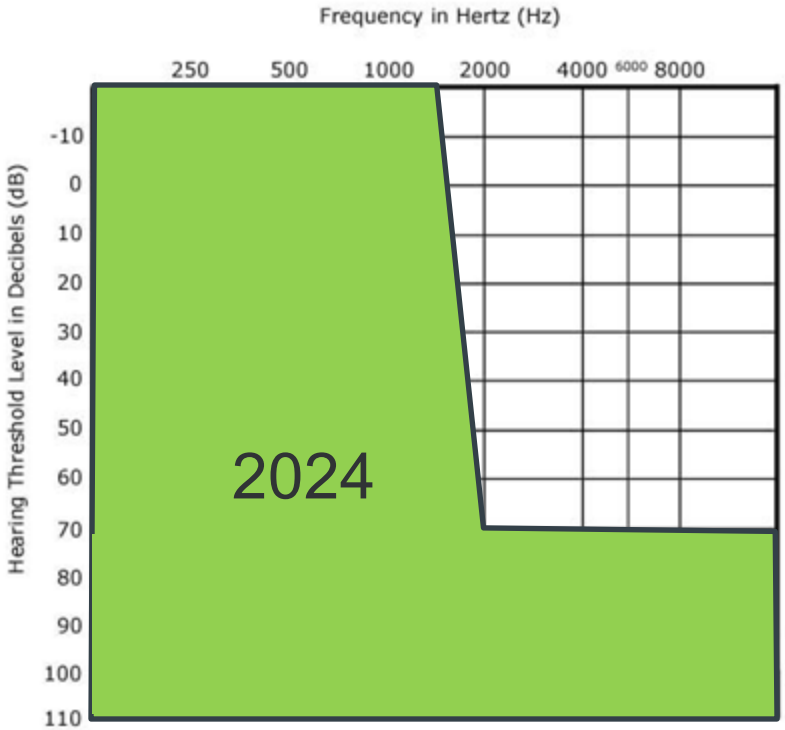

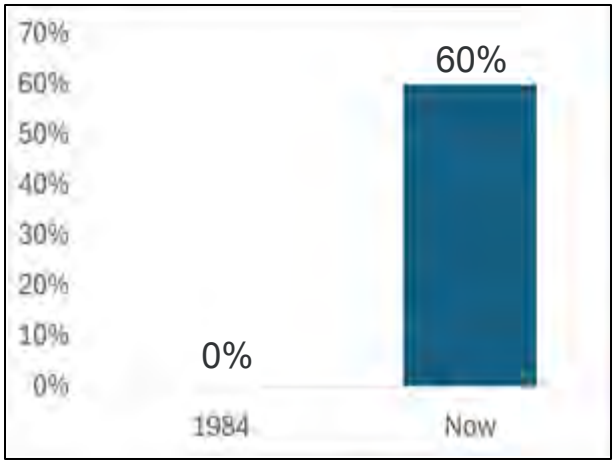

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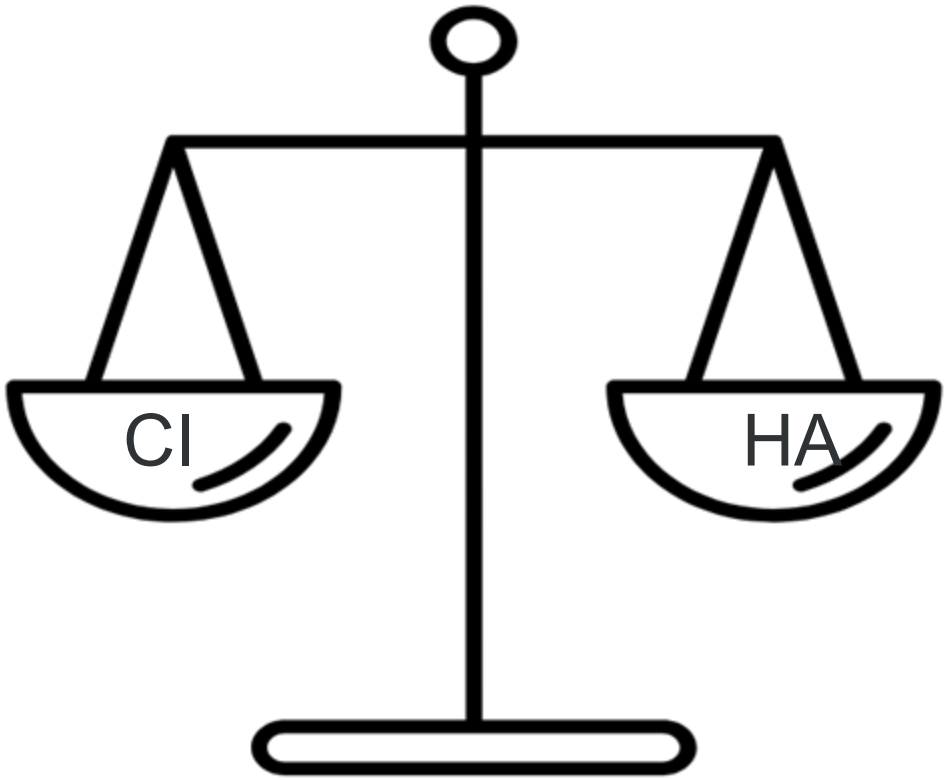

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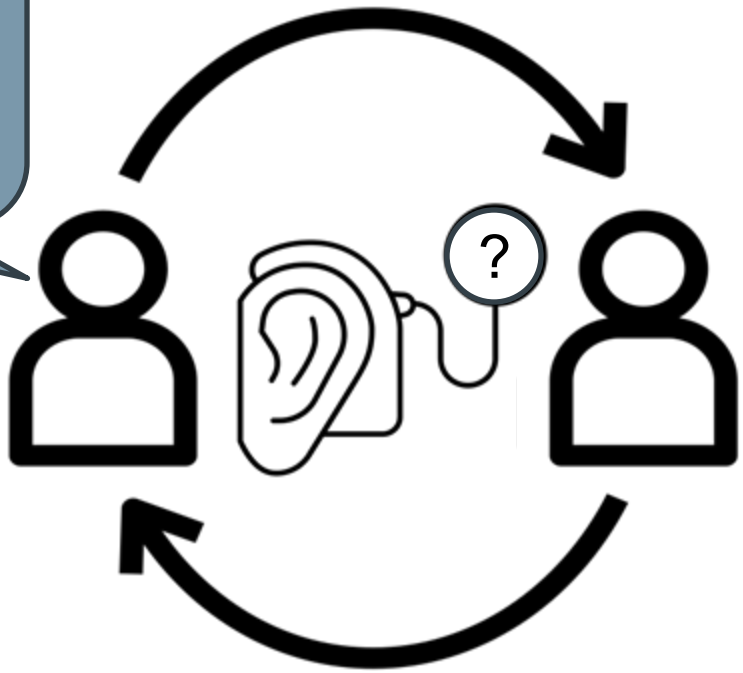
Patient:
How will I perform with a cochlear implant?



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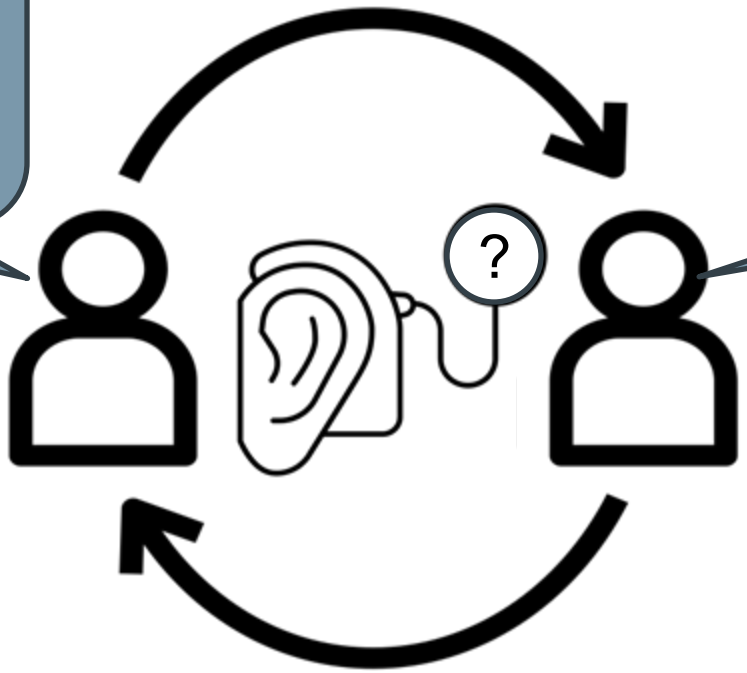
Prentiss et al. JAMA-oto. 2019
Zeitler DM et al. Laryngoscope 2024
Fabie JE et al. Ear Hear under rev

Patient:
How will I perform with a cochlear implant?

Clinicians:
Does the patient have realistic outcome expectations?



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Prentiss et al. JAMA-Oto. 2019
Zeitler DM et al. Laryngoscope 2024
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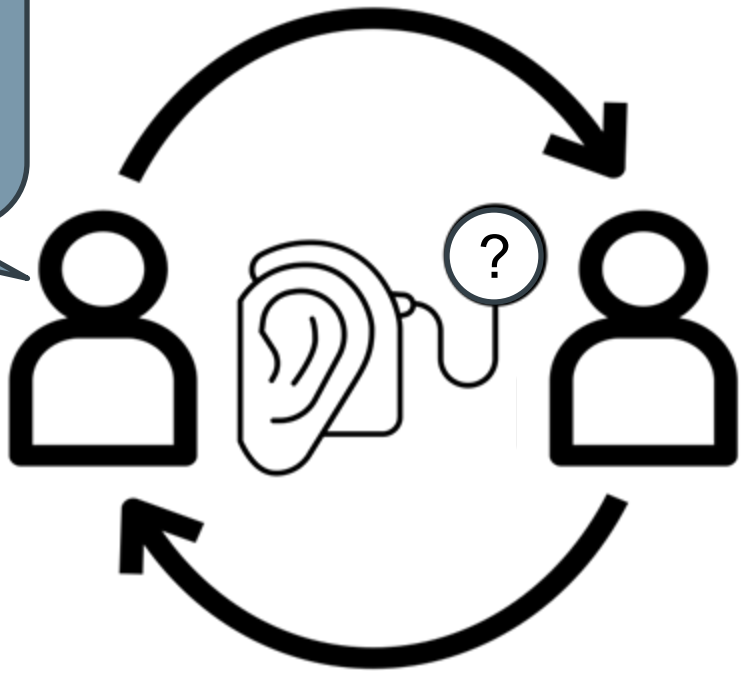

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Prentiss et al. JAMA-oto. 2019
Zeitler DM et a. Laryngoscope 2024
Sturm JJ et al Laryngoscope 2023
Illg A Cochlear Implants Intl 2021

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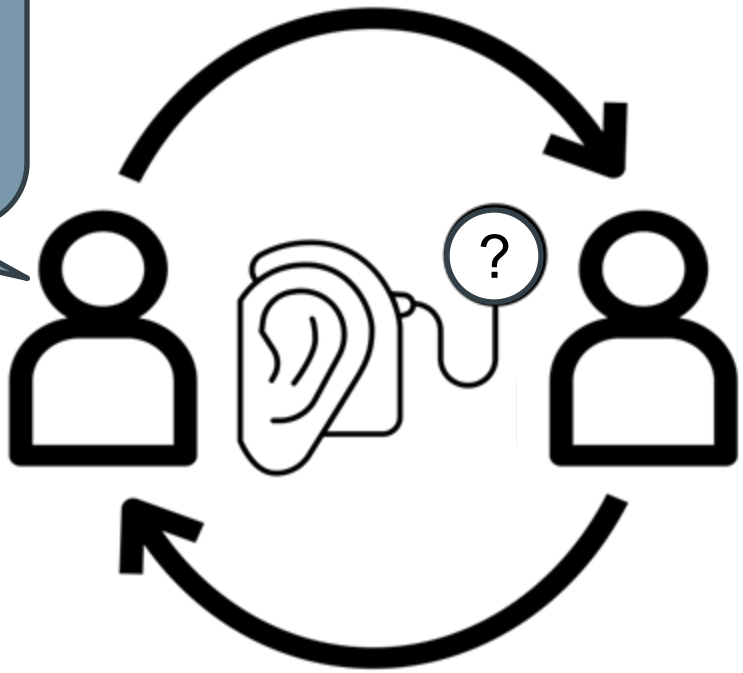

Current Standard

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Zeitler DM et a. Laryngoscope 2024
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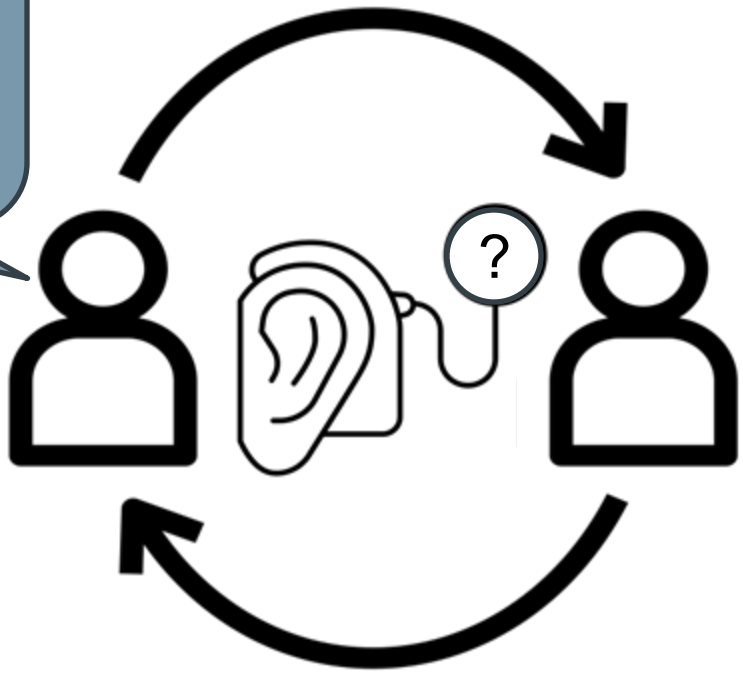

Current Standard

- ~1/3 potential CI users report significant reservations
- ~20-36% of CI candidates do not proceed with CI

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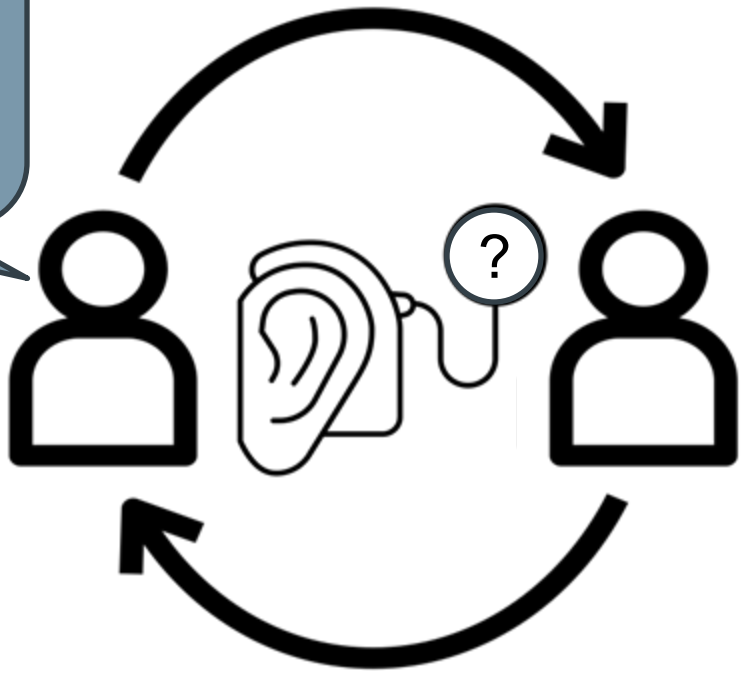
Prentiss et al. JAMA-oto. 2019
Zeitler DM et al. Laryngoscope 2024
Sturm JJ et al. Laryngoscope 2023
Illg A Cochlear Implants Intl 2021
Bierbaum ett al. Ear Hear 2019
Redmann et al Laryngo Invest Oto 2021

Patient:
How will I perform with a cochlear implant?



Current Standard

- Lack of understanding of CI outcomes is most common reason for CI candidates to forgo CI (85%)

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Prentiss et al. JAMA-oto. 2019
Zeitler DM et a. Laryngoscope 2024
Sturm JJ et al Laryngoscope 2023
Illg A Cochlear Implants Intl 2021

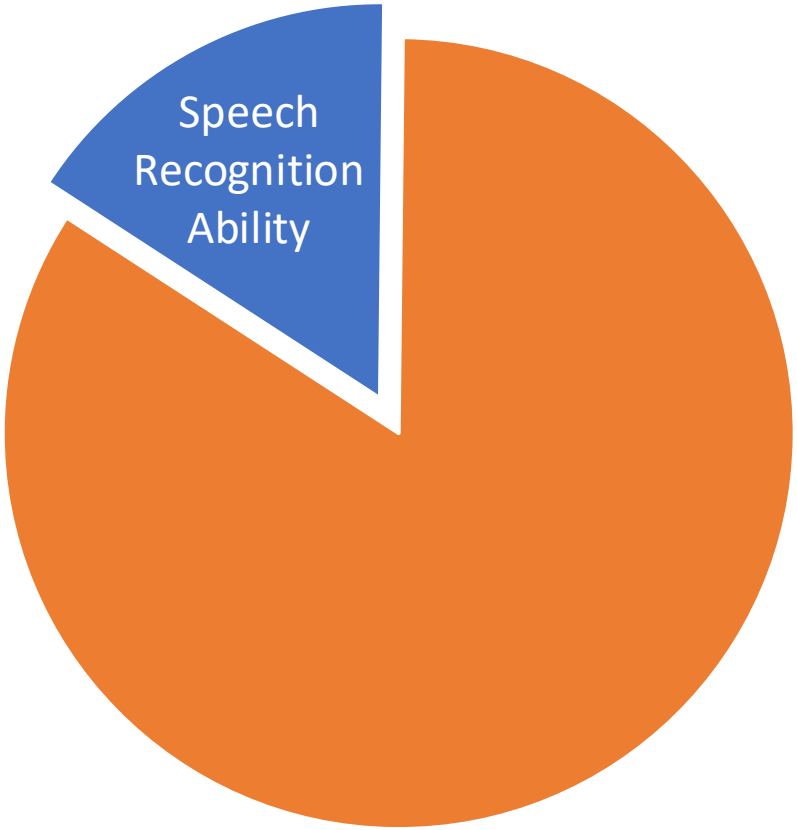
Cochlear implant standard outcome measure

	Pre-op (SD)	12mo post-CI(SD)
Words in quiet	12.8% (±15.8)	59.5% (±22.2)
Sentences in quiet	20.2% (±20.3)	79.6% (±23.8)
Sentences in noise	21.6% (±19.2)	57.5% (±25.1)

Ma, Cheng, et al. Laryngoscope. 2021

Cochlear implant standard outcome measure

≠



- Speech recognition ability only accounts for 4-16% of variance in patient self-reported communication ability
- Even lower in multivariable regression models (β=0.0 (0.0-0.1))

Olze H, et al. Laryngoscope. 2012
Calvino M, et al. Eur Arch Oto. 2016
Capretta NR, Moberly AC*. Laryngoscope.2016
McRackan TR, et al. Ear and Hearing. 2021
McRackan TR, et al. Laryngoscope. 2018
McRackan TR, et al. Otol Neurotol. 2018

Current Standard

Ignores

- Social engagement
- Emotional state
- Listening effort

Hughes S. et al. Ear Hear. 2018
Stika CJ, Hays RD. Int J Audiol. 2015
McRackan TR, et al. JAMA-Oto. 2017
Damen GW, et al. Oto-HNS. 2007
Knutson JF, et al. Ear Hear. 1998.

Cochlear Implant QOL (CIQOL) Instruments

- Developed using rigorous development standards
- **No previous patient-reported outcome measure (PROM) has been validated in CI users that meets current standards**

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Qualitative + Quantitative

Mixed methods research design
development and validation

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Qualitative + Quantitative

- CI user focus groups
- Cognitive interview

Mixed methods research design development and validation

Outcomes are reported within a meaningful patient-centered framework

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Qualitative + Quantitative

Mixed methods research design development and validation

- CI user focus groups
- Cognitive interview

Outcomes are reported within a meaningful patient-centered framework

- Confirmatory factor analysis
- Item response theory

Provide scores that are interval in nature

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Cochlear Implant Quality of Life-35 Profile

ID:_____ Date:_____

INSTRUCTIONS: Think about your daily life with your cochlear implant (and/or hearing aid, if you also use one). Answer how often each of the following statements applies to your feelings and experiences. Answer how often each statement applies even if you don't use cochlear implants or hearing aids.

	Never	Rarely	Sometimes	Often	Always
1. I am able to have a conversation in a quiet place without asking the other person to repeat themselves					
2. Other people's voices sound clear and natural to me					
3. I am able to have a conversation with a group of three or more people					
4. I am able to have a conversation without asking the other person to repeat themselves					
5. I can hear and understand without looking at the person speaking					
6. I have to ask a lot of questions about what is being said in a conversation					
7. I can understand a conversation in a crowded environment (restaurant, party, etc.)					
8. I am able to have a conversation with someone in a noisy place without asking them to repeat themselves					
9. I can understand strangers without lip-reading in a noisy place					
10. I can follow the conversation in a group of five people in a crowded restaurant when I cannot see everyone					
11. I feel comfortable being myself					
12. My hearing loss makes me feel inadequate					
13. My hearing loss makes me irritable					
14. I keep quiet in a conversation to avoid saying the wrong thing					
15. I become frustrated when I cannot follow a conversation					
16. My hearing loss prevents me from listening to TV or radio					
17. I am able to enjoy listening to the radio and TV					
18. I am able to enjoy music					
19. I can recognize certain melodies in music					
20. Music sounds clear and natural to me					
21. Everyday sounds (birds chirping, rain, car horns, etc.) are clear to me					
22. Everyday sounds (microwave, birds chirping, rain, car horn) sound natural to me					
23. I am able to distinguish sounds in nature					
24. I am able to hear cars approaching in traffic					
25. I can hear someone approaching from behind					
26. I am able to follow a conversation with minimal effort					
27. I am able to ignore competing sounds and focus on the person who is speaking					
28. I can easily have a conversation in a noisy place (restaurant, party, store)					
29. I have to concentrate when having a conversation					
30. I have to concentrate when having a conversation with strangers when in a noisy place					
31. If I am interested, I will join family or friends for a social event					
32. I have the confidence to socialize					
33. I avoid socializing with friends, relatives, or neighbors due to my hearing loss					
34. I avoid social situations due to my hearing loss					
35. I feel left out when I am with a group of people due to my hearing loss					

Communication

Emotional

Entertainment

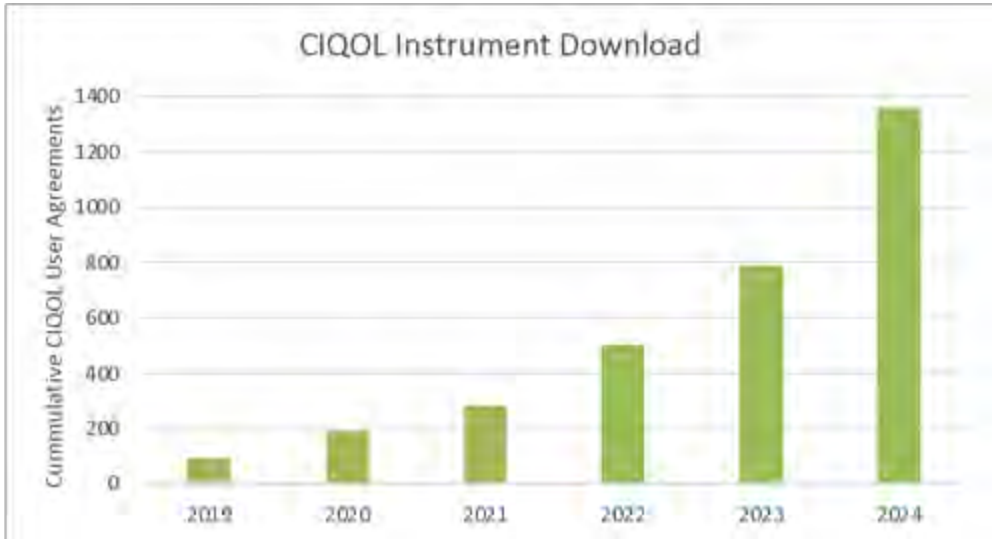
Environment

Listening Effort

Social

Qualitative + Quantitative

CIQOL Instruments

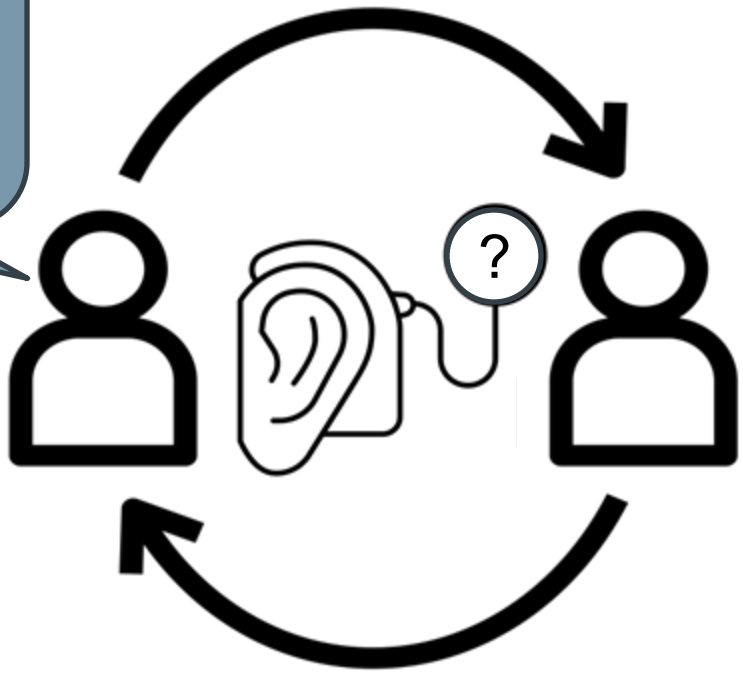


- >1300 user agreements
- Has undergone cross-cultural adaptation and translation into 9 languages
  - 4 additional languages in process
- Included in French national CI registry
- Included in Minimal Speech Test Battery V3

https://education.musc.edu/ciqol

McRackan TR, et al. Ear Hear. 2021
Laplante-Lévesque A et al. Front Neurosci. 2021

Patient:
How will I perform with a cochlear implant?



