NCHA response to NICE consultation: Hearing aids for adults with hearing loss, draft guidance

1. Has all of the relevant evidence been taken into account?

On balance, yes.

NICE appears to have undertaken a reasonable and proportionate assessment of the available evidence within the scope of this evaluation. We therefore have no substantive objection to the evidence identified or to NICE's assessment of its limitations.

We also recognise the difficulty of evaluating the incremental benefit of individual features within an established medical device technology. Hearing aids do not develop in the same way as medicines – e.g. as NICE recognises, features are frequently introduced as part of successive product generations and in combination with other changes, rather than as isolated interventions suitable for individual RCTs.

There are also practical limitations regarding the evidence that might reasonably become available for such technological 'add-ons'. For example, generating sufficiently powered trials capable of isolating small changes in health-related quality of life attributable to an individual feature such as connectivity, rechargeability or a particular form of signal processing would be complex and expensive. In addition, the fact that EQ-5D and other generic QALY tools are not sensitive to hearing loss would still require professional consensus to assign weights and be subject to uncertainty for such features.

Market access (commercial structure, product cycles and supply chains) for medical devices also differ substantially from those for pharmaceuticals. It may therefore be unrealistic to expect an evidence base for every incremental hearing aid feature that is equivalent to those available for a new medicine.

On balance while we agree that NICE has considered the available evidence, we believe the final guidance should make clearer that lack of feature-specific evidence is not uncommon in the medical device sector and such research is complicated to perform for the reasons outlined above.

This distinction is particularly important because NICE's user preference work demonstrates that people value different hearing aid features and that no single feature or collection of features is likely to meet everyone's needs. Some benefits may be highly important to some individuals despite having little measurable effect on generic health-related QoL instruments.

2. Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?

Yes, subject to a qualification concerning how the conclusions are framed.

We understand and broadly support the methodological conclusions reached by NICE given the limitations set out in the public documents. Given the uncertainty around the evidence base on marginal effectiveness, it is reasonable for NICE to conclude that it should not undertake a more detailed cost-effectiveness analysis. While noting, where cost of additional features are not material, then a cost-effectiveness analysis is not necessary in the NHS decision making process.

We are concerned however that the guidance, as it stands, might be misread by some key stakeholders – including NHS commissioners – as a general view on hearing aids and this could result in worsening inequalities.

To mitigate this risk, we would ask that NICE states much more prominently that this assessment does not revisit the established clinical and cost effectiveness of hearing aids as an intervention for hearing loss. That NICE's guideline on hearing loss in adults, NG98, has already considered the clinical effectiveness and health economics of hearing-aid provision. The clinical evidence underpinning NG98 included systematic review evidence supporting the effectiveness of hearing aids, and NICE's economic modelling found hearing-aid provision to be highly cost effective. That this latest NICE assessment is addressing a materially narrower question: whether sufficient evidence exists to estimate the additional or marginal value associated with hearing-aid features compared with devices without those features.

We strongly feel that distinction should appear prominently at the beginning of the final guidance and in its summary and recommendations. We would suggest wording along the following lines:

- "NICE’s guideline on adult hearing loss (NG98) has already established that hearing aids are clinically effective and cost-effective and its recommendation to improve access to hearing care and hearing aids still stands. This latest assessment only considers the available evidence on the clinical benefit and cost effectiveness associated with additional hearing-aid features."

The same caution applies to the cost analysis. For example, NICE estimates that rechargeable devices have higher direct NHS purchasing costs than non-rechargeable devices. However, the assessment also acknowledges that some administrative costs, environmental impacts and user preferences are not captured. It would be helpful if NICE can make clear that the NHS might wish to invest additional resource in rechargeable hearing aids based on environmental considerations, even though there is limited high-quality clinical evidence to demonstrate quality of life gains. The key point is to acknowledge this will require additional investment. In addition, related to rechargeable hearing aids, we would add that

- given the average hearing aid user is aged over 70 and dexterity and sight loss issues are likely to be more prevalent, the benefits of using a rechargeable aid vs having to remove/replace small batteries could have been give more consideration in the analysis (see our response to question four)

- these hearing aids lend themselves to increased reliability – e.g. the battery draw in a conventional hearing aid is an additional part likely to fail and, even if for a short period, this could impact patients.

Similarly, NICE recognises that the remote-management analysis is sensitive to assumptions about the specific service model. Where remote contacts are modelled as additional to usual care there is an additional cost, whereas substituting some face-to-face contacts with remote contacts may generate savings. Hence, NICE findings should not be interpreted as demonstrating that remote management is inherently more expensive, nor should a commissioner assume there is sufficient evidence to justify forcing any provider to deliver remote care first solely on cost reduction methods.

3. Are the recommendations sound and a suitable basis for guidance to the NHS?

We feel that further safeguards are necessary to prevent inappropriate interpretation in NHS commissioning and procurement decisions.

