Reviewer's report

Title: A Global Patient Outcomes Registry: Cochlear Paediatric Implanted Recipient Observational Study (P-IROS)

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Reviewer: Che-Ming CMW Wu

Reviewer's report:

This study protocol does make a real contribution to the research field of cochlear implantation as no other studies in this research area have proposed such a protocol. According to the authors, this registry provides an interface to keep proper records of each implanted patient's demographical information and device type as well as to regularly follow up the patients' auditory progress and quality of life after implantation. The recorded data could also provide payers, families and governments with useful information when making decisions regarding cochlear implantation. The purpose of this study is specific, and the literature is well reviewed. The authors also specified the strength of the proposed registry and the areas that still need improvements or further studies. Therefore, I have no reserves in recommending the publication of this study.

More detailed comments are in order:

1. The purpose of the study is well supported by its study design.

2. In the Methods session, the authors described in detail the data to be collected, the user access to the data, the management of the data and the evaluation time points for the assessments (e.g., CAP-II, CuHI-QoL). Therefore, other studies can easily replicate the work for further investigations.

3. However, I have some concern for the comparability of the results with other related analysis. Firstly, as the majority of the studies in literature use CAP instead of CAP-II as the evaluation tool, the follow-up data collected by this protocol may not be comparable to previous studies. Yet, longitudinally speaking, CAP-II may become a standard tool in the future as its nine-point scale provides better insight into the patients' auditory performance. Secondly, in order to allow better comparability between different languages, I would suggest that only assessment tools that have been validated in other languages are used. Therefore, the CuHI-QoL may require further validation.

4. The SSQ scale was included in the protocol but only as an optional tool. I would suggest the SSQ evaluation to be conducted compulsorily at least at the time point 24 months post-implant. The data of this scale may better reflect the patients' progress than that of the CAP-II. Also, aided and unaided hearing thresholds are suggested to be assessed pre-implant (0 month) and post-implant (at least at one of the time points during 6-60 months post-implant) as a reference in evaluating the patients' post-implant progress.
Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
Our cochlear implant center uses the products of Cochlear Limited, which is the sponsor of the current study, and it is also possible that we would use the registry proposed in this study when it is available.