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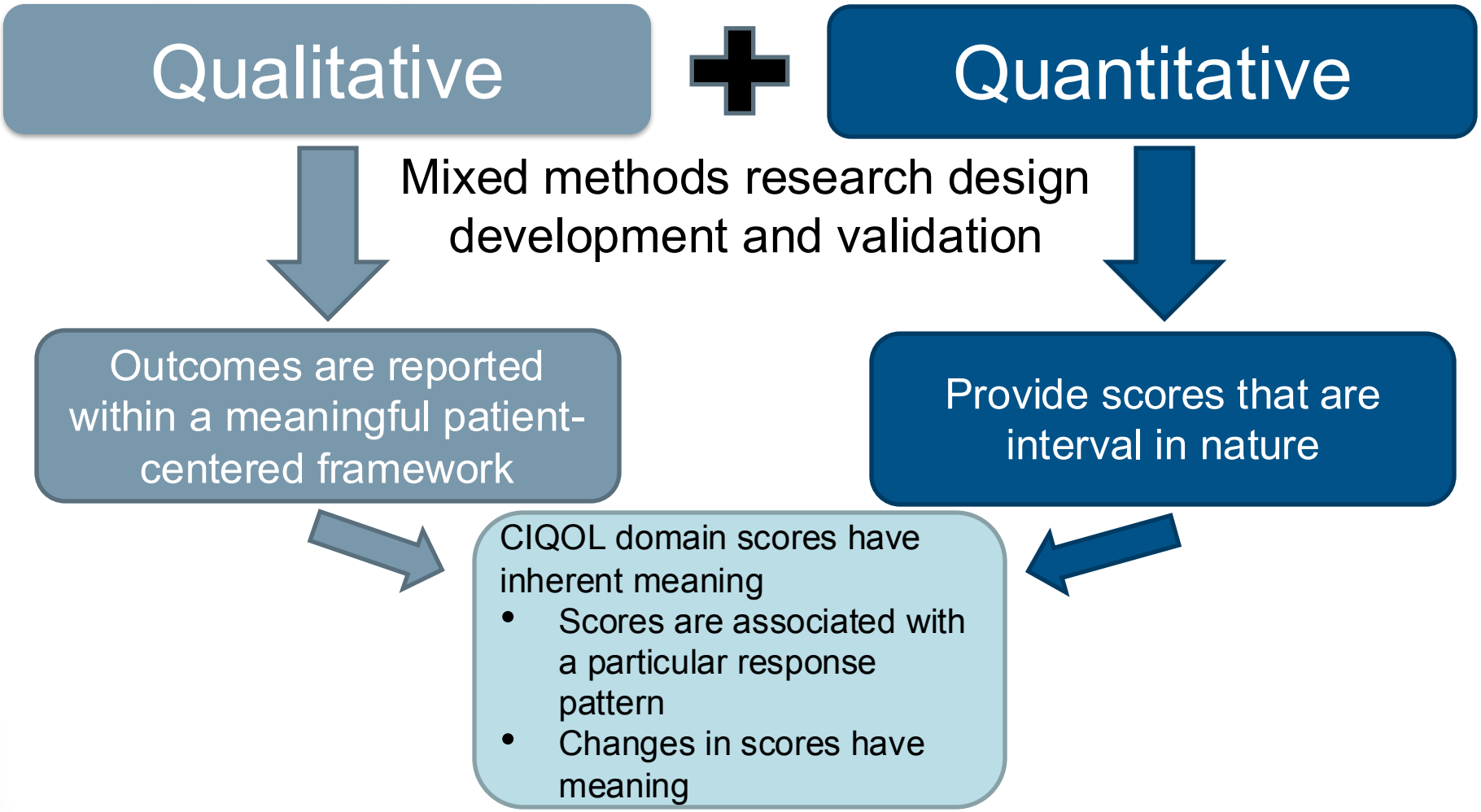
Prentiss et al. JAMA-oto. 2019
Zeitler DM et al. Laryngoscope 2024
Fabie JE et al. Ear Hear under rev



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Functional Staging Systems

- Enhance the interpretability of PROM scores
  - Provide detailed descriptions of patient-reported abilities via clinical vignettes
  - Maintain psychometrically derived (item response theory; IRT) hierarchy of quantitative scores

- Used in other health care settings

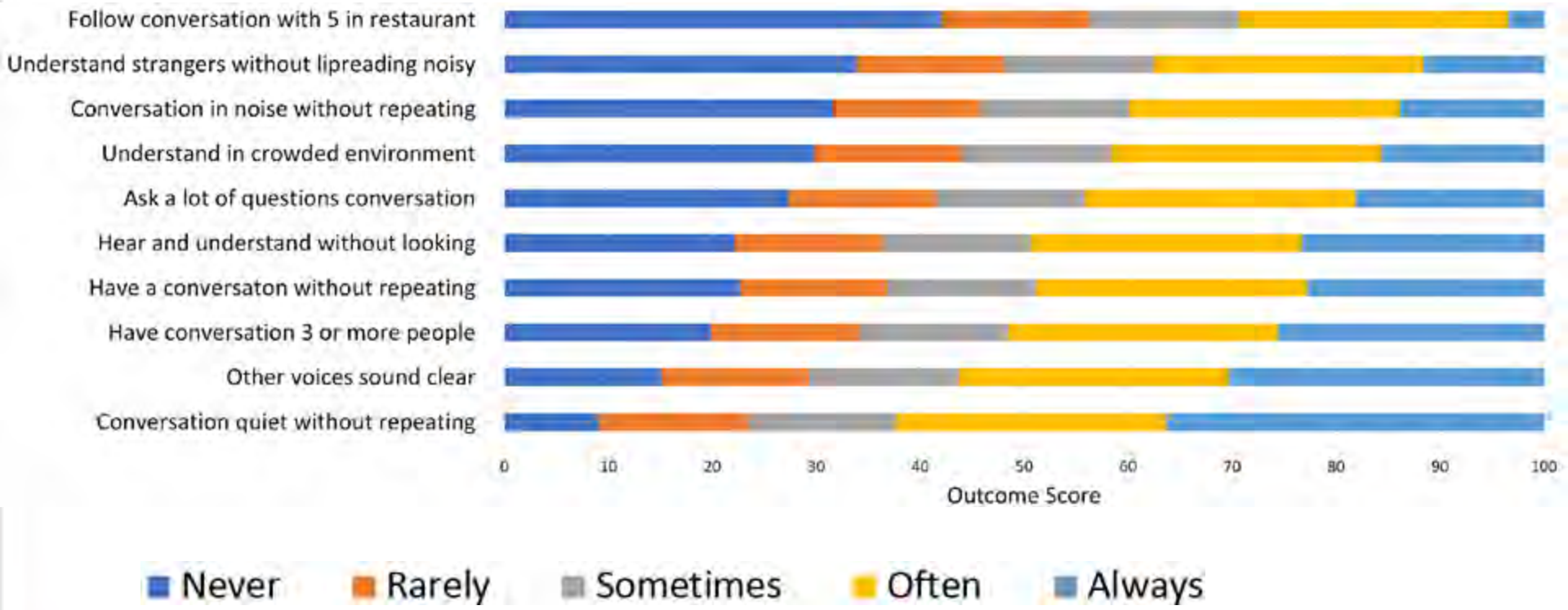
Tao W, et al. Arch Phys Med Rehabil 2008
Stineman MG, et al. Arch Phys Med Rehabil 2003
Jette AM, et al. J Rehab Med 2007

CIQOL-Communication example

- n=705 adult CI users from 30 centers (≥12-month CI experience)
- Item response theory analyses used to:
  - Determine number of functional stages for each domain
  - Determine abilities associated with domain outcome score (0-100)

McRackan et al. Laryngoscope 2022

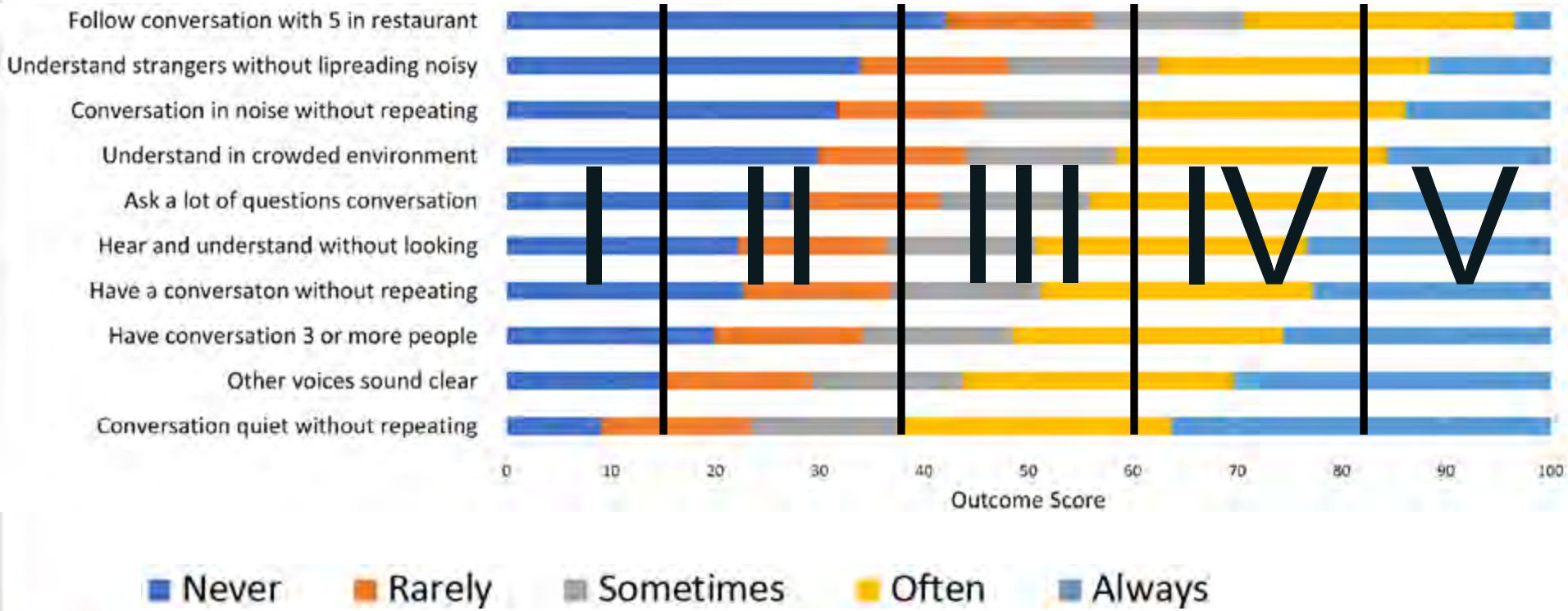
CIQOL-Communication Functional Staging System



McRackan et al. Laryngoscope 2022

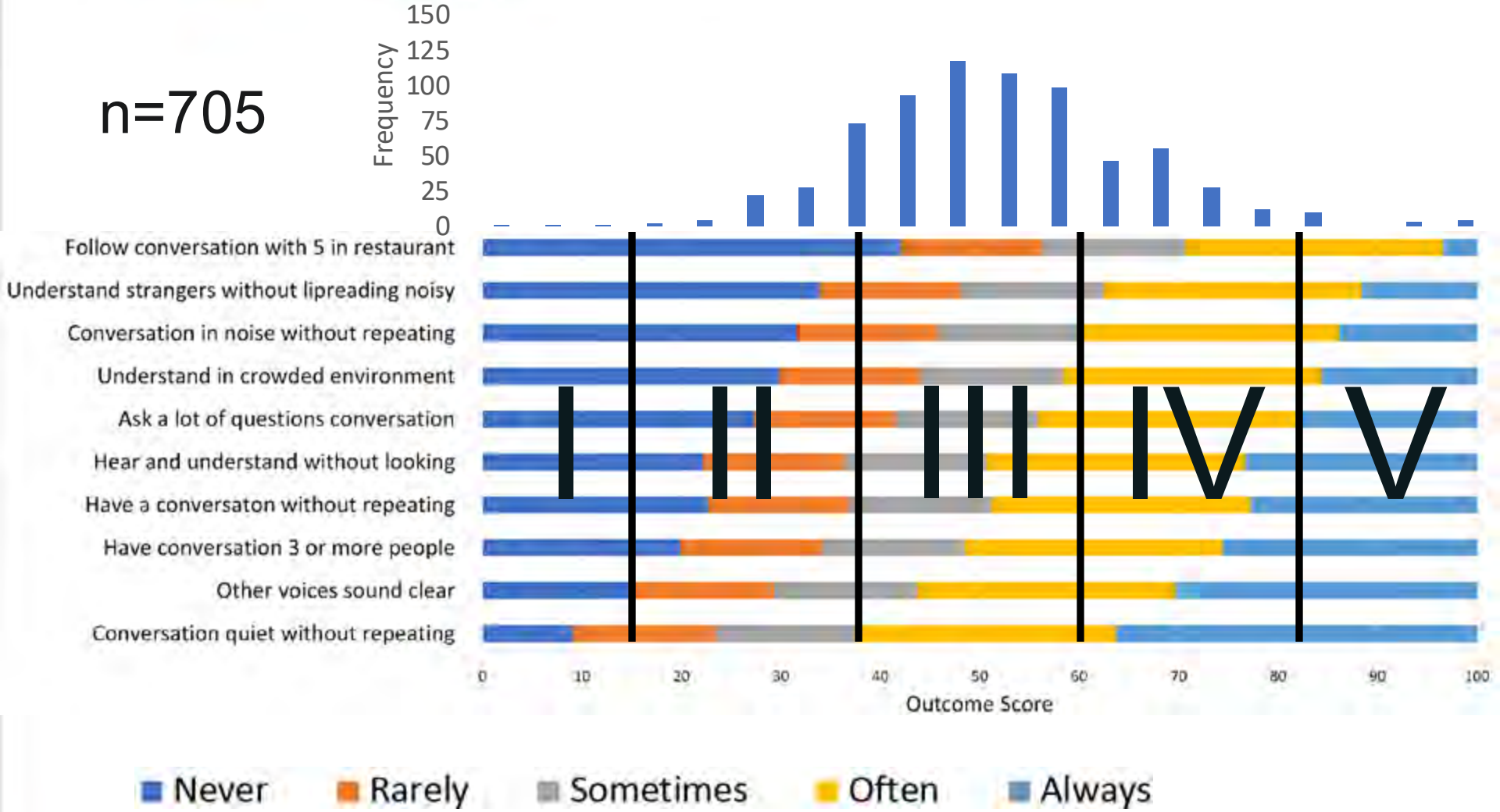
CIQOL-Communication Functional Staging System

- IRT analyses and patient/clinician engagement to identify cut-scores that separate stages
- Develop clinical vignettes



McRackan et al. Laryngoscope 2022

n=705



McRackan et al. Laryngoscope 2022

CIQOL-Communication Functional Staging System

Patient:
How will I perform with a cochlear implant?

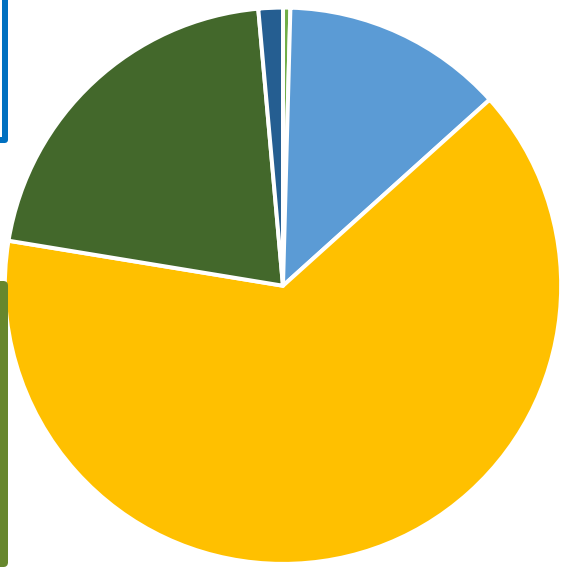
I (0.4%):
- Unable to have a conversation in any listening environment

II (12.9%):
- Can sometimes have a conversation in quiet environments
- Need people to repeat themselves to understand conversation in quiet environments

III (64.3%):
- Sometimes able to have a conversation in small group in quiet
- Has difficulty understanding, even with lip reading, in noisy environments

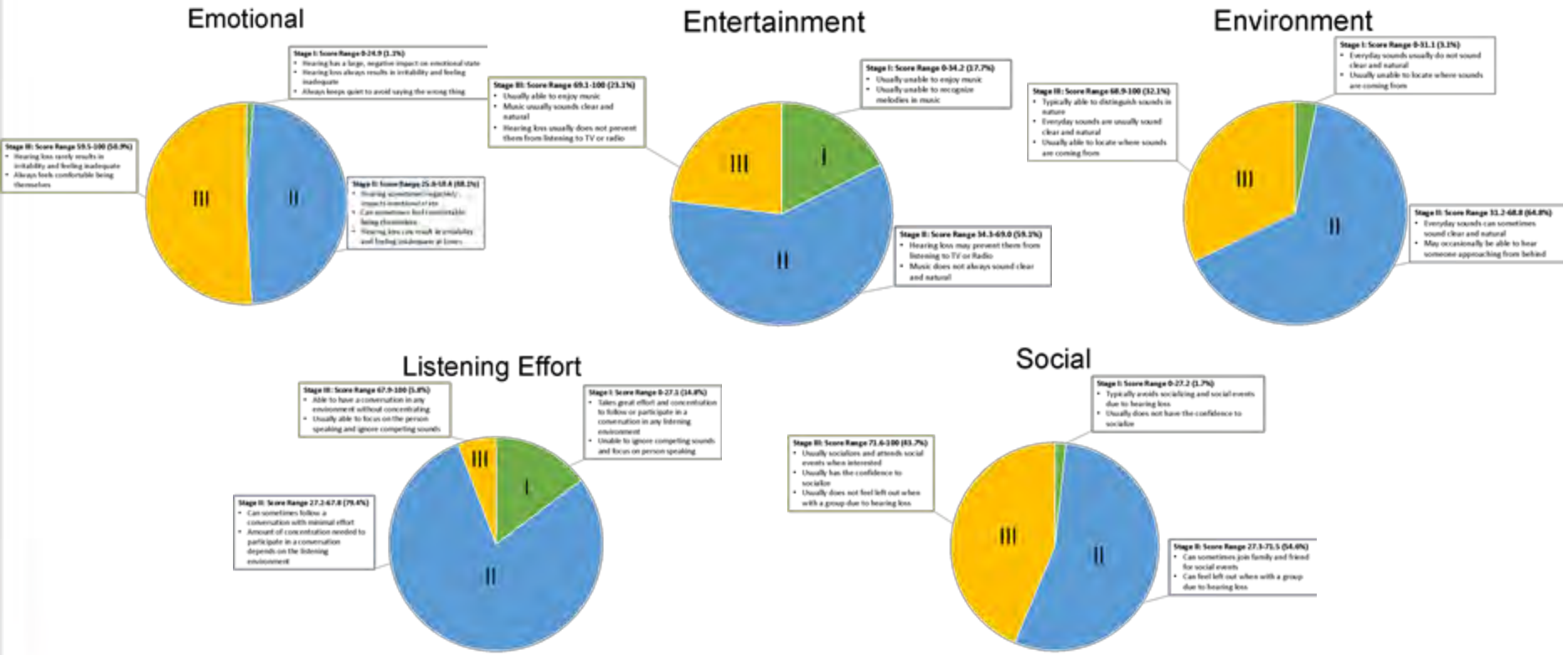
IV (20.0%):
- Able to have a conversation in small groups in quiet
- Can sometimes have a conversation in noisy environments without lip reading

V (1.4%):
- Able to have a conversation in all listening environments with essentially no lip-reading