We welcome that NICE acknowledges that user preferences and shared decision making are important. We also welcome NICE clearly setting out limitations in this analysis and transparency on cost analysis etc. Our principal concern however is how recommendations could be misinterpreted by commissioners and procurement teams who are not specialists in health economics or hearing-aid technologies. An ICB or other commissioner could incorrectly interpret the guidance and recommendations. For example:

- It might be used as justification for setting procurement specifications at the lowest possible level, reducing tariffs further, or requiring providers to purchase the lowest-cost devices on the basis that expenditure on alternative features is unsupported by evidence
- It might worsen already misplaced biases about hearing technologies, resulting in further reductions in access and choice for patients. For example, we already see unevidenced indicative activity plans (IAPs) imposed on NHS adult hearing care services and ICBs might misread the current guidance as hearing aids do not work. Of course that is not what NICE has stated, but those not familiar with health economics and not reading this in the context of NICE NG98 (no hearing aid vs hearing aids) and this guidance (hearing aids vs hearing aids with additional features) might miss that.

On balance, it would helpful if the final guidance could make clear that:

1. NG98 continues to apply, including its recommendations to improve access to appropriate hearing care and hearing aids.
2. This evaluation only assesses the incremental value of specified features, not the underlying clinical or cost effectiveness of hearing-aid provision itself.
3. The assessment should not be used to justify commissioning or procurement policies based solely on provision of the lowest-cost or most basic device.
4. Commissioners should continue to, and in doing so enable providers to, take account of clinical need, accessibility, individual circumstances, informed patient preference and shared decision making when determining appropriate hearing-aid provision.
5. Some relevant benefits are outside, or are incompletely captured by, the economic perspective used in this assessment. These may include environmental sustainability, administrative and logistical consequences, accessibility for people with reduced dexterity or sight loss, digital inclusion, independence, convenience and wider social or

economic value. That commissioners should still give due regard to these factors as part of their Public Sector Equality Duty (PSED) given hearing loss is recognised as a disability under the Equality Act 2010.

It would also be helpful for NICE to make more explicit that an NHS purchaser perspective is different from an individual's assessment of value. A feature for which NICE cannot establish a sufficiently robust NHS-ICER may nevertheless have considerable value to an individual hearing-aid user. Questions of individual preference and willingness to pay in self-funded care are of course also separate from NICE's assessment of value from an NHS perspective.

Finally, we welcome NICE acknowledging that potential environmental and user benefits associated with rechargeable devices might not be fully reflected in the cost comparison. The fact that such benefits cannot currently be incorporated robustly within the model should not prevent commissioners from considering them separately when pursuing NHS sustainability objectives or meeting patient needs. However, it is helpful that NICE has confirmed that rechargeable aids cost more as this will help reduce the risk of NHS commissioners imposing such devices without uplifting tariffs.

4. Are there any equality issues that need special consideration and are not covered in the HealthTech consultation document?

Yes. There is a potential health-inequality risk arising from the interpretation and implementation of the guidance, and we ask NICE to consider this explicitly as part of its Public Sector Equality Duty (PSED).

There is a potential downstream equality impact arising from commissioning behaviour in response to this NICE guidance, in particular misunderstanding and/or misapplying this NICE guidance.

If commissioners interpret the findings as evidence that additional hearing-aid features have little or no value, NHS provision could progressively be restricted towards the lowest-cost devices. People able to self-fund hearing care would continue to be better enabled to select devices and features that reflect their individual needs and preferences, while people dependent on NHS provision could have progressively less choice. That could widen existing inequalities, especially given the importance of joint decision making in outcomes for long-term conditions like hearing loss.

There may also be specific groups for whom features that produce small or difficult-to-measure changes in generic quality-of-life scores nevertheless make a substantial practical difference. Examples include people with reduced manual dexterity or sight loss who might struggle to replace small batteries and might benefit from rechargeable hearing aids; people with particular communication or occupational needs who might benefit from enhanced features; and people whose independence or participation is supported by connectivity, remote management or other accessibility features.

NICE's own user preference assessment reinforces the importance of individual choice. The fact that users could not agree a universally optimal set of features should support personalised and shared decision making rather than a conclusion that features have no value. That said we recognise the need for scarce NHS resources to be allocated effectively and that NICE must use a common framework to try and achieve a theoretical efficient allocation of healthcare resources.

On balance, we would ask NICE to consider, as part of its equality duties and final guidance, the foreseeable risk that the assessment could be used to justify:

- inappropriate downward pressure on hearing-care tariffs
- procurement based primarily on minimum device cost
- reduced choice for NHS patients and
- a widening gap between the options available to people accessing NHS-funded care and those able to self-fund.

We would recommend that NICE includes an explicit implementation statement making clear that the absence of sufficient evidence to quantify the incremental cost effectiveness of individual features should not be used, in isolation, to restrict clinically appropriate choice or reduce access to hearing-aid features where these address a person's individual needs, circumstances or preferences. It would also be helpful to note that where patients feel part of the decision-making process – be it deciding on features that they feel will positively impact their own lives – the willingness to continue to use hearing aids could improve compared to feeling a medical device without those discussions/options has been imposed on them. This is because, for reasons set out above, the thresholds of evidence required to properly investigate such features will most likely require state funded clinical trials.

5. You are about to submit your final response to NICE. You must answer the following questions before you submit.

   Are you responding on behalf of an organisation?

Yes

   Do you or the organisation you represent have any links with the tobacco industry?

No