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Consider the costs of aiding mild hearing loss in the absence of clear benefits: Response to McCreery and colleagues

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Response to McCreery and colleagues

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Dear Dr Logan,

Re: Letter in Reply (CCH-2017_0423.R1) to Drs McCreery, Moeller, Ambrose, Walker, Oleson and Tomblin (Mild hearing loss is a developmental risk: Response to Carew and colleagues).

We thank the aforementioned authors for their interest and their comments, and are pleased to discuss some points in more detail than was possible in the manuscript itself.

We firstly clarify that we do not conclude children with mild hearing losses are experiencing developmental harm from earlier detection and hearing aid fitting. Such a conclusion would be at odds with our measures of health-related quality of life and behaviour, which show no evidence of change with falling ages at detection and fitting. What we do conclude is that these children do not show clear language development benefits accompanying the consistent trend towards earlier diagnosis and hearing aid fitting.

Our exploration into this “lack of net benefit” (Carter *et al.* 2015) considers two angles. The first is insufficient use of consistent amplification to accrue measurable benefit via “cumulative auditory experience” (Walker *et al.* 2015). The second angle raises ‘harm’ as the logical counter-balance to benefit. In the absence of clear benefit, any potential harm becomes important. However, the term ‘harm’ should not be interpreted solely as ‘developmental harm’. ‘Harm’ may be considered a multi-faceted concept, here covering challenging areas to measure such as treatment burden, stigma, parental discordance creating conflict, and financial imposts both to the family and to society. At the very least, directing resources to ineffective treatments can be considered harmful simply because these resources could have been used to benefit another problem. In this regard, all healthcare has the potential to be harmful.

When considering early amplification of mild losses, are the potential ‘harms’ across these early years of life greater than or less than any benefits to the child? If benefits are not clear, harms and costs should be considered, with questions asked about the optimal management of these children. This is the approach we have taken to interpreting our findings, i.e. for our cohorts of children with mild hearing loss who did not display clear benefits to language outcomes with earlier detection and amplification fitting.

McCreery and Colleagues make specific reference to our use of the terms “over-diagnosis” and “over-treatment”. There is ambiguity amongst clinicians and researchers alike on what these terms mean and how they are applied (Carter *et al.* 2015). These terms do not indicate that no problem exists; rather, they imply that there is a diagnosable condition, and yet identification and efforts to ‘treat’ do not appear to improve outcomes. We use these terms when considering the impact of earlier identification and amplification for mild losses and the cost-benefit balance outlined above.

We acknowledge that conclusive evidence of over-treatment can only be made when the highest quality data demonstrates no benefit resulting from treatment (Brodersen *et al.* 2018). Thus, the possibility of early amplification representing over-treatment for mild hearing loss is indeed that: an important possibility to consider and evaluate in children that are representative of the general population rather than clinical samples.

Our conclusions were drawn using due caution to the acknowledged small sample size of our mature UNHS cohort. Convergence seen in our results across different analysis methods provides reassurance that our conclusions are appropriate, given the level of evidence. McCreery and Colleagues recommend direct statistical comparison between the outcomes of children with mild and moderate losses. This was not the aim of our study. We were examining evidence for changes in outcomes for two degrees of hearing loss across successive population systems of detection, rather than a comparison between two groups of children with hearing loss who are likely to be different for many reasons. As a benchmark of performance, we reported the outcomes of children with mild losses as still not consistently reaching those levels achieved by children without hearing loss.

We are unable to address questions posed regarding hearing aid use and optimisation. Our population cohorts were predominantly from an era when hearing aids did not support automatic recording of usage, nor were parents consistently surveyed about their child's hearing aid use. Therefore, hearing aid use could not be employed within our study framework and aims. This limitation, alongside the issues of potential harm discussed above, is why we have concluded that well-designed randomised controlled trials of early amplification usage for mild loss would be optimal for accurately measuring these factors at a population level. With the current lack of conclusive evidence for broad population efficacy of early versus later aiding for mild hearing loss, ethical considerations of such a trial are not insurmountable. In fact, such trials offer the tantalising opportunity to learn more about the appropriate management approach for all children with early-diagnosed mild hearing loss.

Yours sincerely,

Peter Carew, on behalf of the study authors.

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