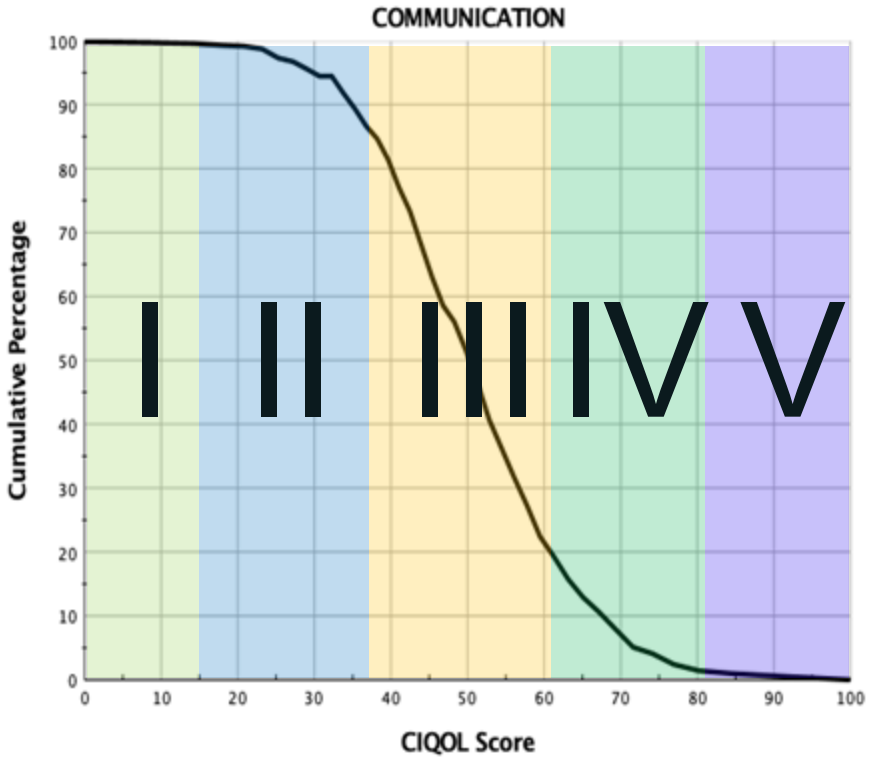
McRackan et al. Laryngoscope 2022

CIQOL Functional Staging System



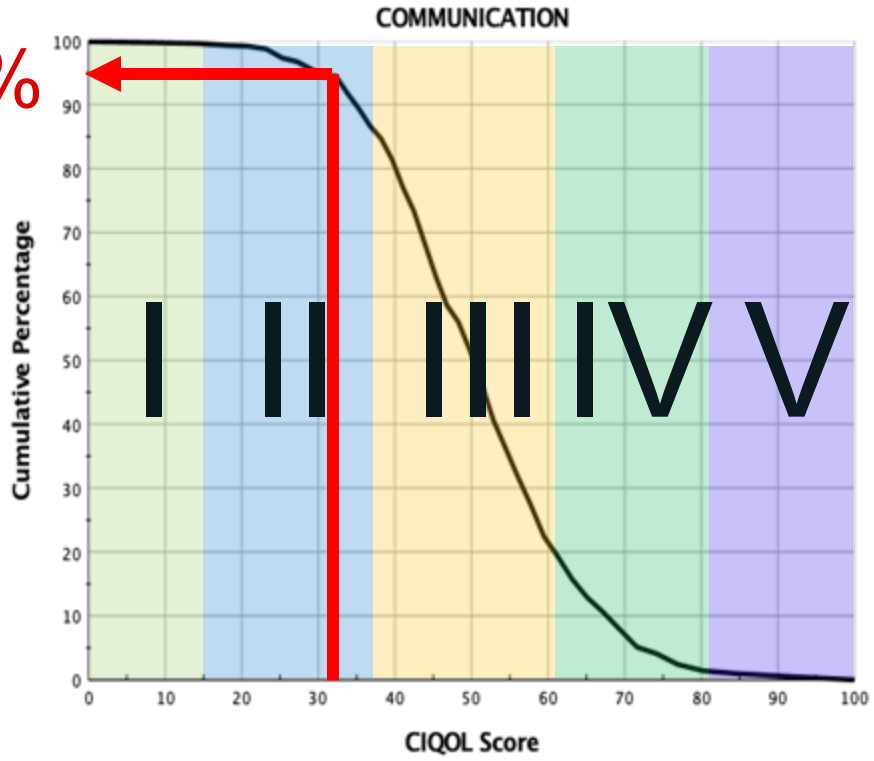
McRackan et al. Laryngoscope 2022

Pre-CI counseling



Pre-CI counseling

Baseline (pre-CI) CIQOL scores



Pre-CI counseling

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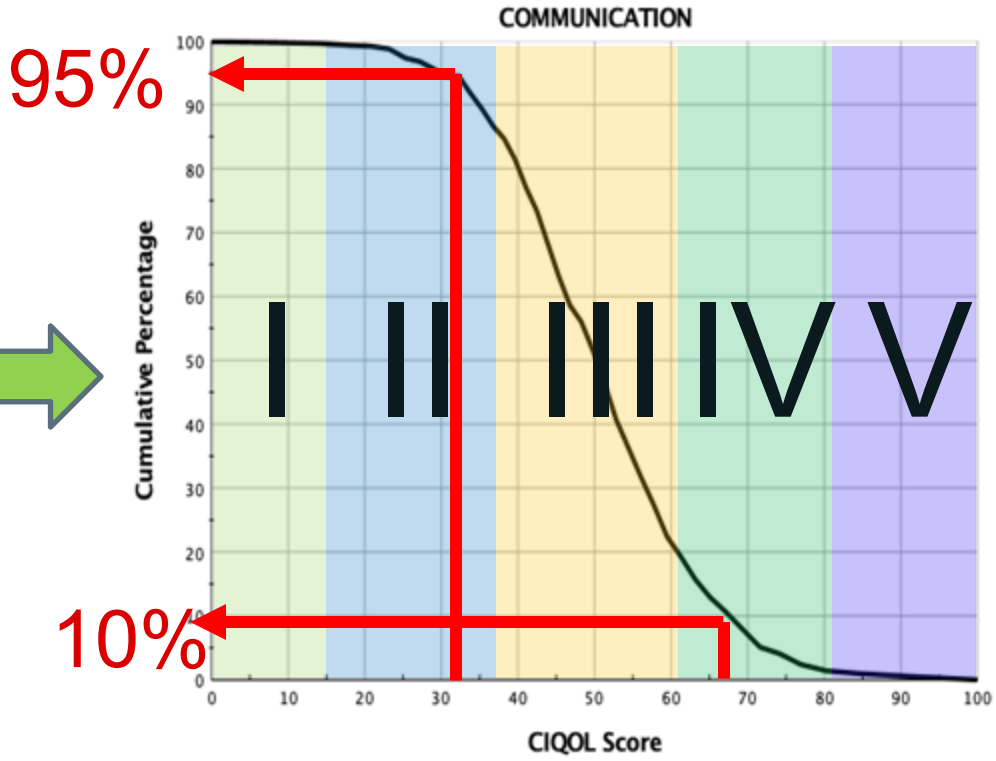
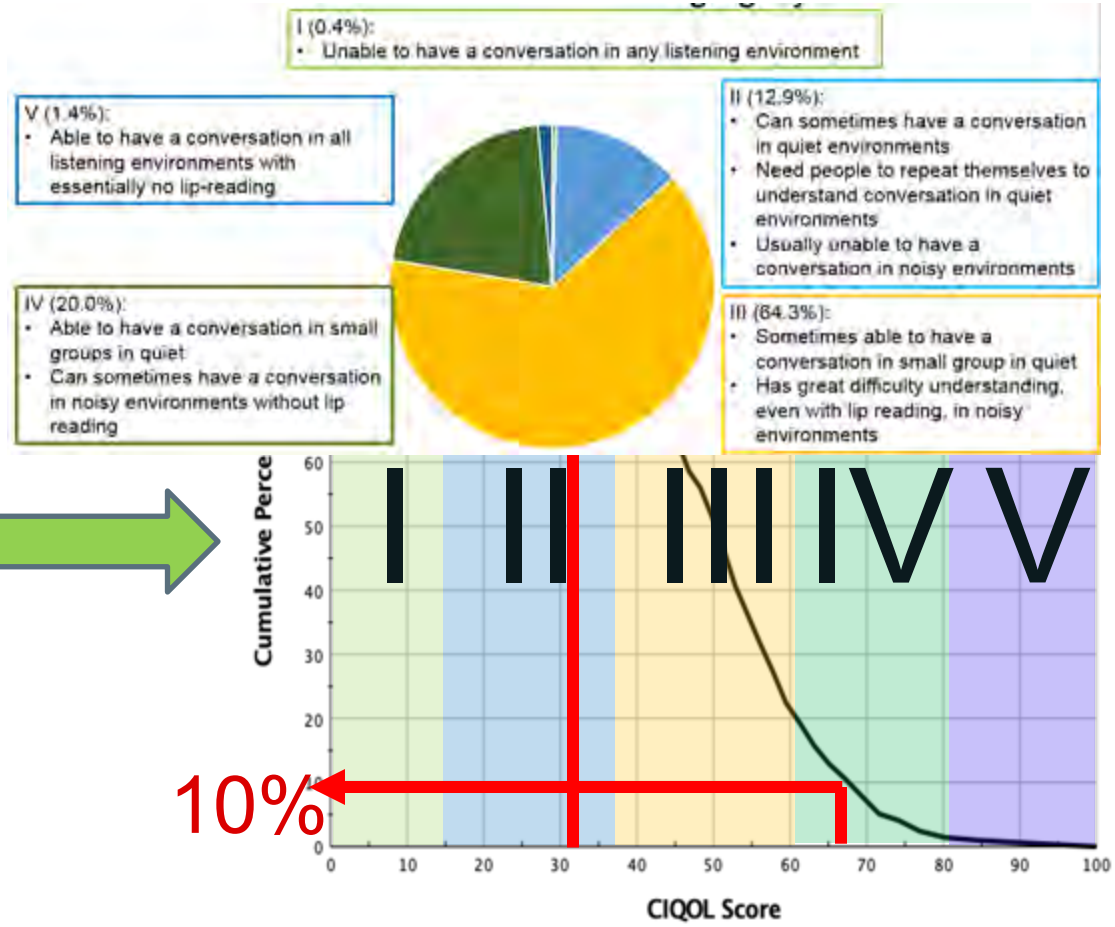


https://education.musc.edu/ciqol

Clinician: Lack of standardized counseling practices

Baseline (pre-CI) CIQOL scores



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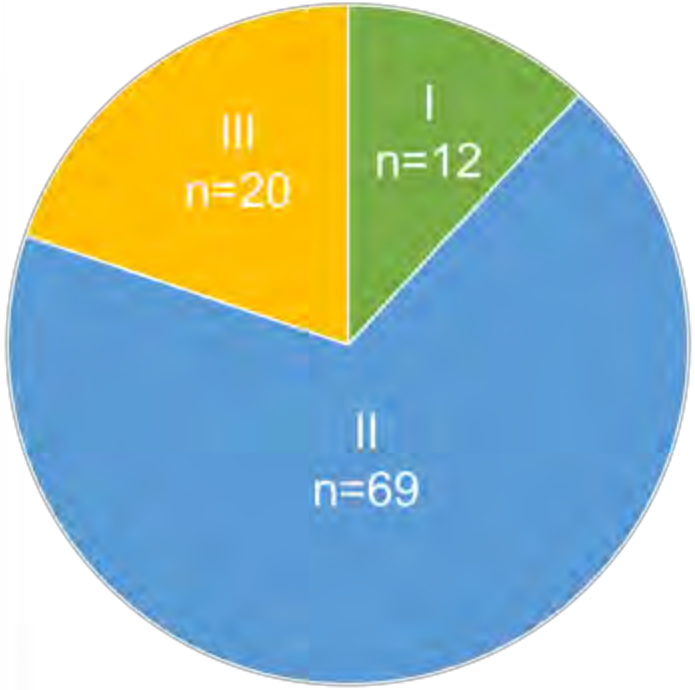
Pre-CI counseling

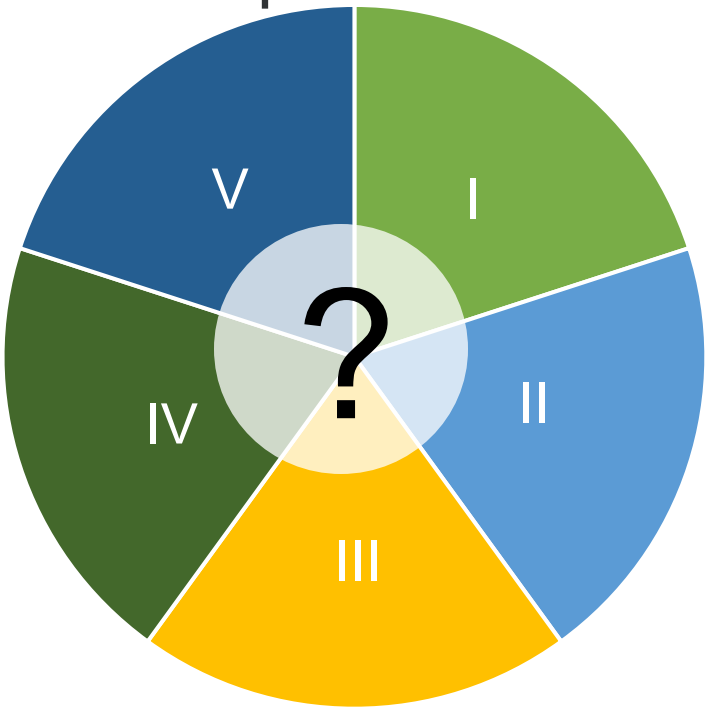
- Can we give more precise patient counseling?

Pre-CI

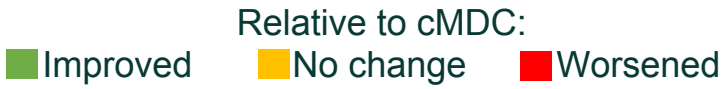


N=101

12-month post CI

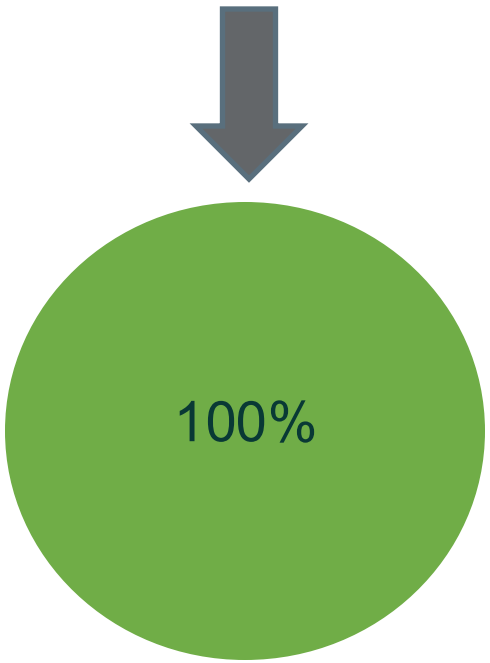


Pre-CI to 12-month Individual Communication Data



Pre-CI to 12-month Individual Communication Data

Pre-CI Stage I

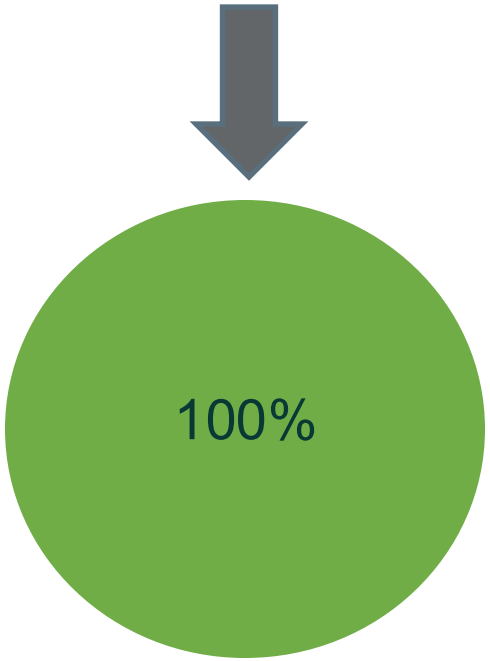


Relative to cMDC:

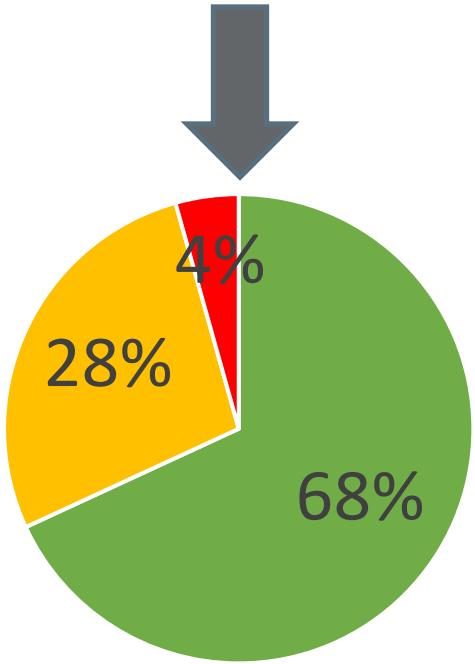
Improved No change Worsened

Pre-CI to 12-month Individual Communication Data

Pre-CI Stage I



Pre-CI Stage II

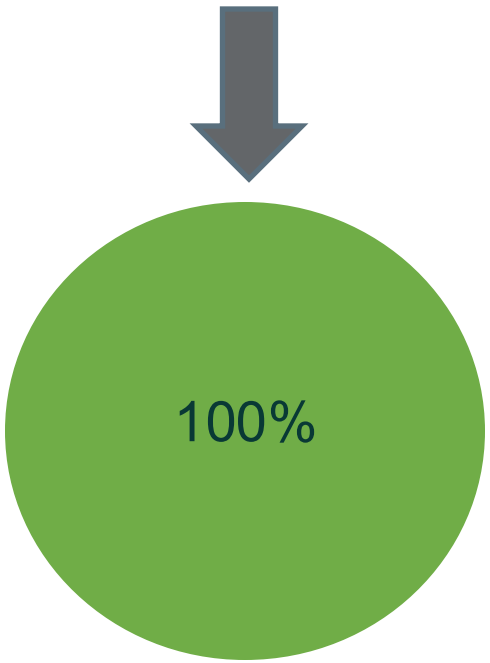


Relative to cMDC:

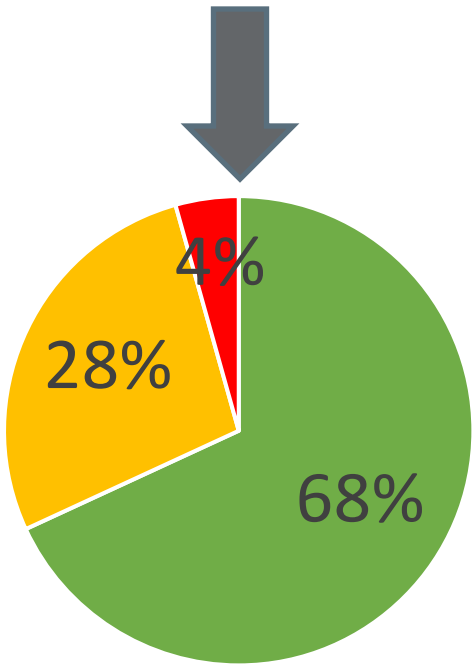
Improved | No change | Worsened

Pre-CI to 12-month Individual Communication Data

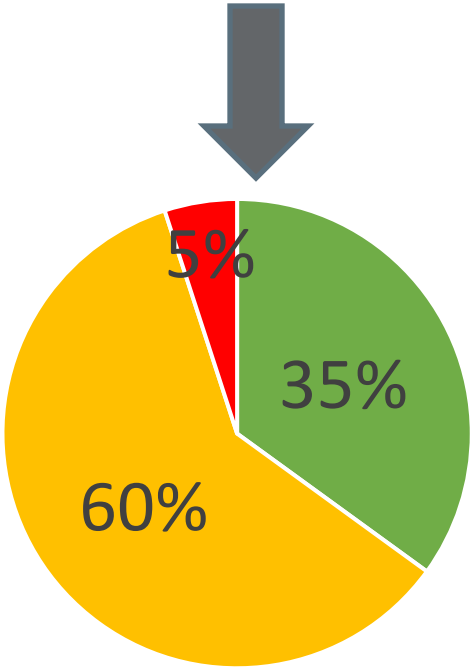
Pre-CI Stage I



Pre-CI Stage II

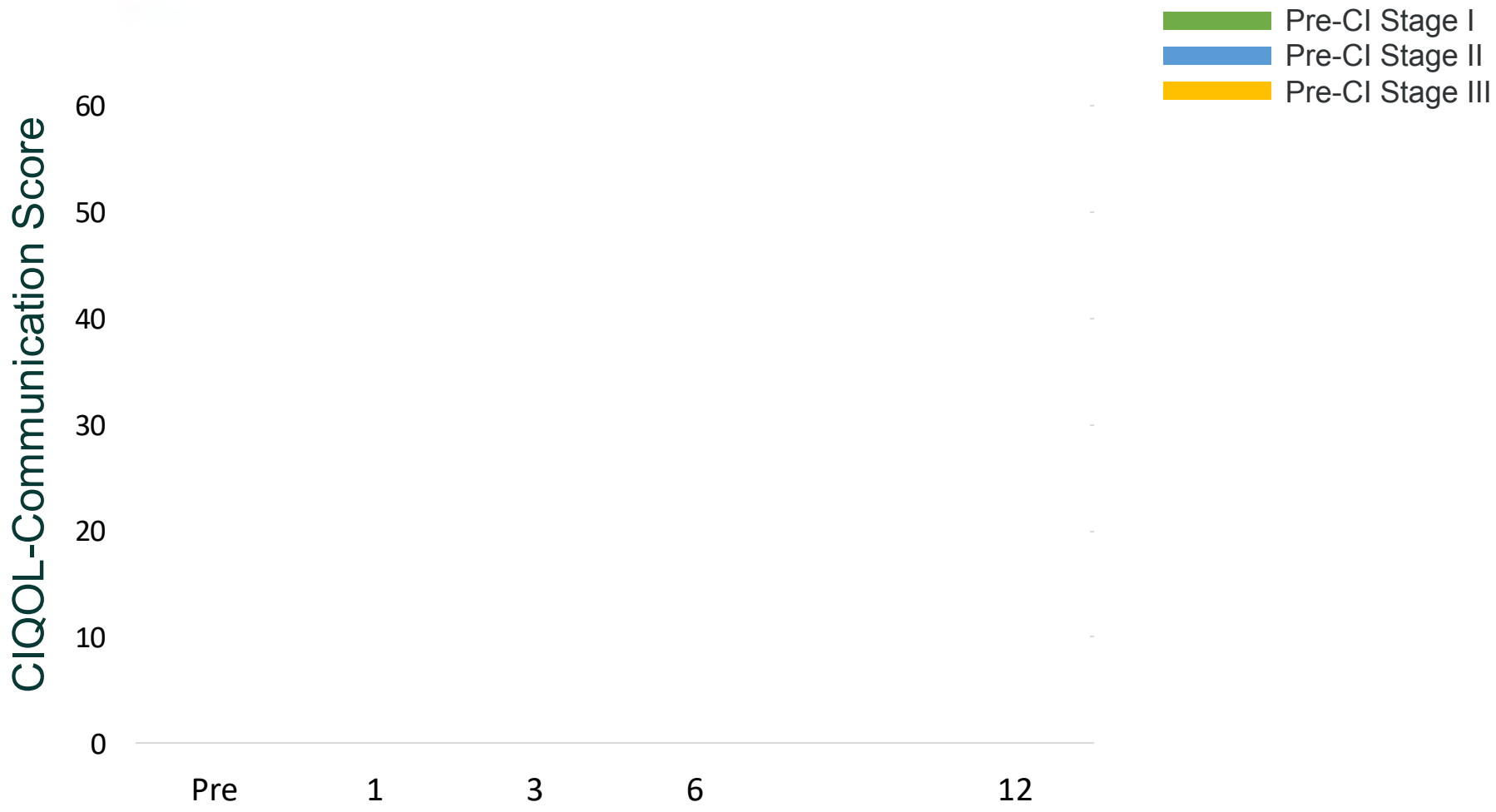


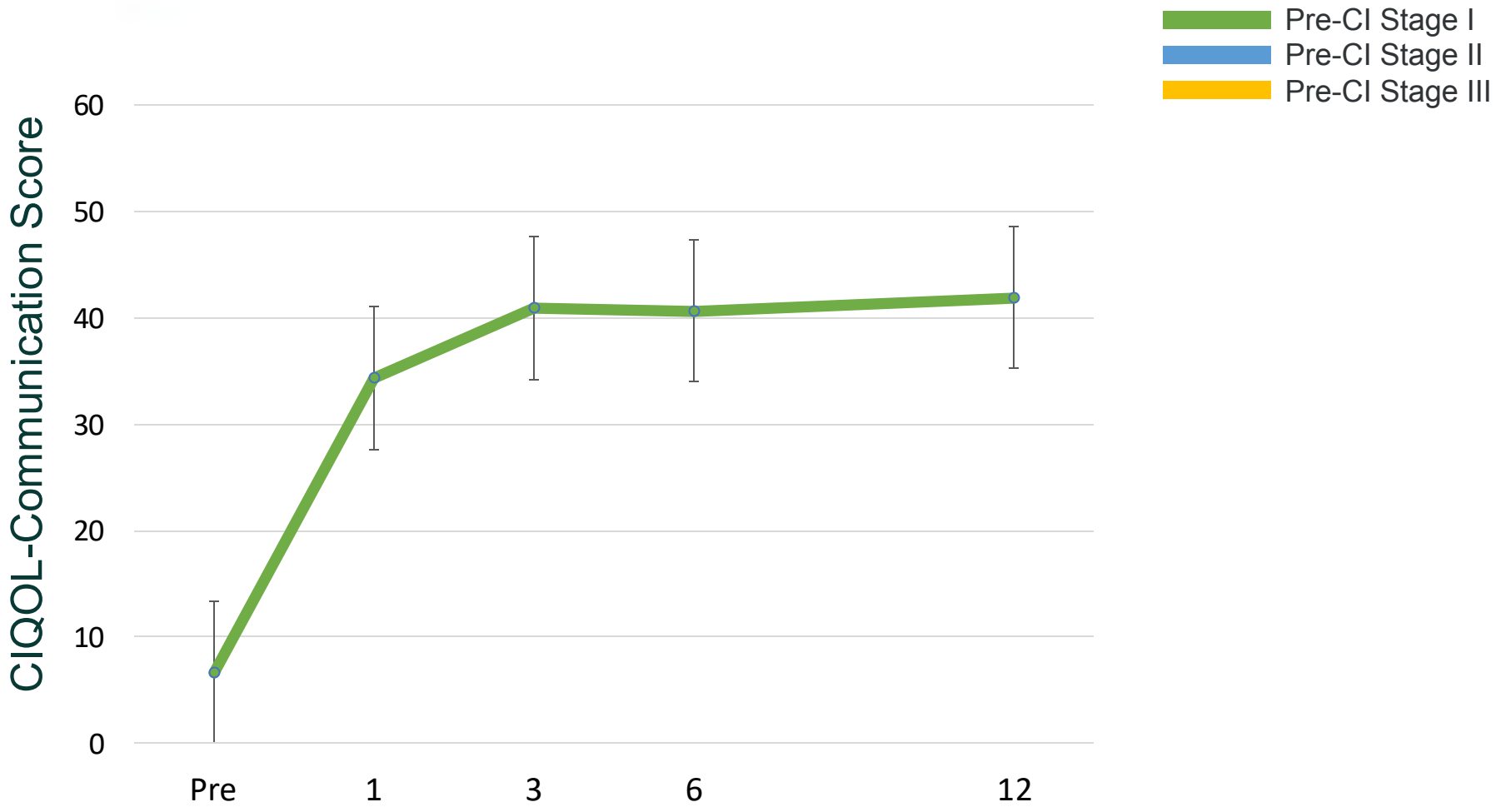
Pre-CI Stage III



Relative to cMDC:

Improved | No change | Worsened


Pre-CI Stage I
Pre-CI Stage II
Pre-CI Stage III
CIQOL-Communication Score
60
50
40
30
20
10
0
Pre
1
3
6
12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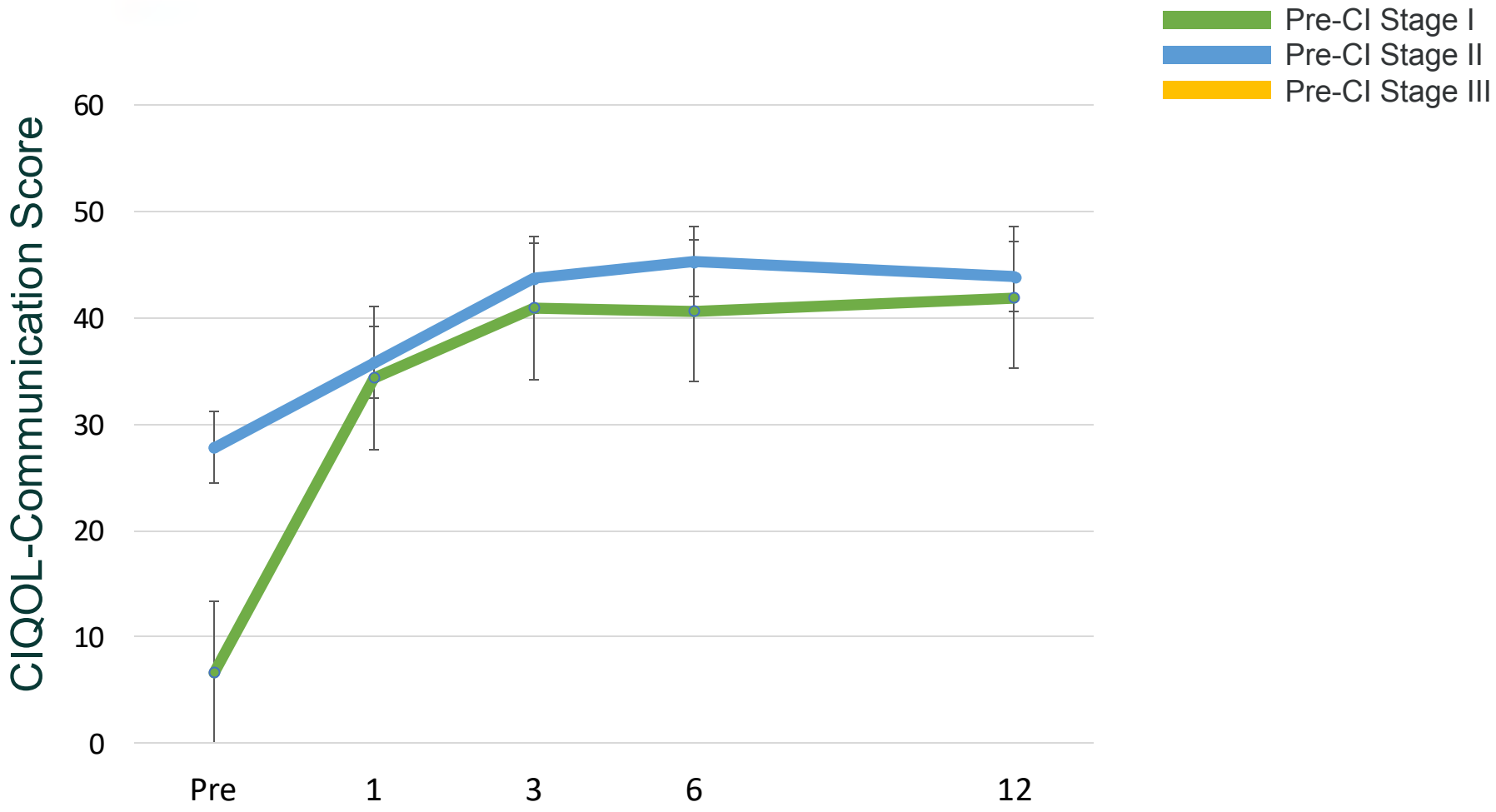
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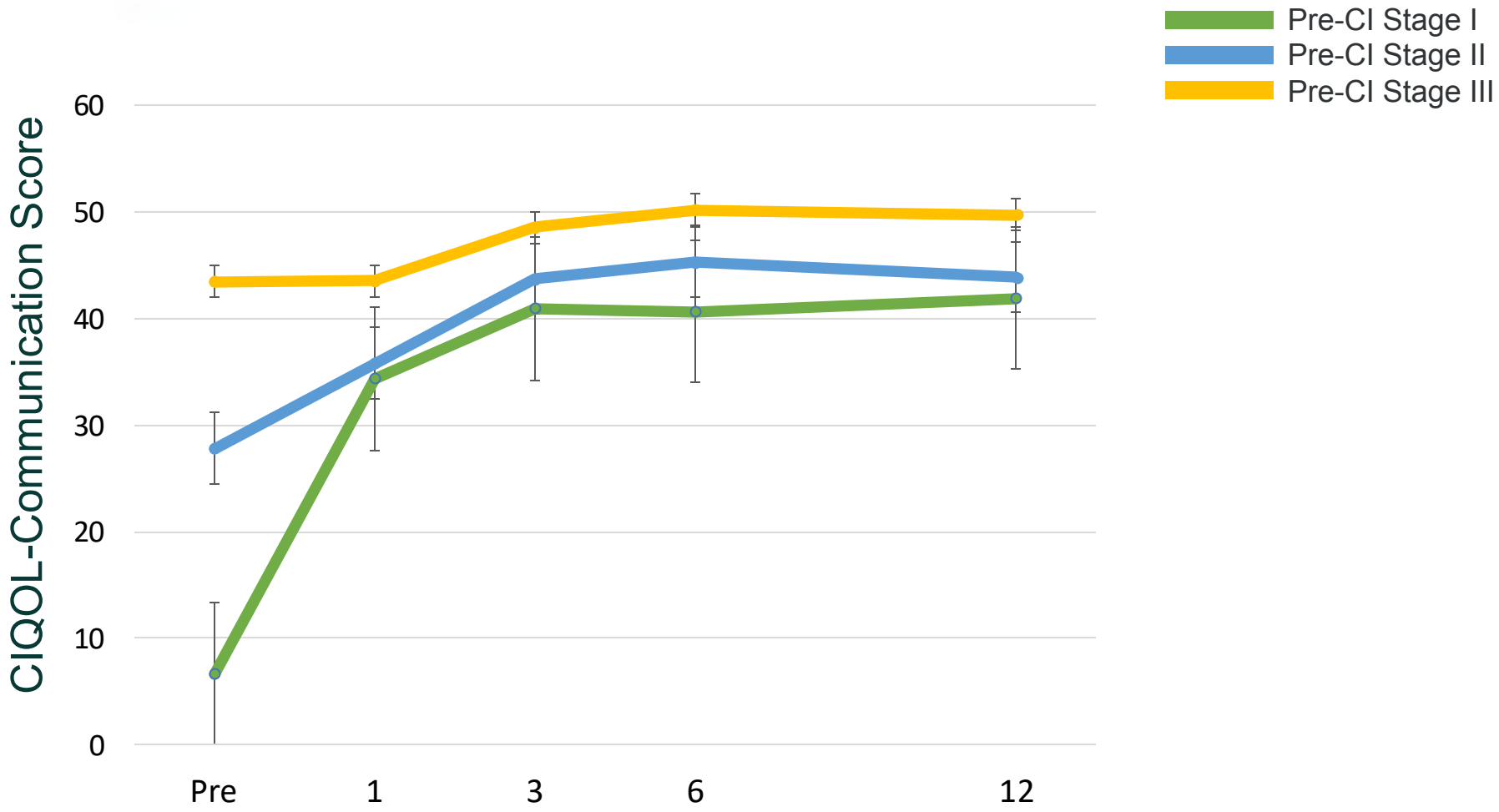
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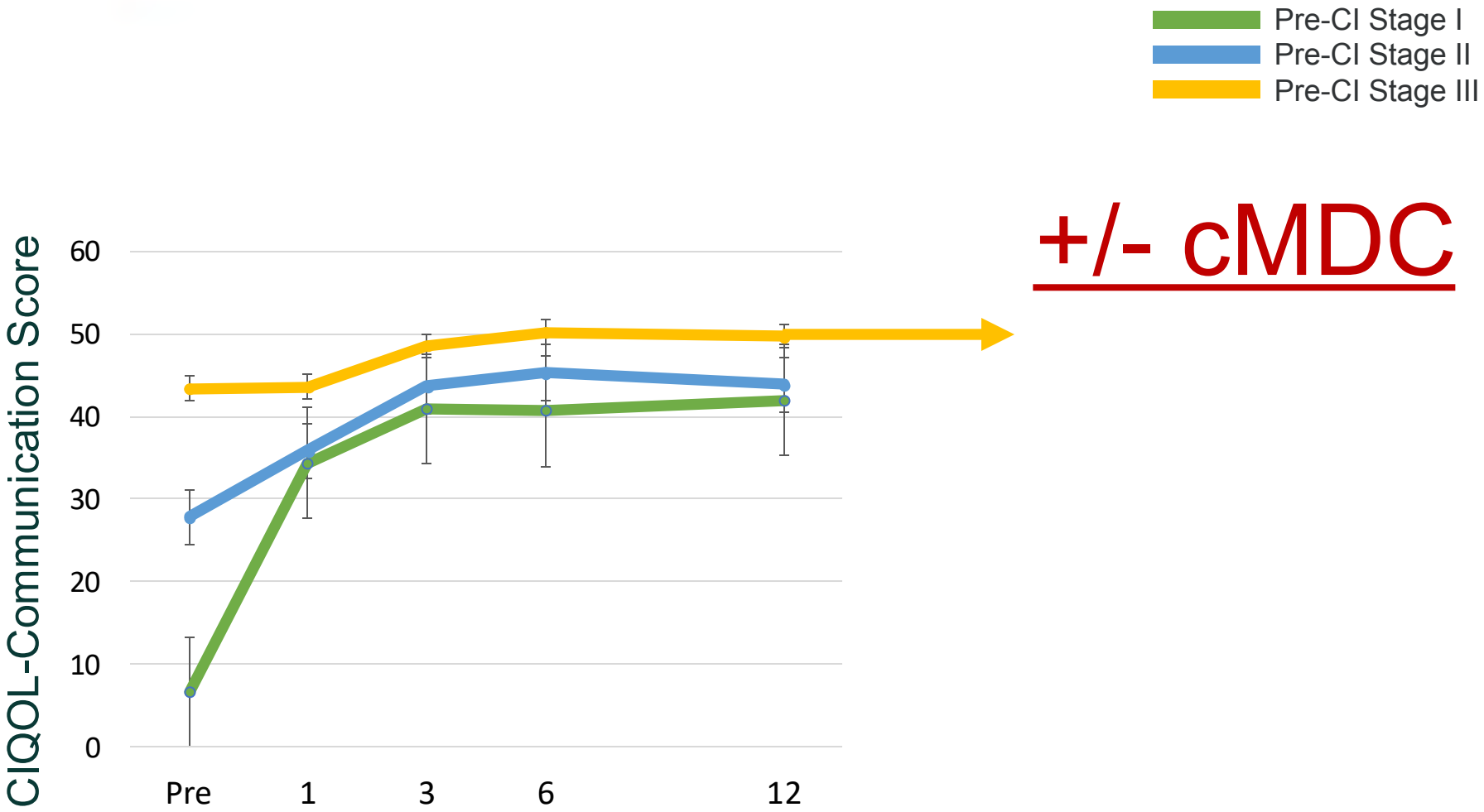
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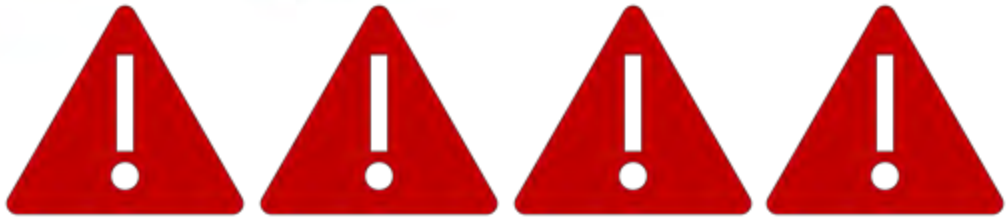
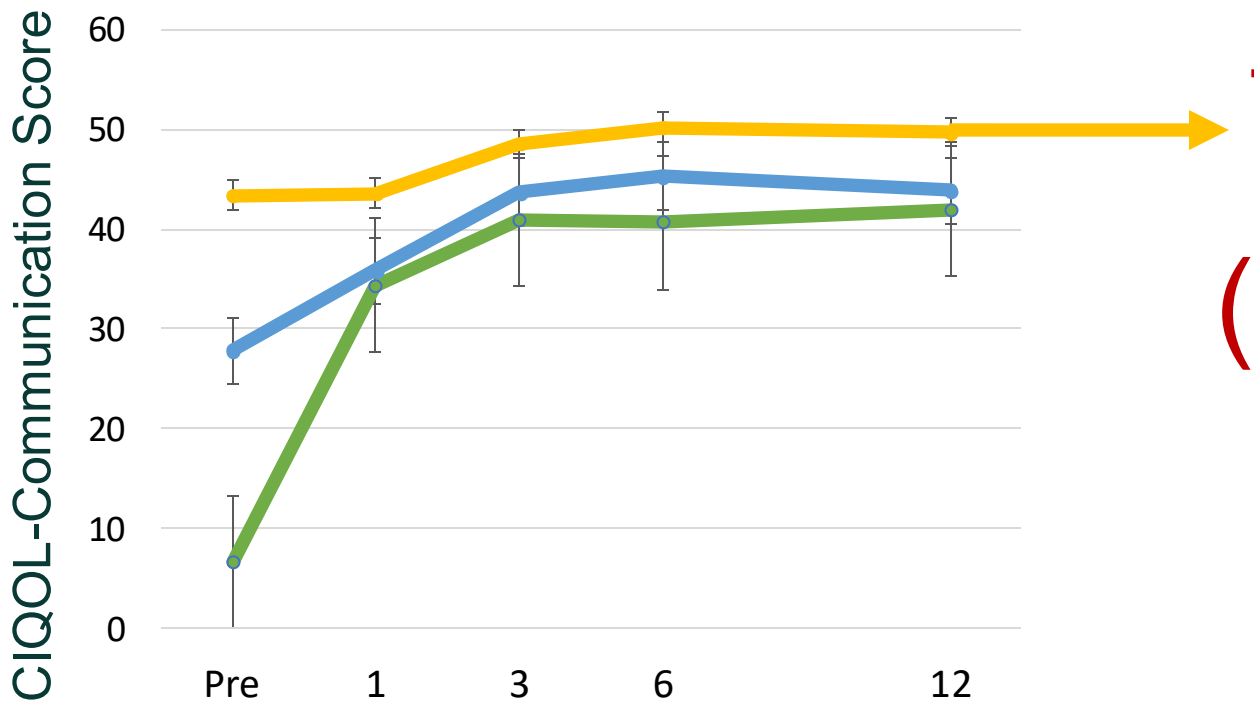
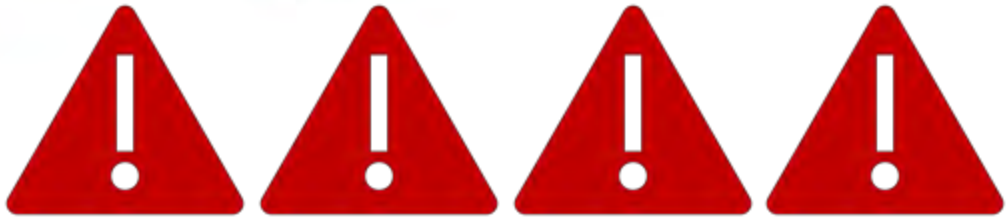
+/- cMDC



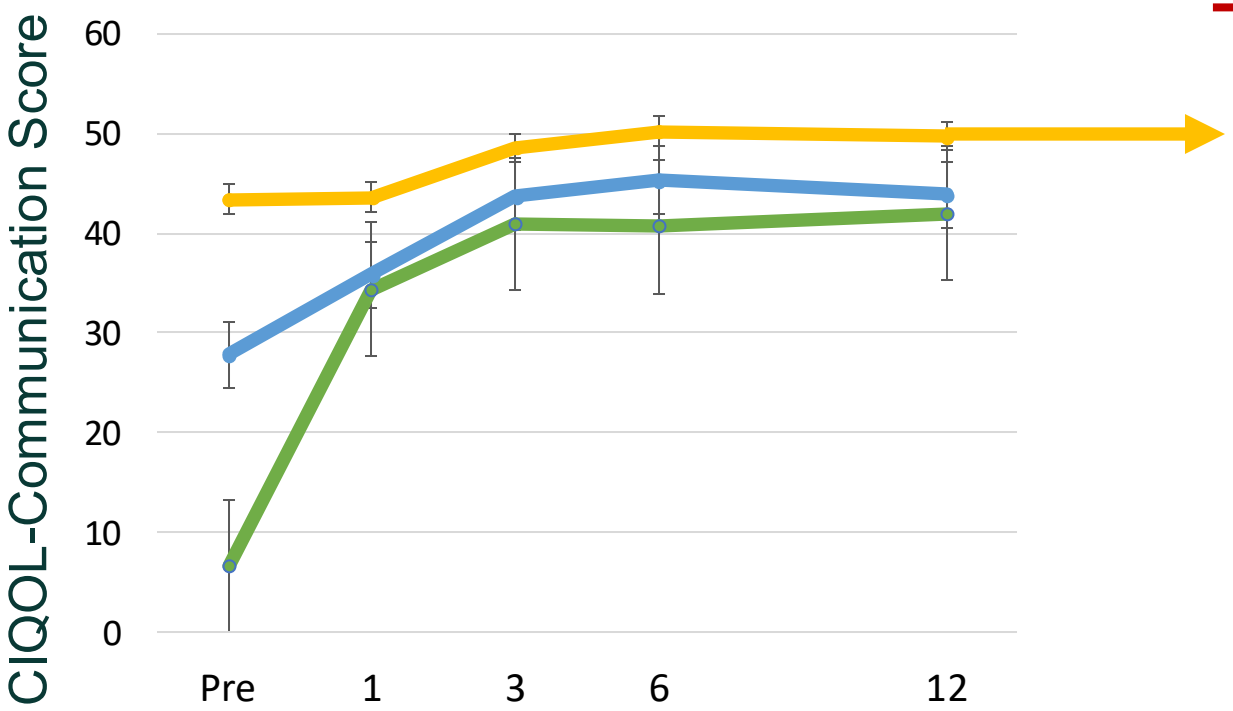


+/- cMDC

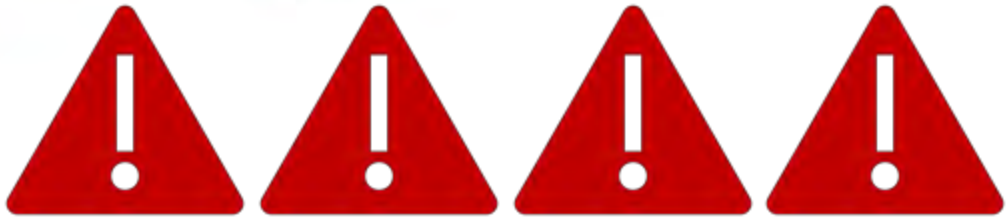
HR: 2.08 (1.13-3.81)

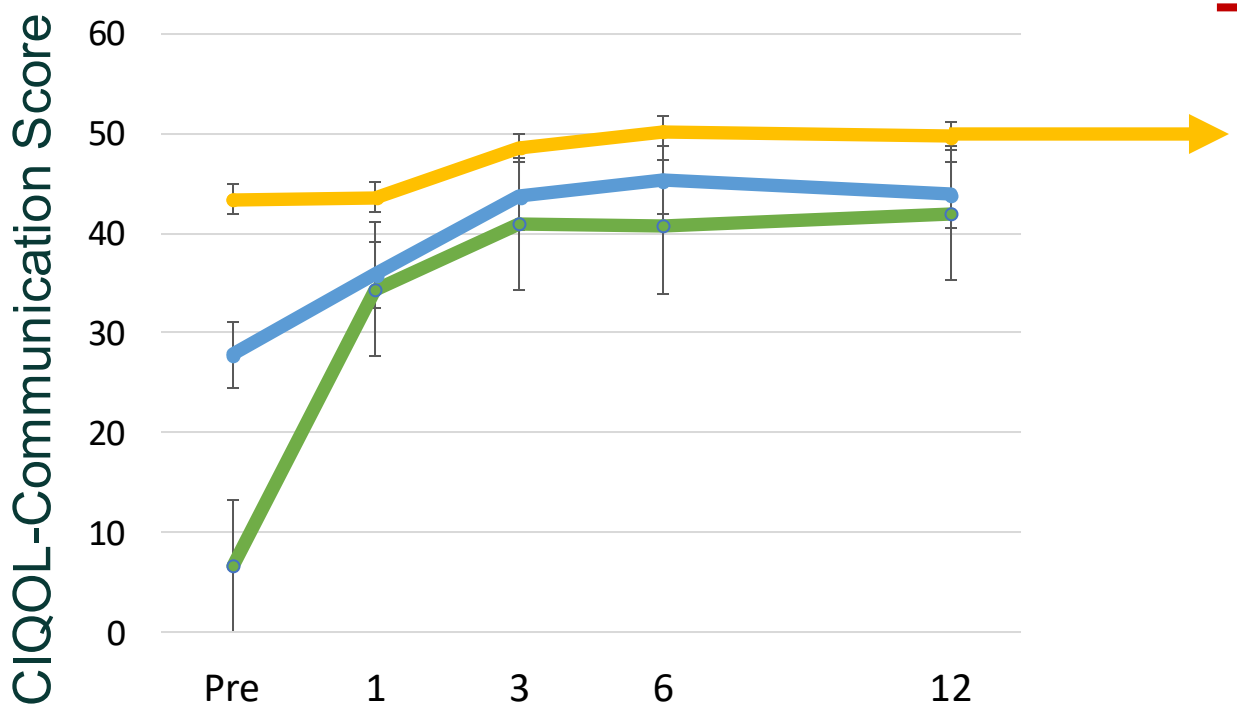


Pre-CI Stage I
Pre-CI Stage II
Pre-CI Stage III



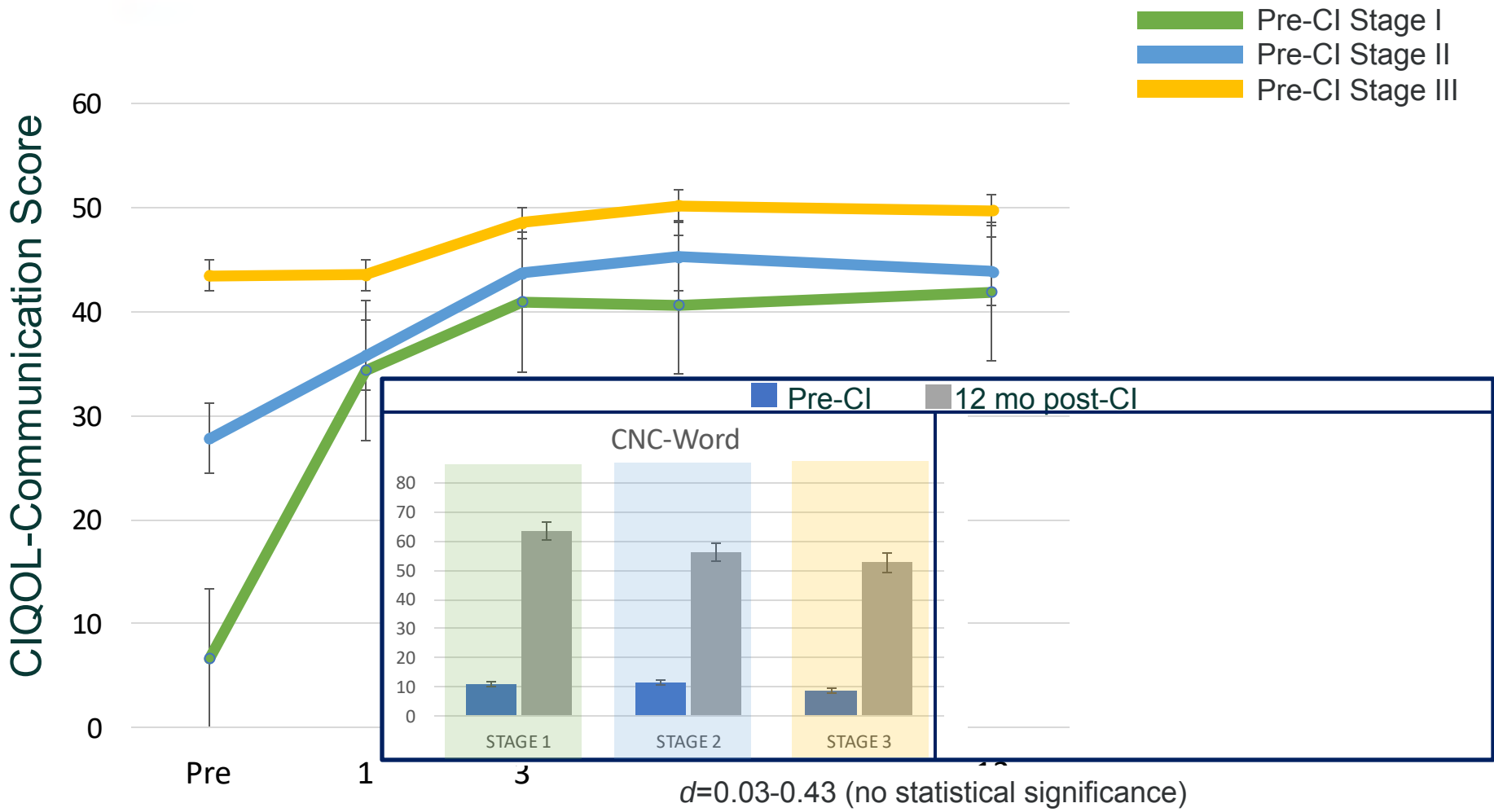
Improvement
≥ 1 Stage



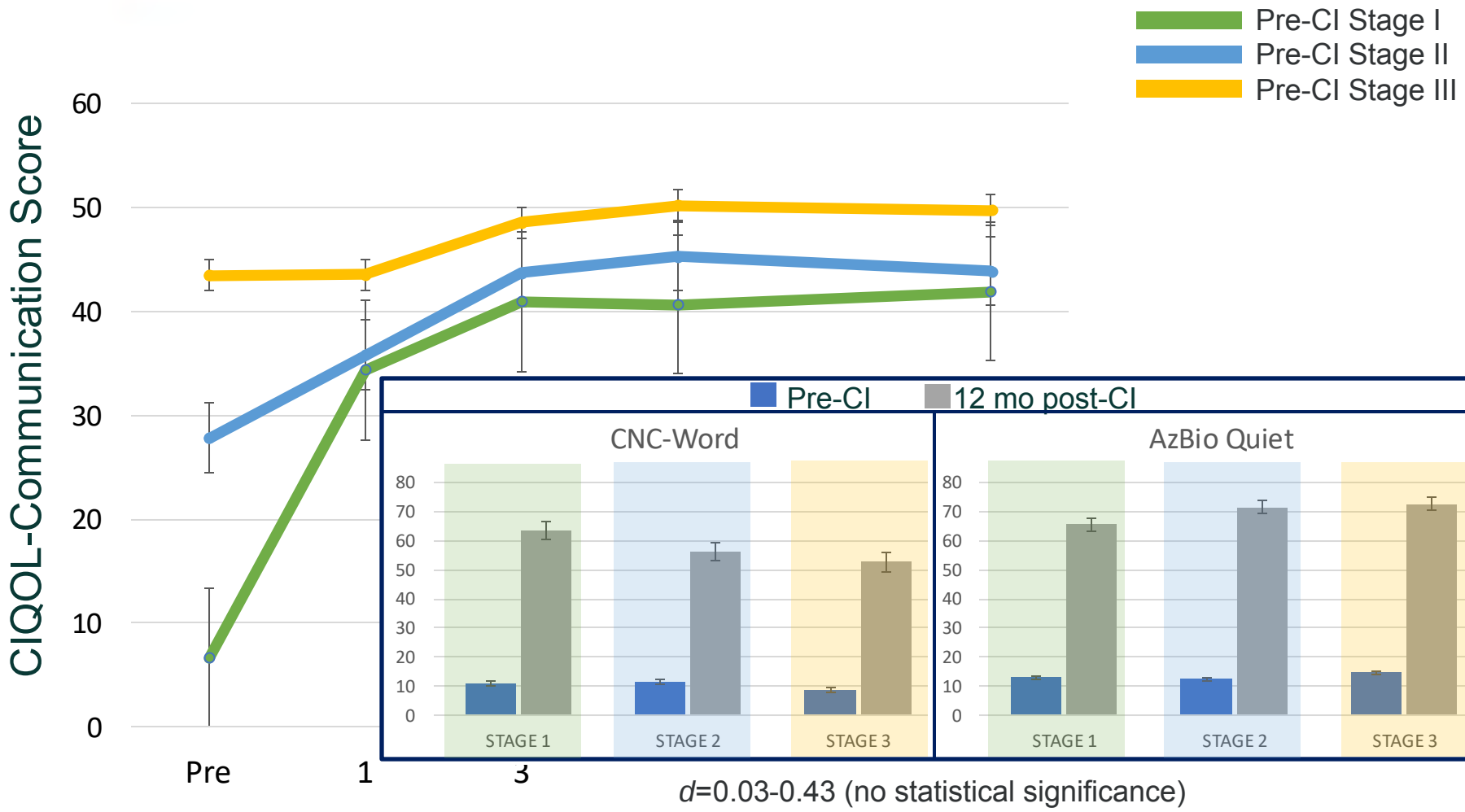


Improvement ≥ 1 Stage

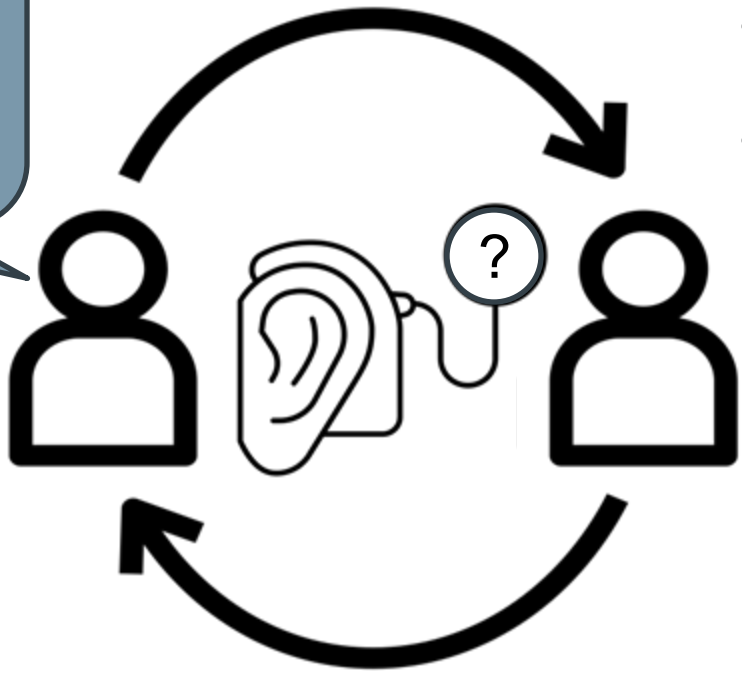
HR: 7.65 (2.04-28.66)



d=0.03-0.43 (no statistical significance)


Pre-CI Stage I
Pre-CI Stage II
Pre-CI Stage III
CIQOL-Communication Score
60
50
40
30
20
10
0
Pre
1
3
Pre-CI
12 mo post-CI
CNC-Word
AzBio Quiet
80
70
60
50
40
30
20
10
0
STAGE 1
STAGE 2
STAGE 3
d=0.03-0.43 (no statistical significance)

Patient:
How will I perform with a cochlear implant?



CIQOL Instruments:

- Provide evidence-based real-world vignettes of CI users' functional abilities
- Allows for comparison to normative data
- Potential future role in modeling potential outcomes

https://education.musc.edu/ciqol

Prentiss et al. JAMA-oto. 2019
Zeitler DM et a. Laryngoscope 2024
McRackan et al. Laryngoscope 2022
McRackan TR et al. Otol Neurotol. 2022

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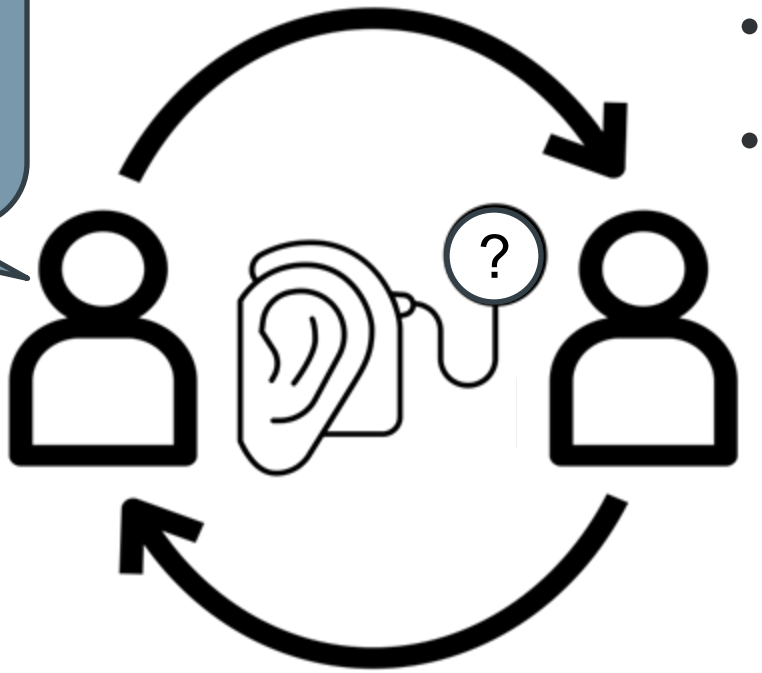

CIQOL Instruments:

- Provide evidence-based real-world vignettes of CI users' functional abilities
- Allows for comparison to normative data
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~75% of potential CI users prefer outcomes discussed using CIQOL Functional Staging System

https://education.musc.edu/ciqol

Prentiss et al. JAMA-oto. 2019
Zeitler DM et a. Laryngoscope 2024
McRackan et al. Laryngoscope 2022
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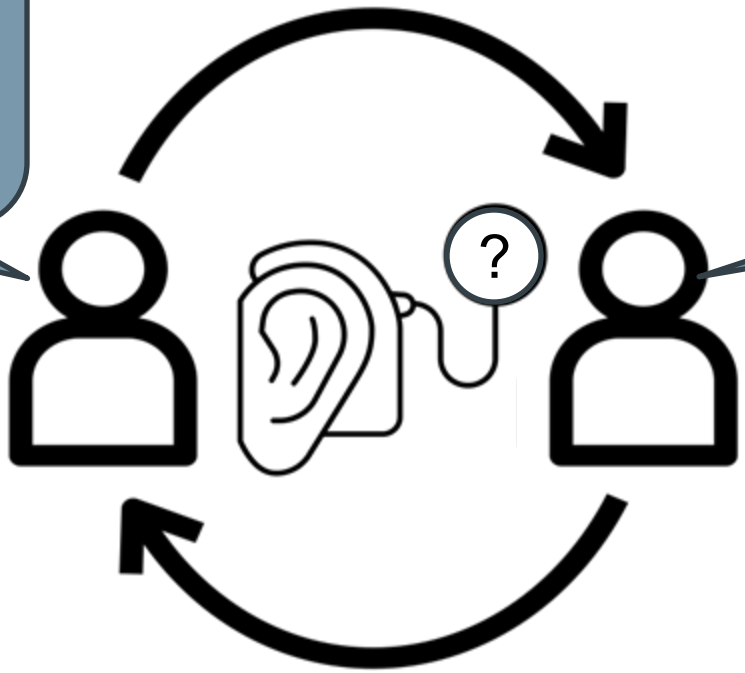
Patient:
How will I perform with a cochlear implant?

Clinicians:
Does the patient have realistic outcome expectations?



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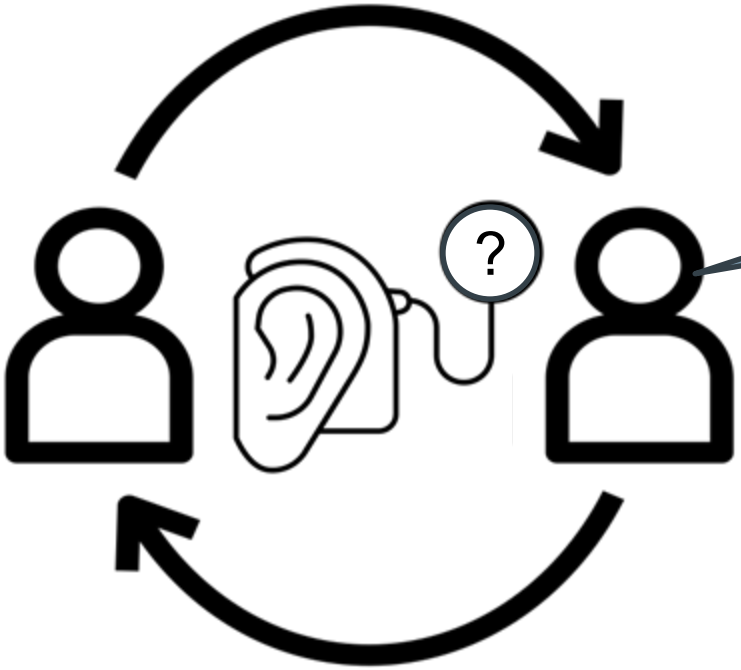
Prentiss et al. JAMA-oto. 2019
Zeitler DM et a. Laryngoscope 2024

General conversations about patients' expectation

Clinicians' personal experiences with CI users



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Prentiss et al. JAMA-oto. 2019
Zeitler DM et a. Laryngoscope 2024

CIQOL-Expectations

JAMA Otolaryngology–Head & Neck Surgery | Original Investigation

Understanding Patient Expectations Before Implantation Using the Cochlear Implant Quality of Life–Expectations Instrument

Theodore R. McRackan, MD, MSCR; Brittany N. Hand, PhD, OTR/L; Shreya Chidarala, BS; Judy R. Dubno, PhD

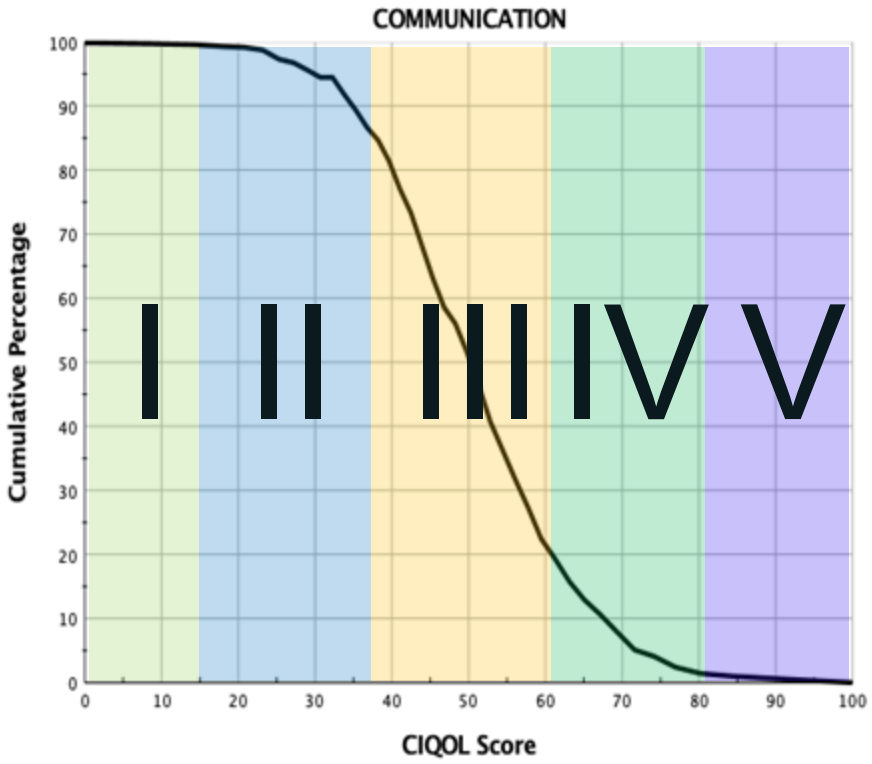
- Using CIQOL framework, validated an instrument that measures pre-CI patient expectations

https://education.musc.edu/ciqol

McRackan TR et al. JAMA-oto. 2022

CIQOL-Expectations

- Corresponds to CIQOL-35 Profile



McRackan TR et al. Otol Neurotol. 2022
McRackan TR et al. JAMA-oto. 2022

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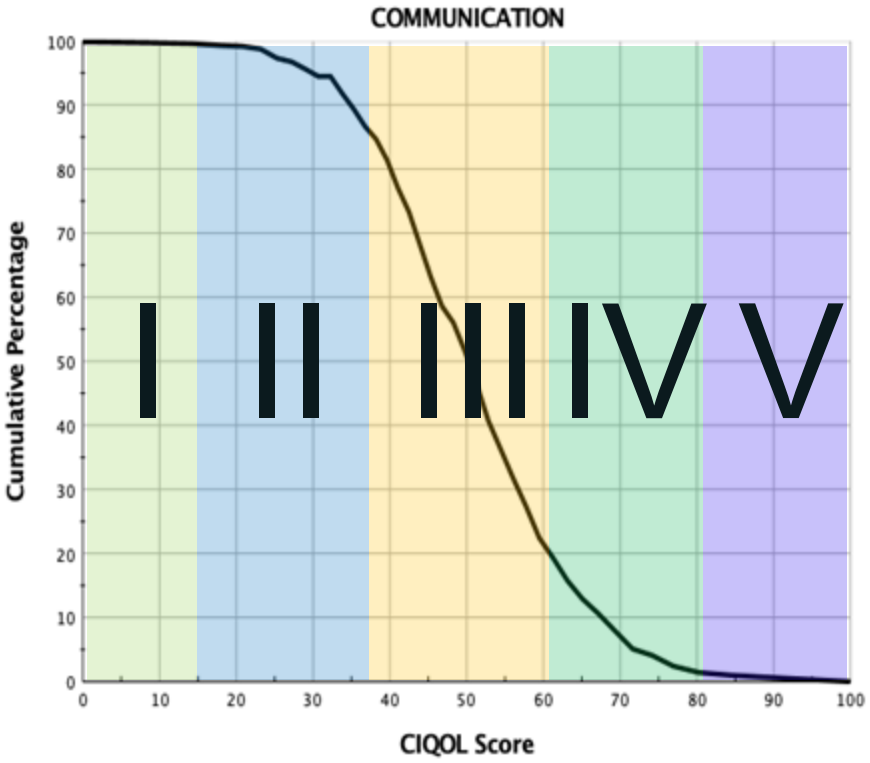

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McRackan TR et al. JAMA-oto. 2022

CIQOL-Expectations

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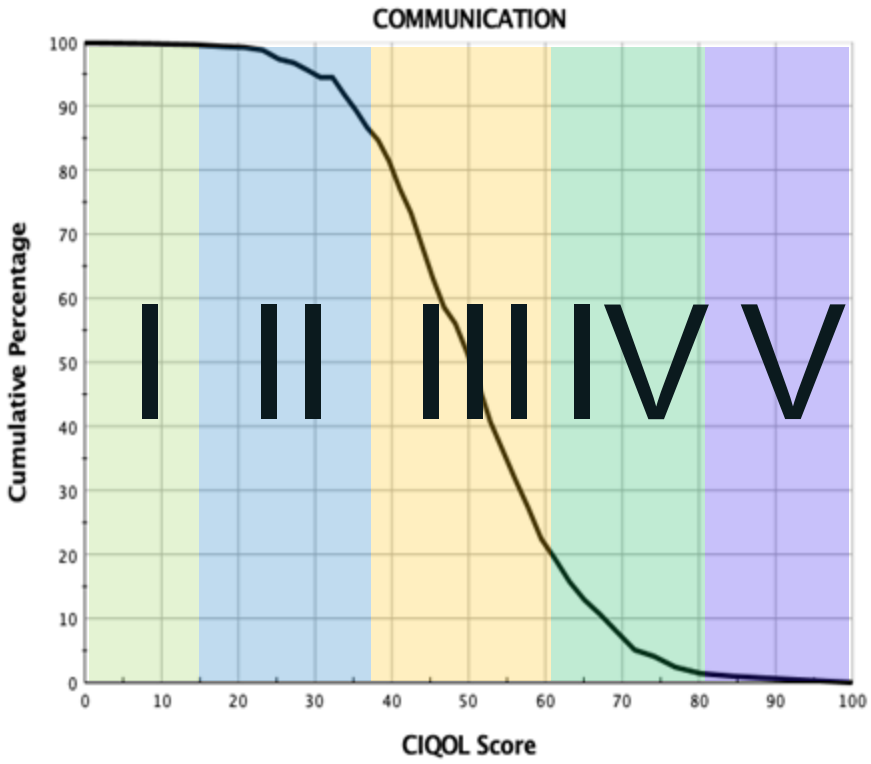
- Goals:

General conversations about patients' expectation → Measure pre-CI expectation

Clinicians' personal experiences with CI users → Compare to normative data



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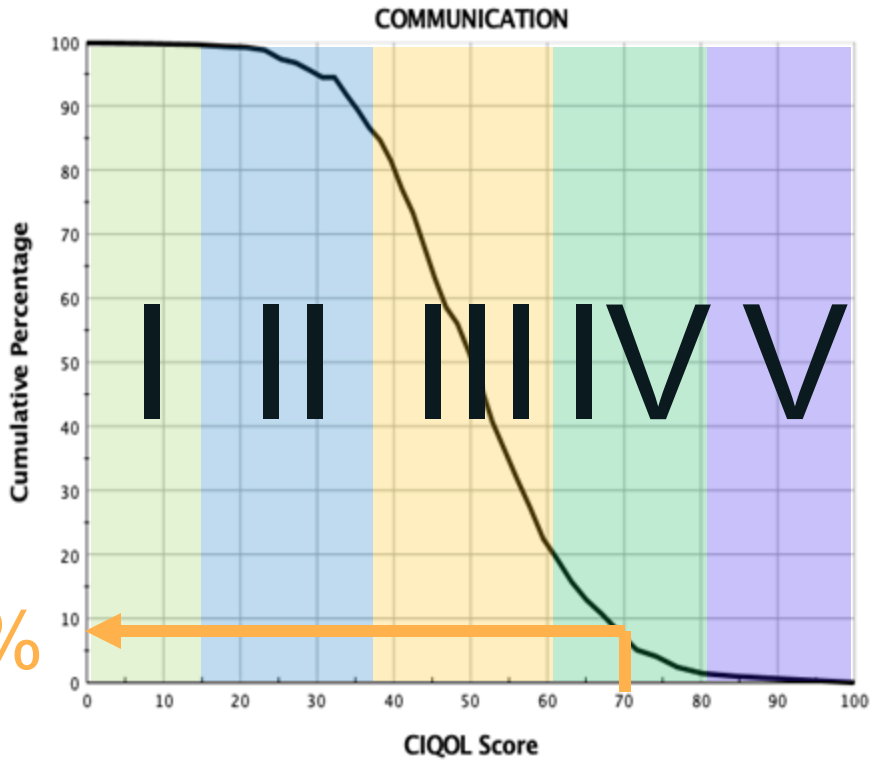

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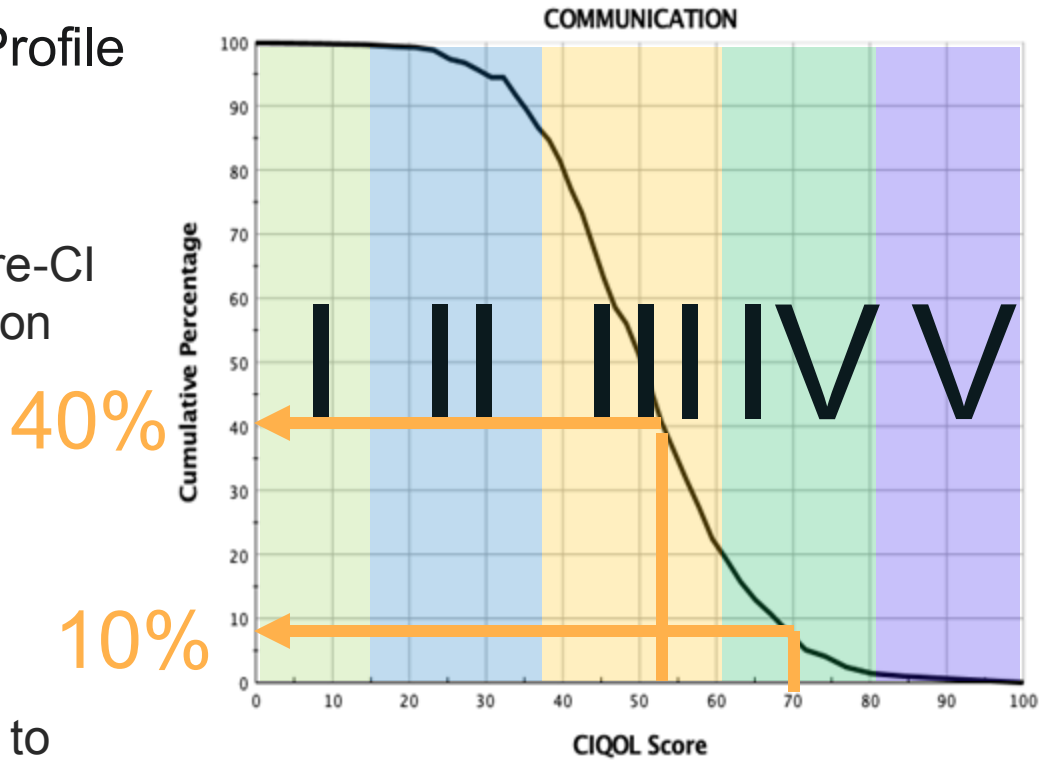

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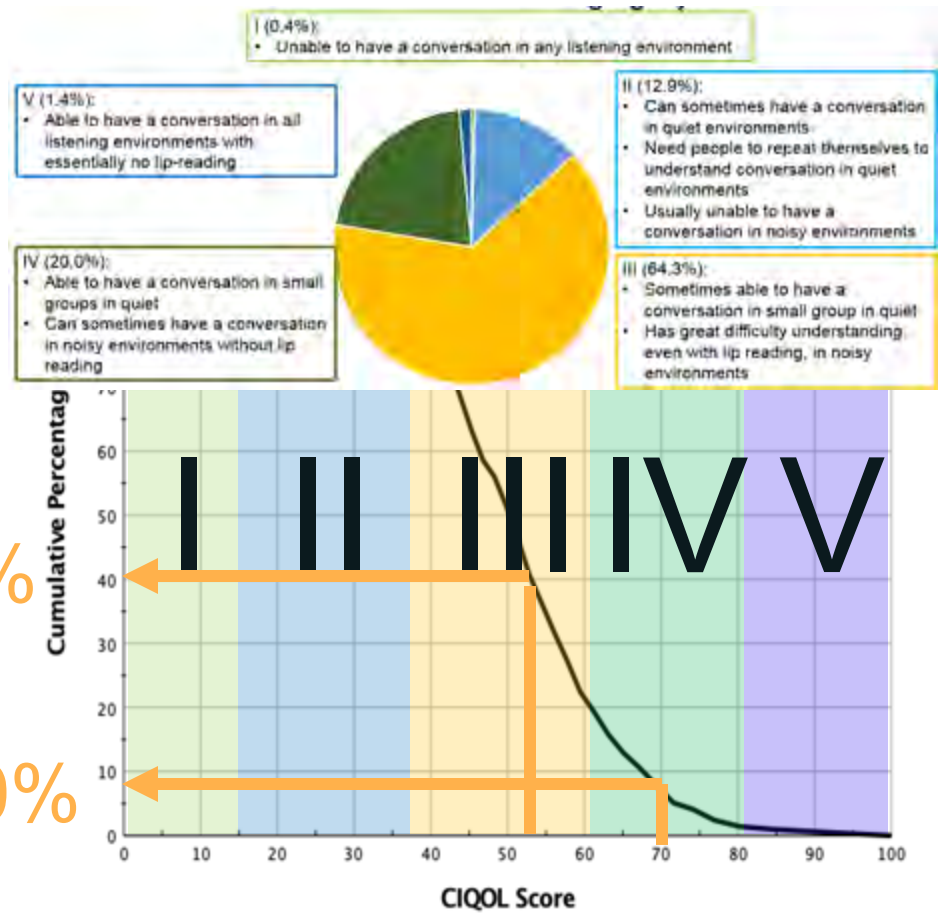


McRackan TR et al. Otol Neurotol. 2022
McRackan TR et al. JAMA-oto. 2022

Pre-CI Expectations

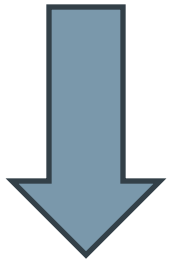
- Do CI users meet their pre-CI expectations?

Fabie JE et al Otol-Neurotol. 2023

Pre-CI Expectations

- Do CI users meet their pre-CI expectations?
- N=60 adult CI users

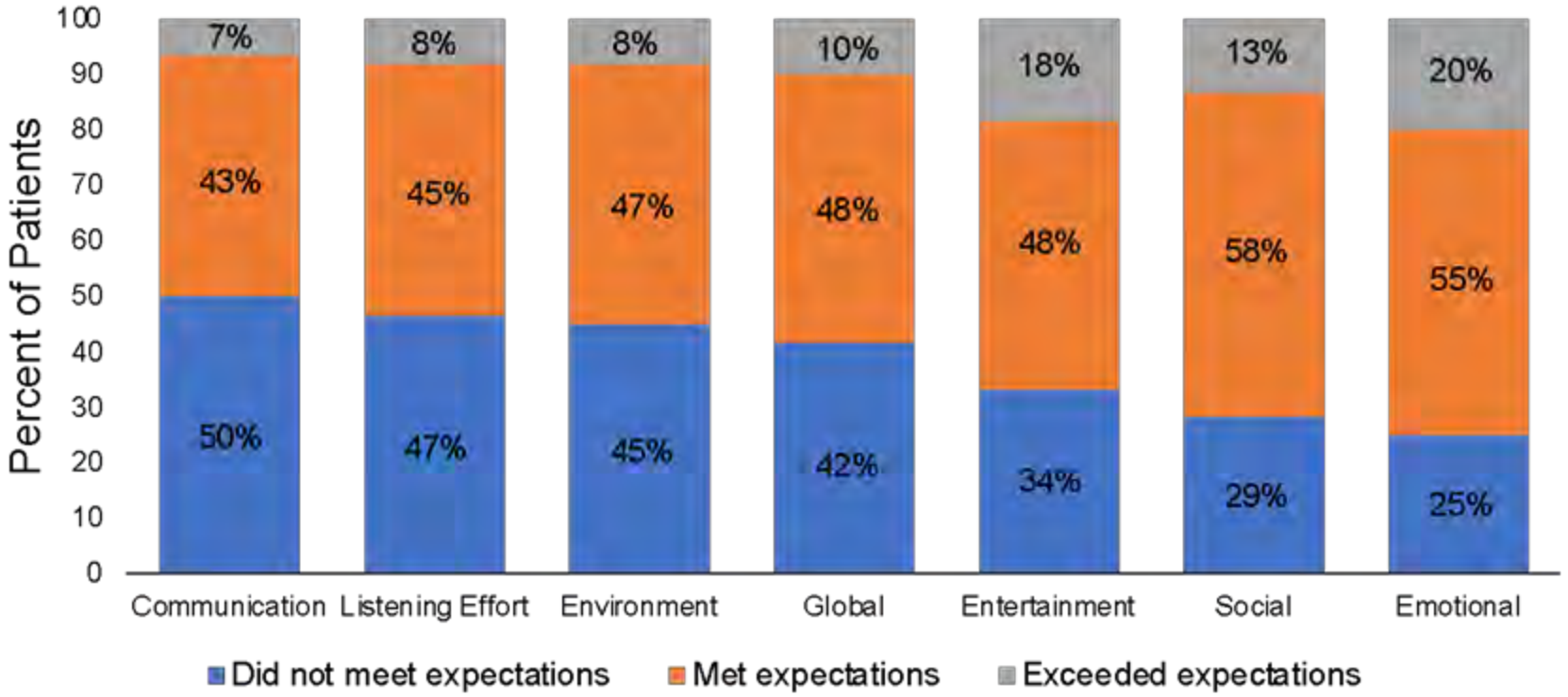
Pre-CI CIQOL-Expectations



12-month post-CI CIQOL domain score

Fabie JE et al Otol-Neurotol. 2023

Pre-CI Expectations >>> Outcomes



Fabie JE et al Otol-Neurotol. 2023

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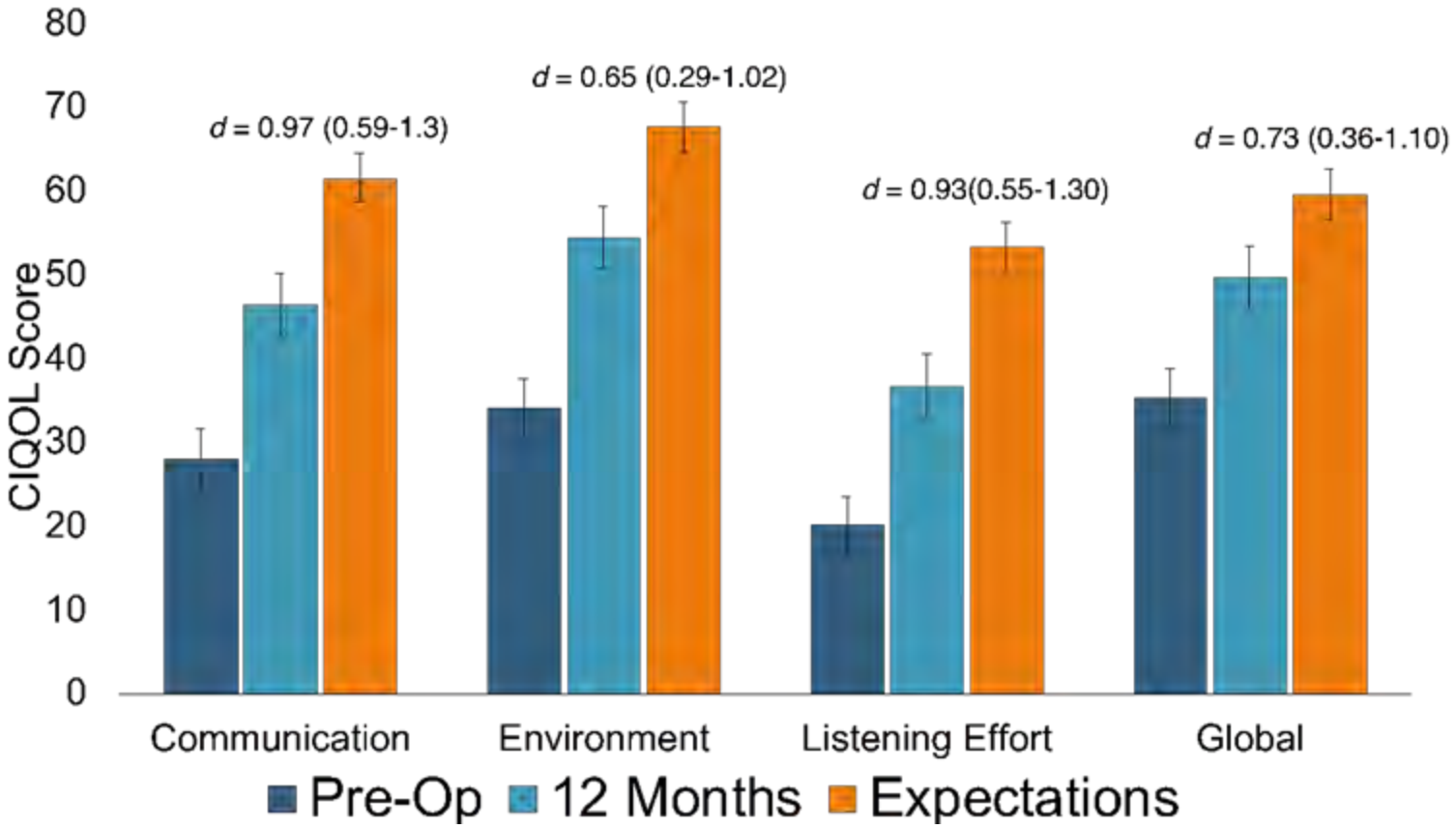
Pre-CI Expectations >>> Outcomes



Fabie JE et al Otol-Neurotol. 2023

Implications of unmet expectations?

Shannon CM et. al Otol-Neurotol. 2023
Ou H et. al, JAAA 2008
Brehaut JC et al Med Decision Making 2003

Implications of unmet expectations?

- N=38 adult CI users

Pre-CI
CIQOL-Expectations

12-month post-CI
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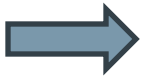


Decision Regret Scale

Satisfaction with
Amplification in Daily Living
(SADL)*

Shannon CM et. al Otol-Neurotol. 2023
Ou H et. al, JAAA 2008
Brehaut JC et al Med Decision Making 2003

Implications of unmet expectations

- N=38 adult CI users

Shannon CM et. al Otol-Neurotol. 2023

Implications of unmet expectations

- N=38 adult CI users

Consistent with another multi-institutional study

Shannon CM et. al Otol-Neurotol. 2023
Prentiss S et. al, CI Int'l 2024

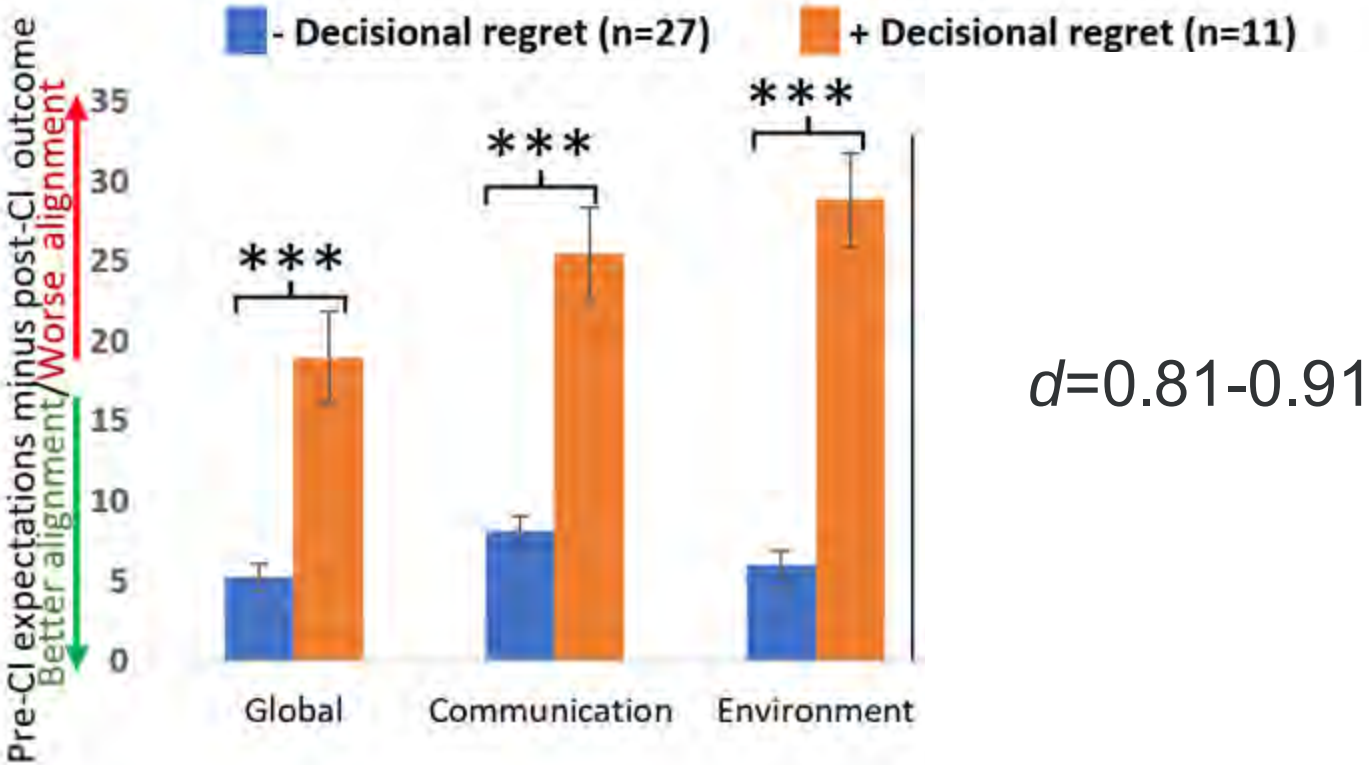
Implications of unmet expectations

- N=38 adult CI users

Shannon CM et. al Otol-Neurotol. 2023

Implications of unmet expectations

- N=38 adult CI users



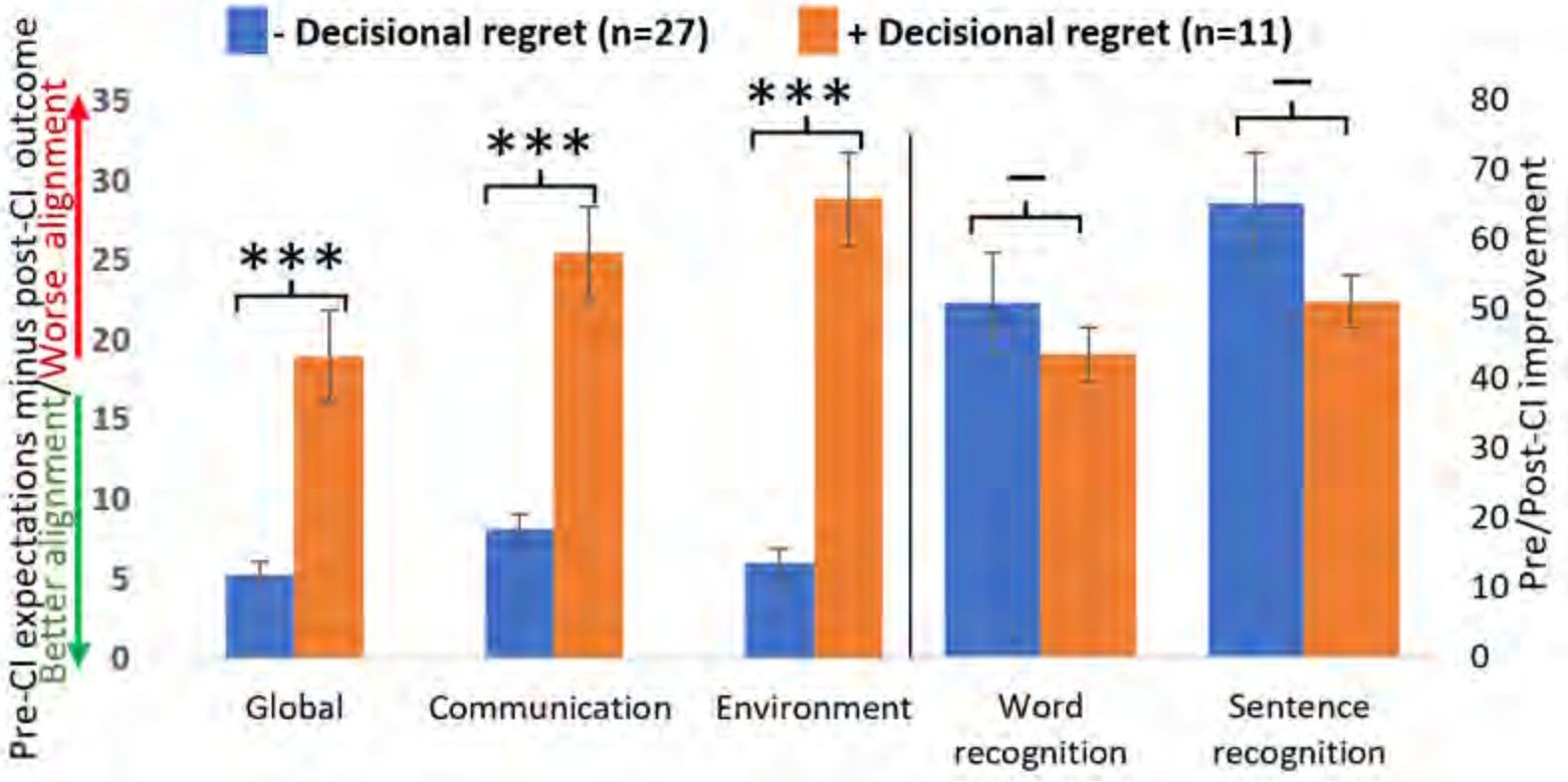
d=0.81-0.91

Shannon CM et. al Otol-Neurotol. 2023

Implications of unmet expectations

- N=38 adult CI users

d=0.29-0.31
Similar pattern for SADL scores



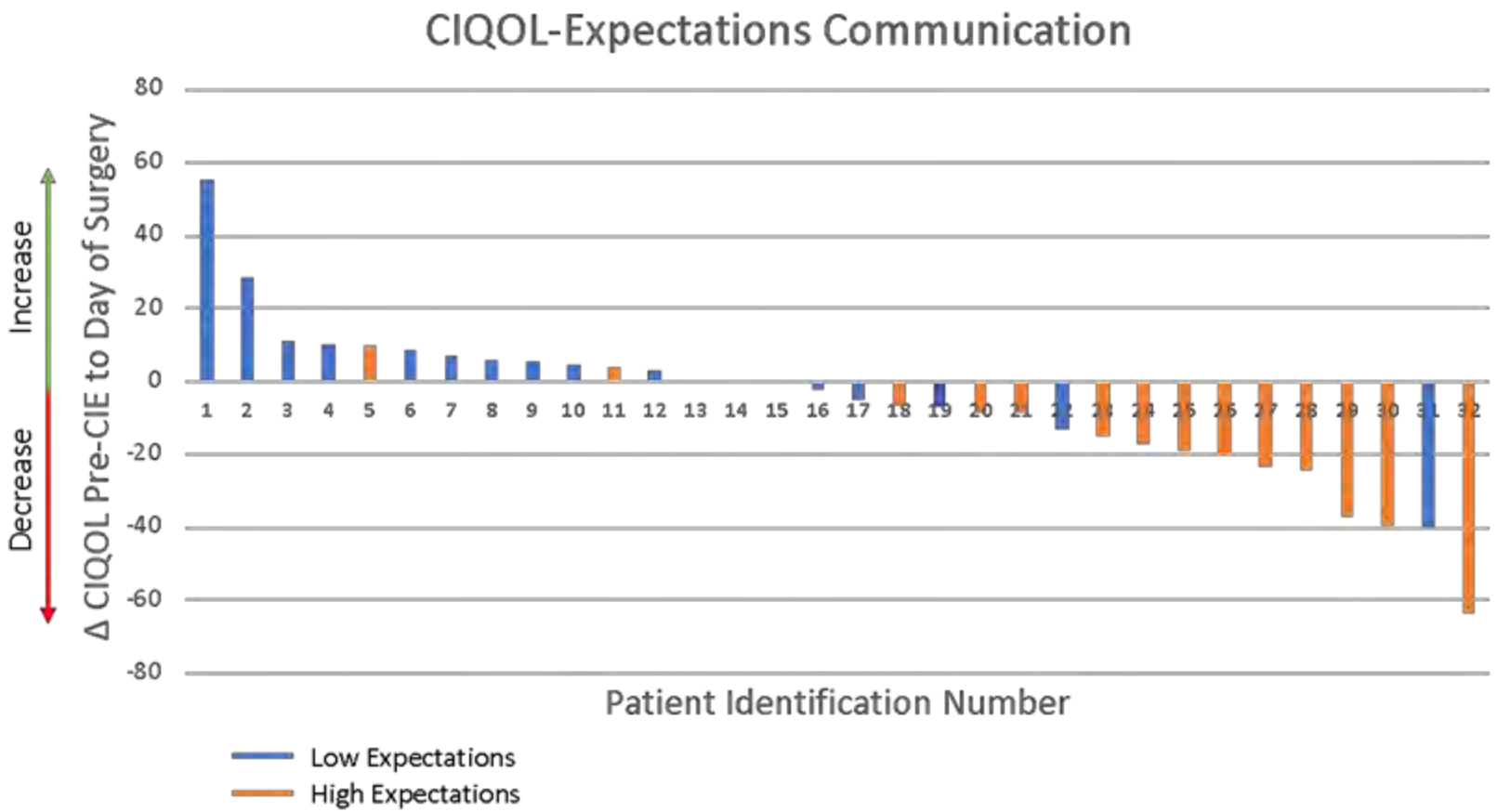
Shannon CM et. al Otol-Neurotol. 2023

Shannon CM et. al Otol-Neurotol. 2023

Are patient expectations modifiable?

Fabie JE et. al Ear Hearing. In press

Are patient expectations modifiable?



Fabie JE et. al Ear Hearing. In press

Bad news:

- Many patients have unrealistic pre-CI expectations
- High levels of decisional regret post-CI

Clinicians:
Does the patient have realistic outcome expectations?

https://education.musc.edu/ciqol

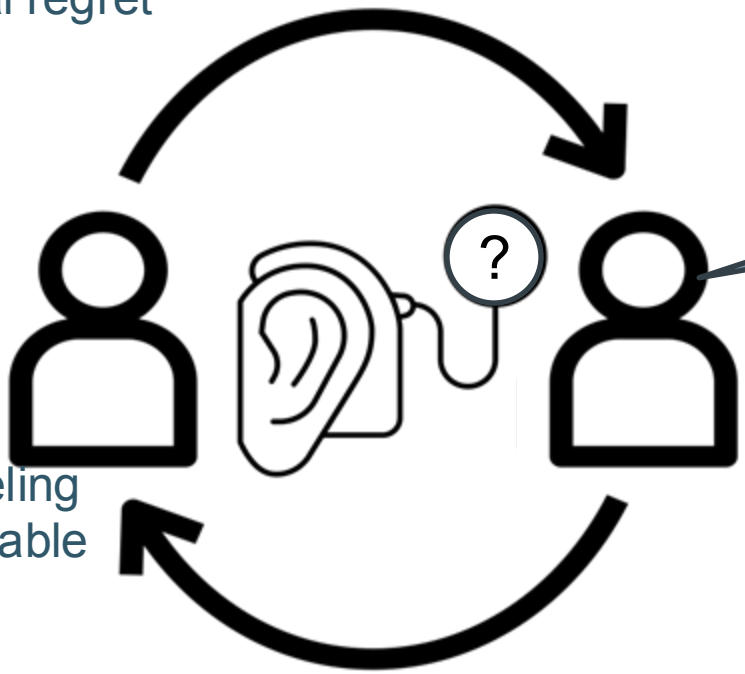
Prentiss et al. JAMA-oto. 2019
Zeitler DM et a. Laryngoscope 2024

Bad news:

- Many patients have unrealistic pre-CI expectations
- High levels of decisional regret post-CI

Good news:

- Have ability to measure patients' pre-CI expectations
- Have data to provide evidence-based counseling
- Expectations are modifiable



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Prentiss et al. JAMA-oto. 2019
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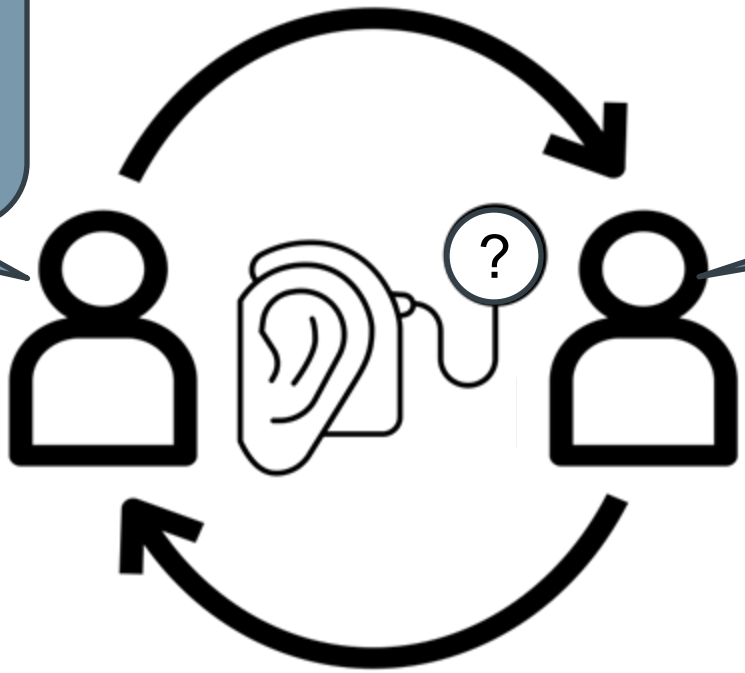
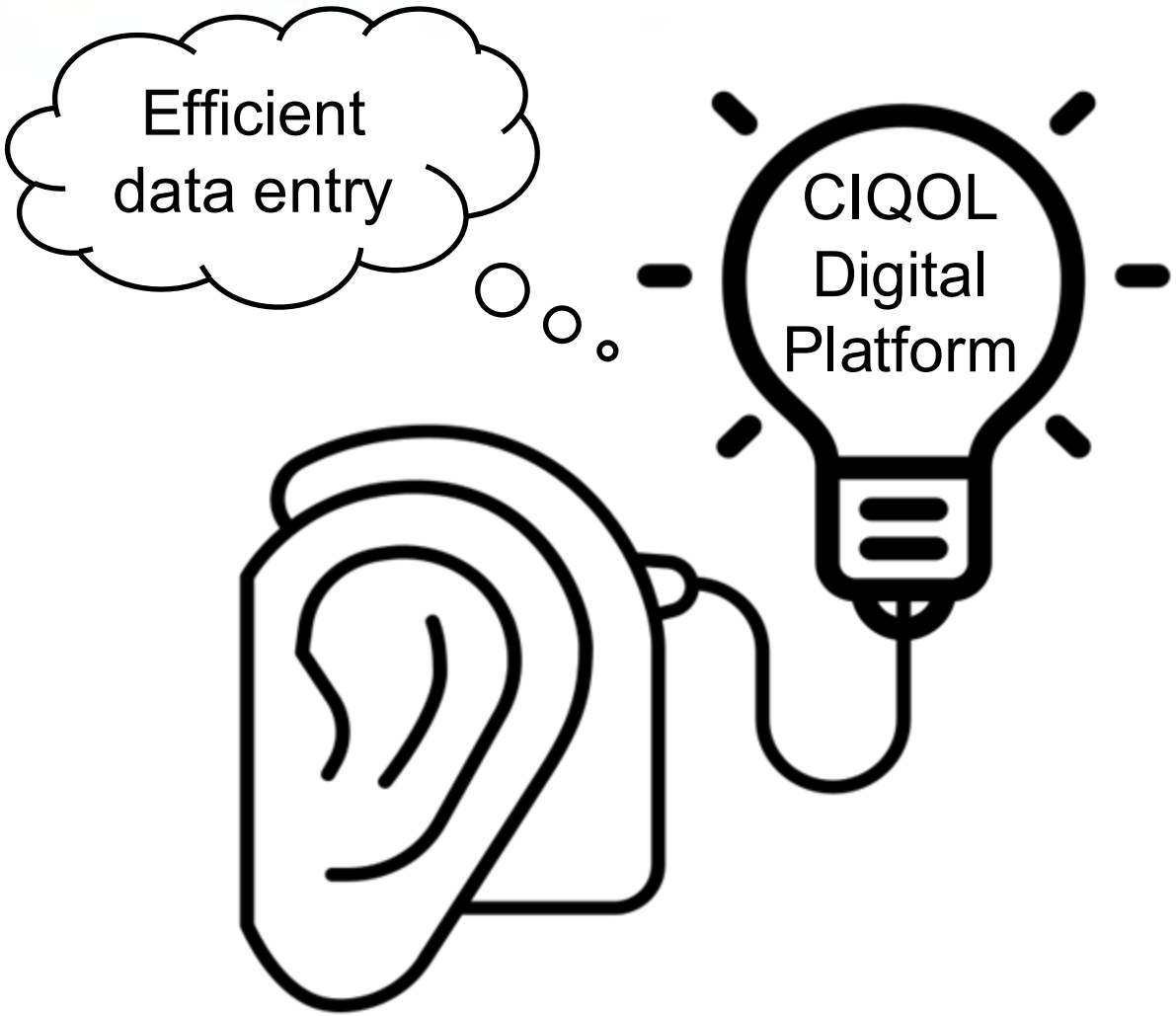
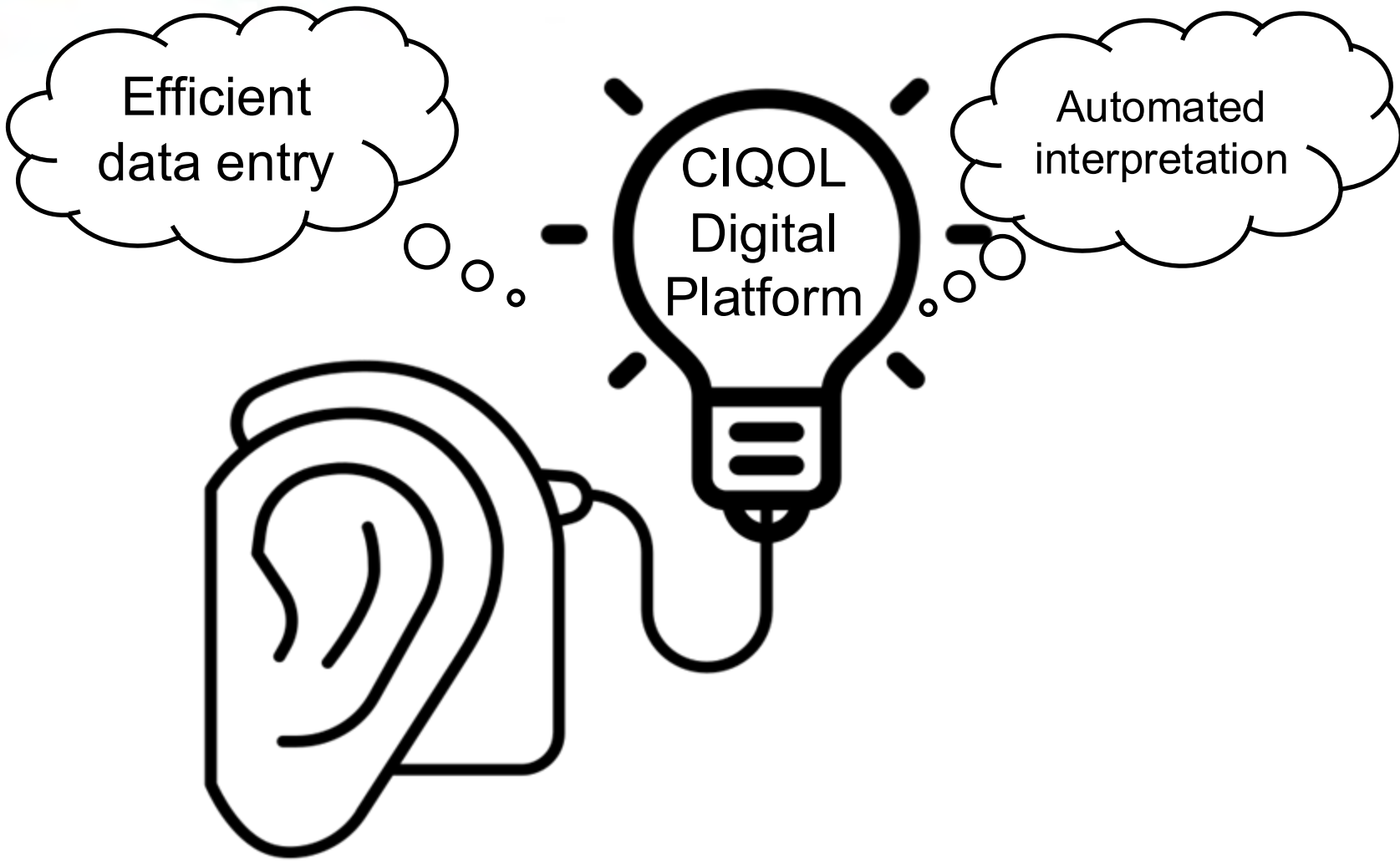


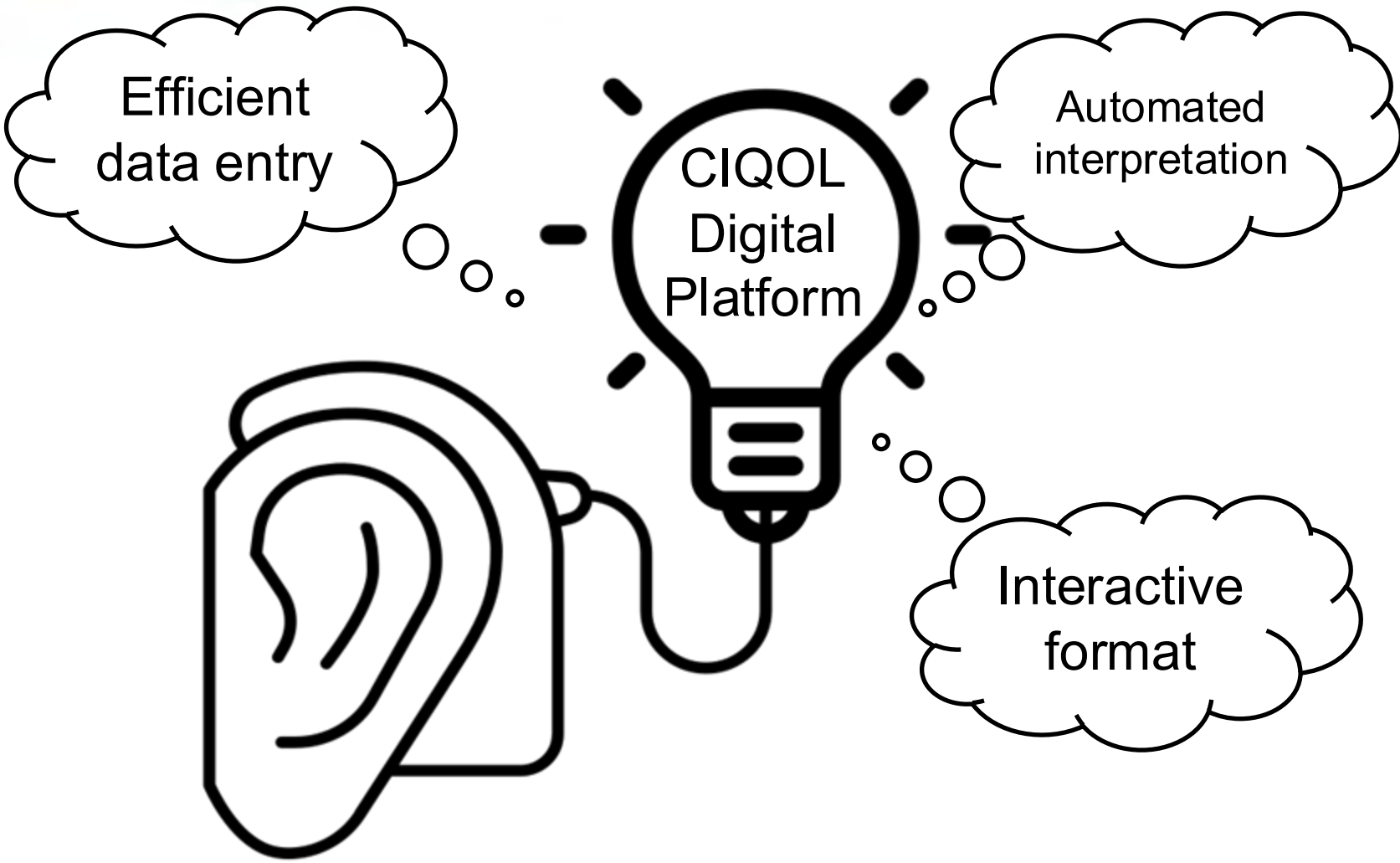
https://education.musc.edu/ciqol

Prentiss et al. JAMA-Oto. 2019
Zeitler DM et al. Laryngoscope 2024
Fabie JE et al. Ear Hear under rev

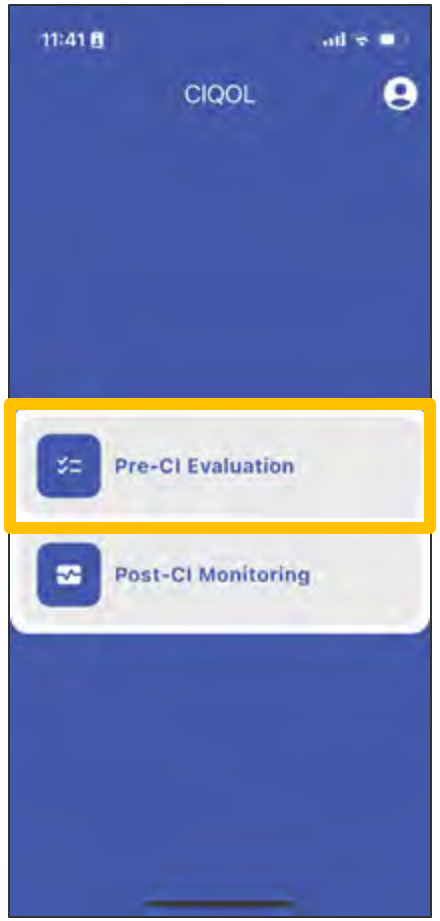

CIQOL
Digital
Platform


Efficient data entry
CIQOL Digital Platform

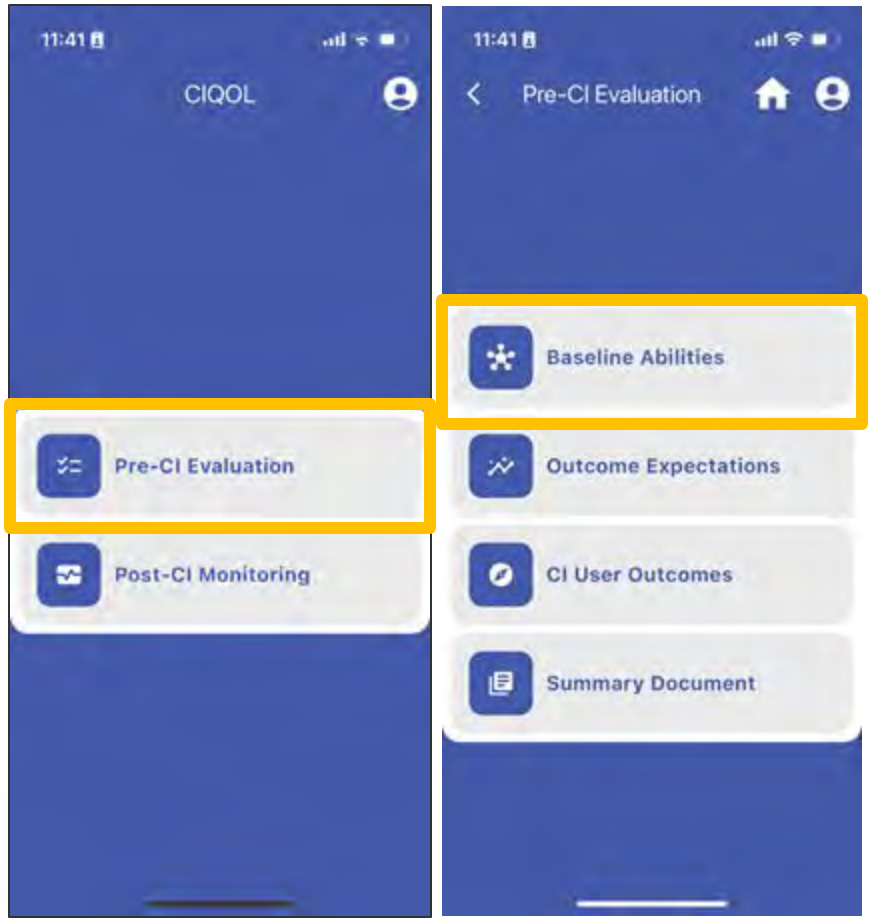

Efficient data entry
CIQOL Digital Platform
Automated interpretation


Efficient data entry
CIQOL Digital Platform
Automated interpretation
Interactive format

CIQOL Digital Platform



CIQOL Digital Platform



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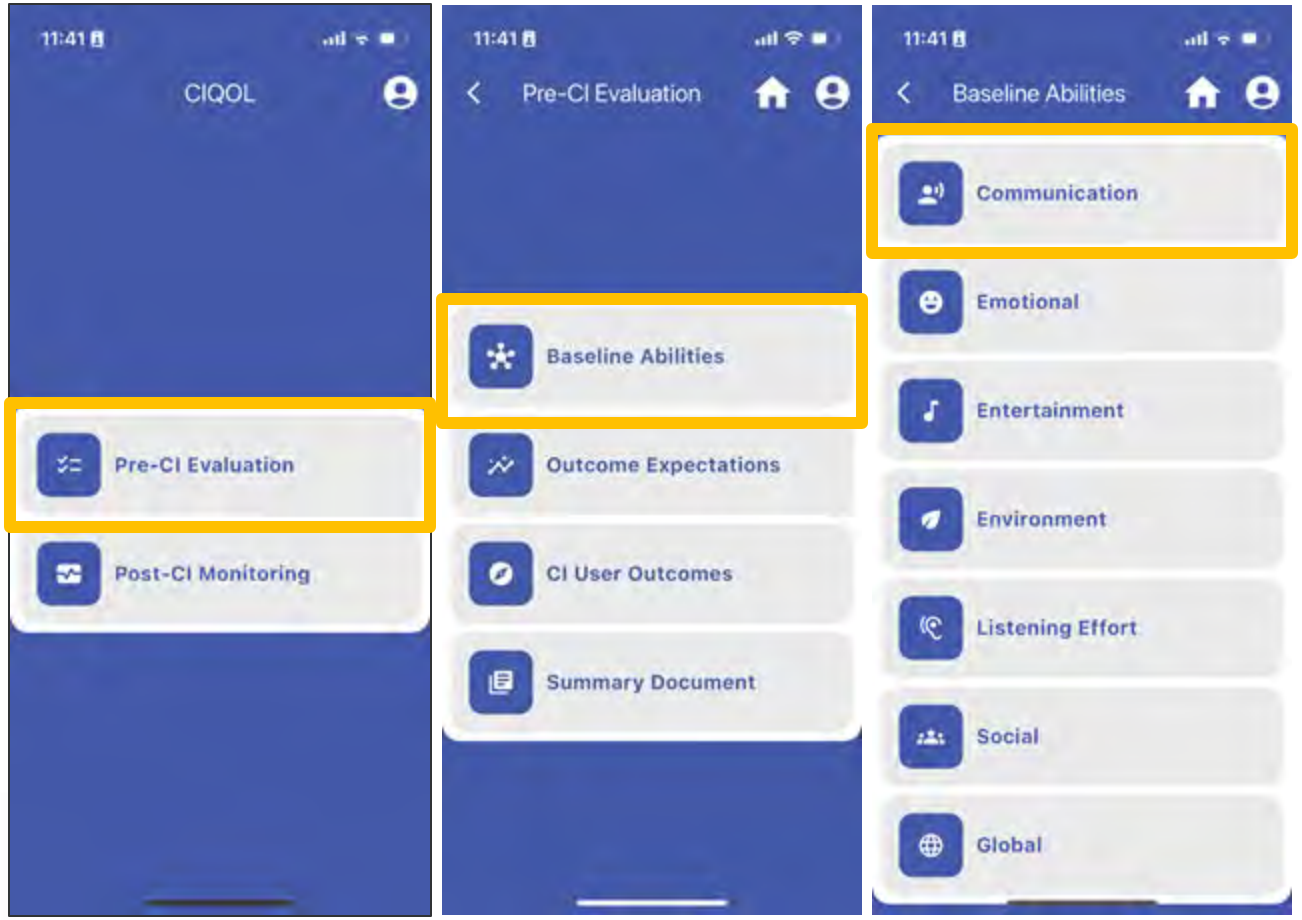

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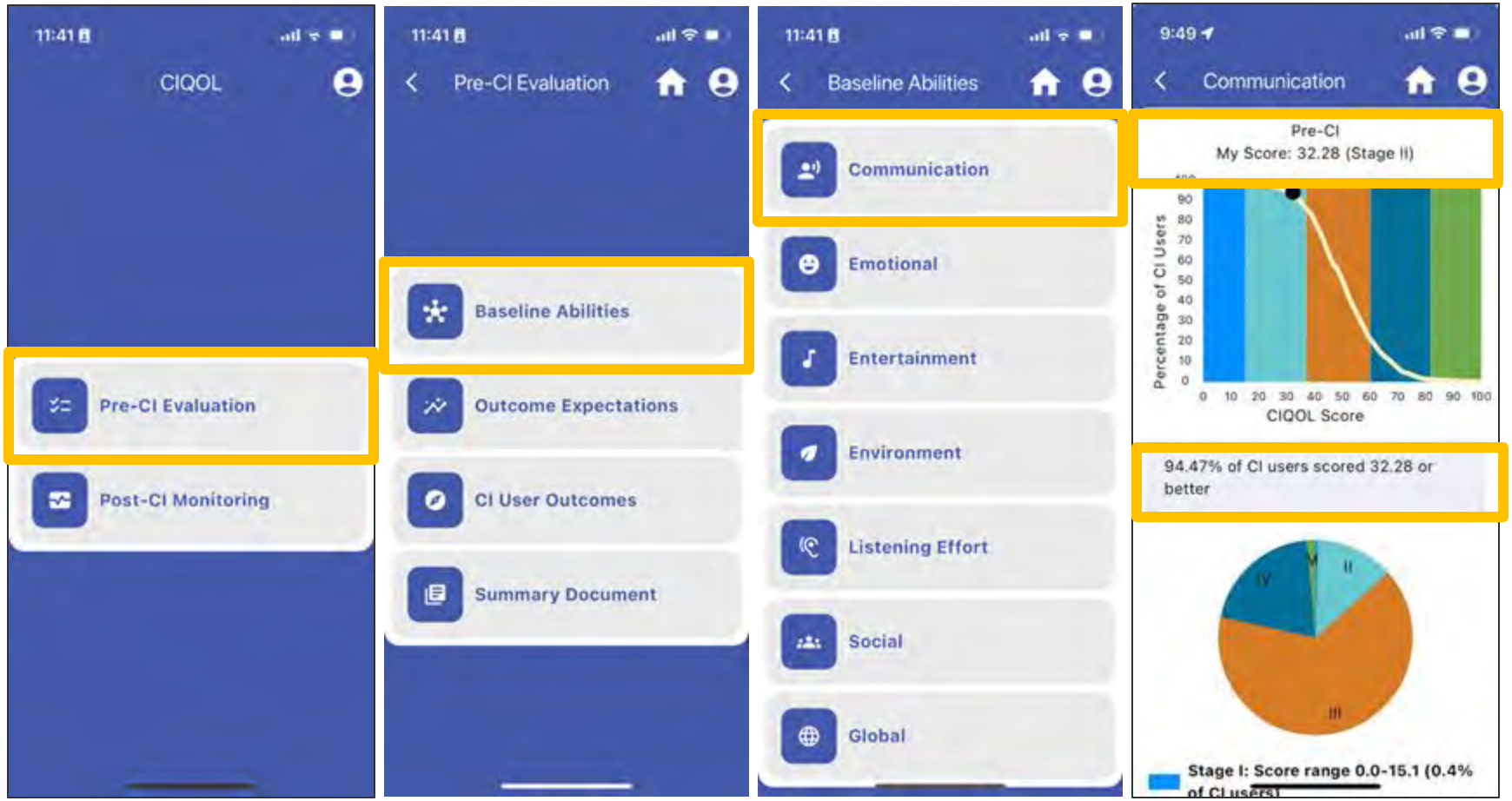

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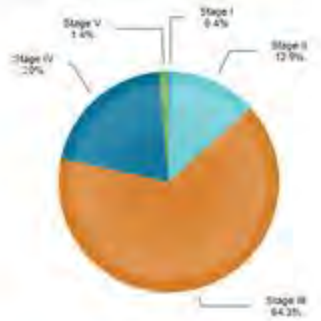

Stage I: Score range 0.0-15.1 (0.4% of CI users)
- Unable to have a conversation in any listening environment

Stage II: Score range 15.2-37.0 (12.9% of CI users)
- Can sometimes have a conversation in quiet environments
- Other people's voices may sometimes sound clear and natural
- Need people to repeat themselves to understand conversation in quiet environments
- Usually unable to have a conversation in noisy environments

Stage III: Score range 37.1-60.1 (64.3% of CI users)
- Sometimes able to have a conversation in small groups in quiet
- Has great difficulty understanding, even with lip reading, in noisy environments
- Can sometimes have a conversation without asking people to repeat themselves

Stage IV: Score range 60.2-81.8 (20.0% of CI users)
- Able to have a conversation in small groups in quiet
- Rarely needs to ask a lot of questions about what is being said in a conversation
- Can sometimes have a conversation in noisy environments without lip reading

Stage V: Score range 81.9-100.0 (1.4% of CI users)
- Able to have a conversation in all listening environments with essentially no lip-reading
- Other people's voices always sound clear and natural

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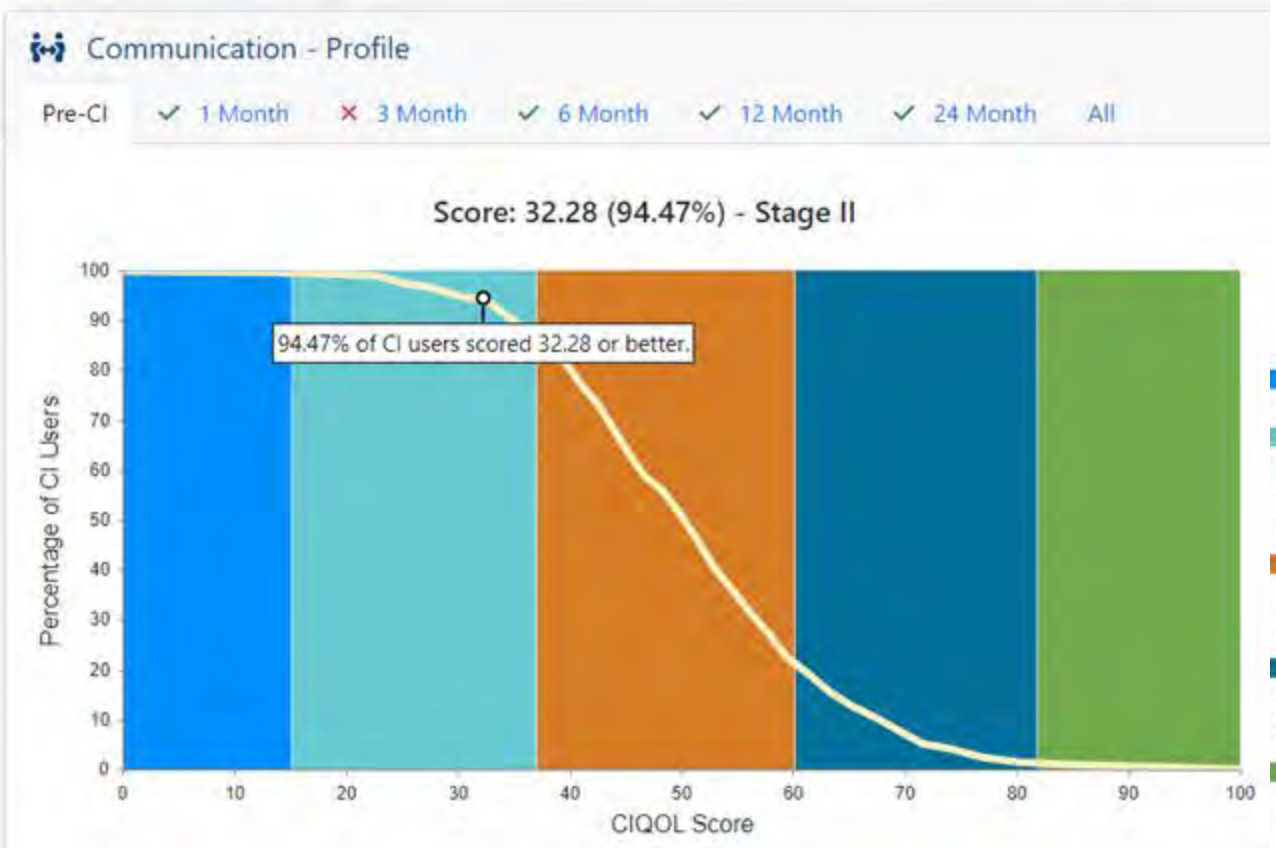

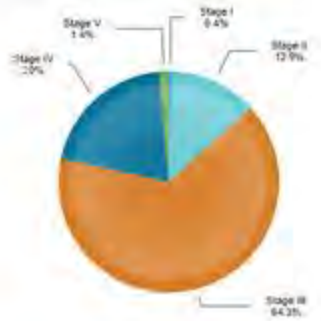

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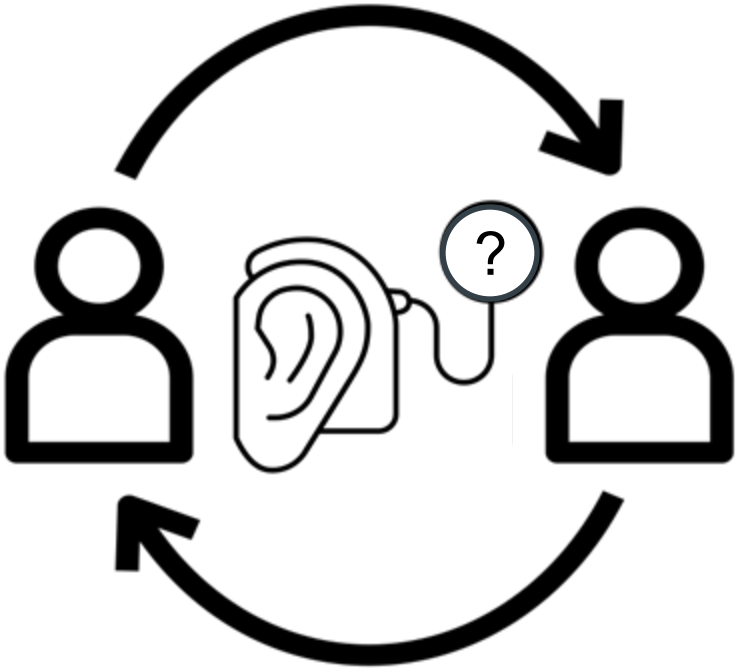
DEcisional support for Cochlear Implantation by Discussing patient Experiences (DECIDE)



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DECIDE

Components

- Comparison of patient baseline functional abilities to potential CI outcomes
- Comparison of patient outcomes expectations relative to normative data
- Timeline for improvement after CI
- Limitations of CI
- Surgical process
- Surgical risks

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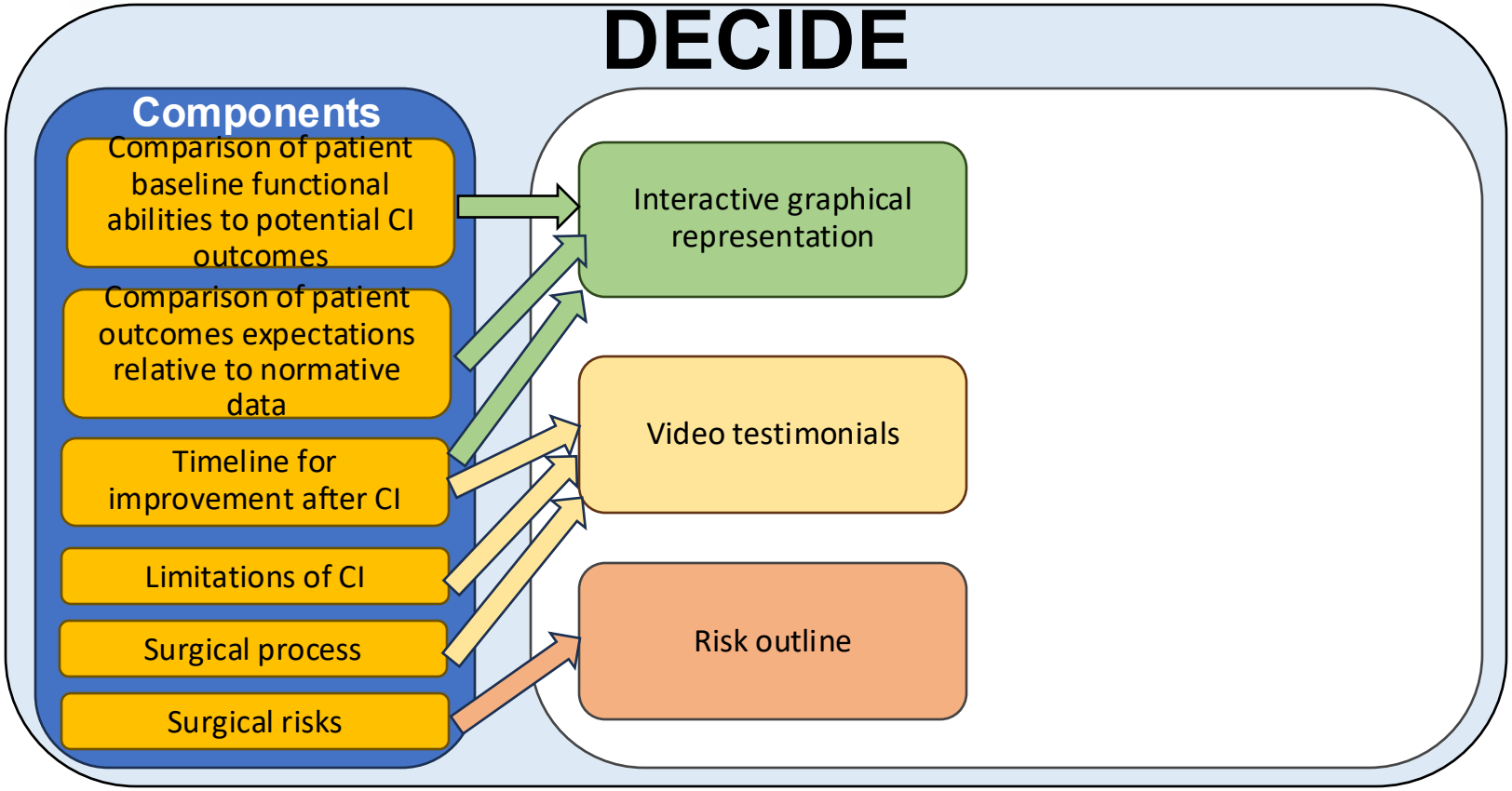

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DECIDE

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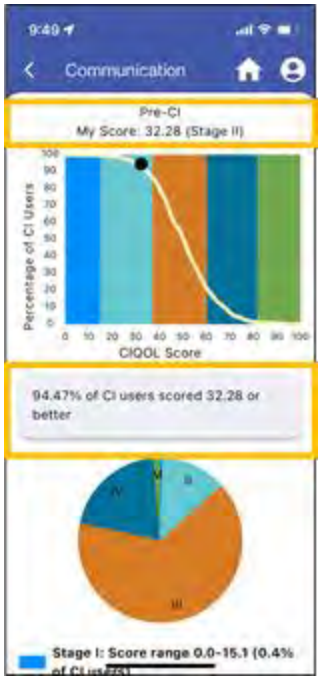
- Interactive graphical representation
- Video testimonials
- Risk outline



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DECIDE

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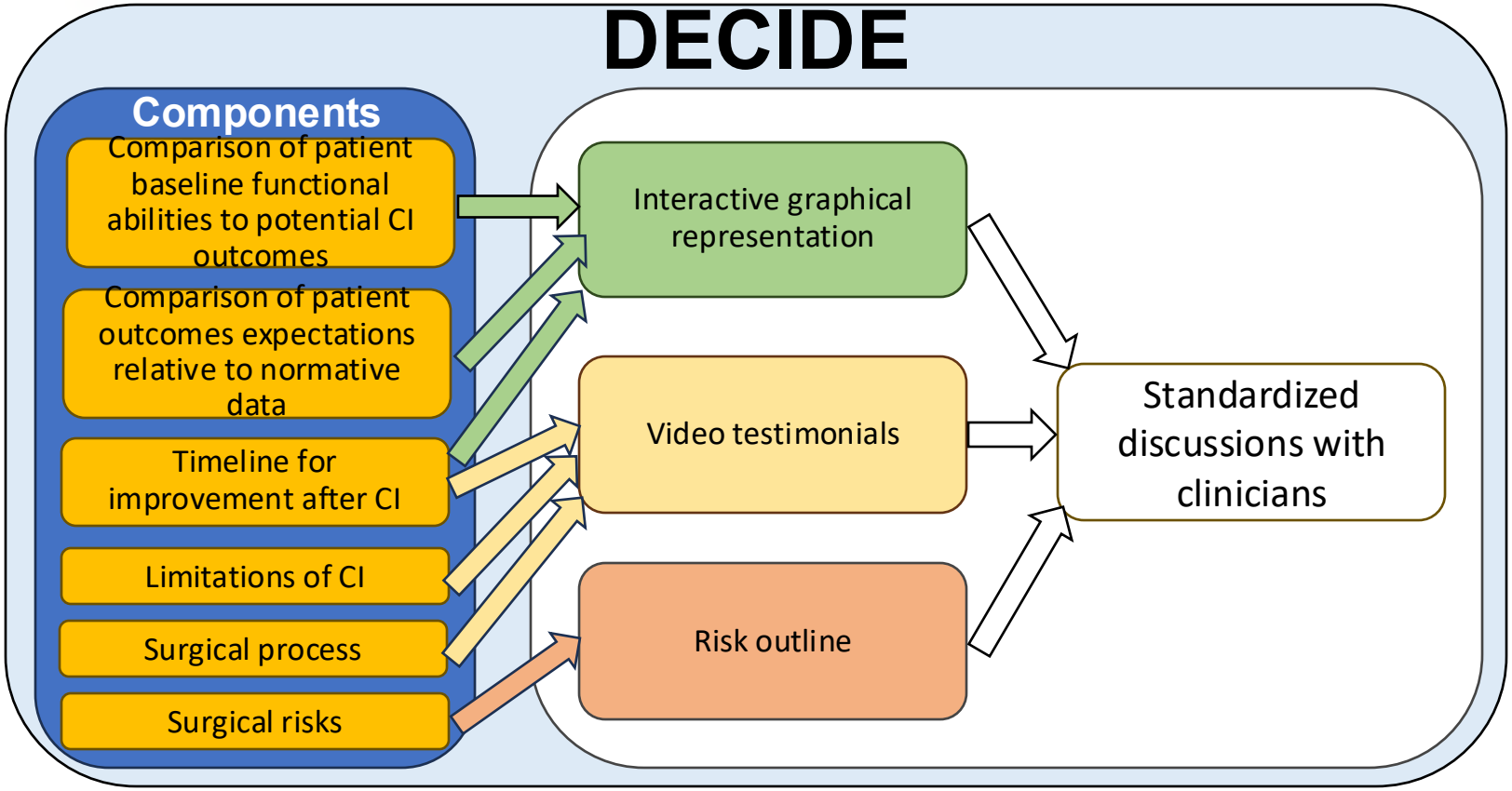

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- Amy Noxon
- Meghan Carter
- Hannah Brown
- Elise Wilson
- Sarah Haslett
- Nevitte Morris
- Claire Keiser

CIQOL Research Consortium

- Columbia University
- Duke University
- Eastern Virginia Medical School
- Georgetown
- House Ear Clinic
- Johns Hopkins University
- Kaiser Health Los Angeles
- Kaiser Health San Diego
- Loyola University
- Mass Eye and Ear Infirmary
- Mayo Clinic Rochester
- MUSC
- New York Eye and Ear Infirmary
- Ohio State University
- Oregon Health Sciences University
- Rush Medical Center
- Stanford University
- Summit Medical Group
- SUNY Downstate
- University of Arkansas
- University of Cincinnati
- University of Colorado
- University of Maryland
- University of Miami
- University of Pennsylvania
- University of Utah
- University of South Carolina
- University of Texas Southwestern
- Vanderbilt University
- Virginia Mason Seattle
- University of Miami
- Washington University
- Advanced Bionics
- Cochlear Corporation
- MED-EL

Questions

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