



2021 exceptional surveillance of otitis media (acute): antimicrobial prescribing (NICE guideline NG91)

Surveillance report

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Surveillance decision

We will update the [NICE guideline on otitis media \(acute\): antimicrobial prescribing](#) to consider the role of topical analgesia (anaesthetic ear drops).

Reason for the exceptional review

During development of the NICE guideline, evidence demonstrated that anaesthetic ear drops (in addition to oral analgesics) may relieve pain in children aged 3 years and over without eardrum perforation. At the time no product was licensed for use in the UK and a recommendation could not be made. The analgesic/anaesthetic ear drops, Otigo ear drops (phenazone/lidocaine), became available in the UK in November 2020 and a reassessment is needed.

Methods

- Considering the evidence used to develop the guideline in 2017.
- Literature searches to identify relevant new evidence, including Cochrane reviews.
- Feedback from the managing common infections guideline development committee, discussing the availability of Otigo ear drops.

For further details about the process and the possible update decisions that are available, see [ensuring that published guidelines are current and accurate in developing NICE guidelines: the manual](#).

Evidence used to develop the guideline in 2017

The NICE guideline currently states in the summary of evidence section:

- Anaesthetic ear drops significantly increased the proportion of children with a 50% and a 25% reduction in pain compared with placebo (NNT 5 [range 3 to 16] for 50% pain reduction 10 minutes after receiving ear drops; low quality evidence). This was based on a systematic review and meta-analysis of randomised controlled trials (RCTs; [Foxlee et al. 2011](#)). These children were aged 3 years and over without ear drum perforation and were also receiving oral analgesia, but no antibiotic.
- No adverse effects were observed with anaesthetic ear drops, but this was based on very small numbers of children (low quality evidence; [Foxlee et al. 2011](#)).

The NICE guideline currently states in the rationale:

- Based on evidence, the committee agreed that anaesthetic ear drops (in addition to oral analgesics) may relieve pain in children aged 3 years and over without eardrum perforation, but there is no product licensed for use in the UK.

The Cochrane review included in the NICE guideline ([Foxlee et al. 2011](#)), includes 5 RCTs:

- 1 RCT of 2% aqueous lignocaine drops ([Bolt 2008](#))
- 1 RCT of anaesthetic ear drops containing antipyrine (phenazone), benzocaine and glycerine ([Hoberman 1997](#))
- 3 RCTs of anaesthetic ear drops containing amethocaine, phenazone and glycerine ([Sarrell 2001](#), [Sarrell 2003a](#), [Sarrell 2003b](#)).

Availability of Otigo ear drops

The analgesic/anaesthetic ear drops, [Otigo ear drops](#) (phenazone/lidocaine), became available in the UK in November 2020. Therefore, the statement in the NICE guideline is no longer correct. Given the availability of a product, it may be appropriate to make a recommendation to use analgesic/anaesthetic ear drops in the management of acute otitis media.

Literature searches to identify relevant new evidence

We searched for new evidence related to the use of analgesic/anaesthetic ear drops in acute otitis media from 2011 (the date of the Cochrane review included in the NICE

guideline).

We found 704 studies in a search for systematic reviews and randomised controlled trials published between 1 January 2011 and 23 February 2021. These references were screened using their titles and abstracts and 5 full text references were obtained and assessed for relevance. One study was included as relevant to this surveillance review ([Hay et al. 2019](#)).

The Cochrane review included in the NICE guideline has not been updated since the guideline was published.

There is no clinical information in the [summary of product characteristics for Otigo](#) or [Public Assessment Report](#).

The Public Assessment Report states:

'Results of pre-clinical tests and clinical trials are replaced by detailed references to published scientific literature relating to the reference medicinal product Otipax ear drops, solution which has recognized efficacy and well-studied safety profile in the local symptomatic treatment of pain in the patients with non-perforative diseases of middle ear. Therefore, in terms of efficacy and safety proposed product is expected to behave similar as the reference product, i.e. available published in the literature preclinical and clinical data on Otipax ear drops, solution can be extrapolated to the proposed product. The absence of the results of new clinical trials is justified.'

The Otipax Public Assessment Report (manufactured by Biocodex, France) is not available online.

The RCT identified from the search, the Children's Ear Pain Study (CEDAR; Hay et al. 2019), is a UK multicentre, primary care RCT in children aged 1 to 10 years with acute otitis media and ear pain not requiring immediate antibiotics. Anaesthetic-analgesic ear drops were compared with usual care in an unblinded comparison (n=74) and placebo ear drops or usual care (in a blinded and unblinded comparison, respectively, n=32). The primary outcome was parent-reported antibiotic use and secondary outcomes included ear pain. The study concluded that anaesthetic-analgesic ear drops can reduce antibiotic use in children with acute otitis media but whether they relieved ear pain was not established.

Topic expert feedback

The information considered in this surveillance review was discussed with members of the managing common infections committee at their meeting on 23 March 2021. They were asked whether the availability of Otigo ear drops (and related information in this review) would impact on the recommendations made in the NICE guideline, and to give reasons for their decision.

The view of the committee was that an update to the NICE guideline would be useful now that an analgesic/anaesthetic ear drop is available in the UK. Reasons given were:

- The new evidence in the CEDAR RCT adds to evidence already included in the NICE guideline, that analgesic/anaesthetic ear drops could be beneficial in acute otitis media (taking account of the limitations with this study that reduced antibiotic consumption, but not reduced ear pain was shown).
- During development of the NICE guideline, the committee already agreed (based on evidence) that analgesic/anaesthetic ear drops may relieve pain in children with acute otitis media, but because no product was licensed in the UK at that time they could not make a recommendation for use. The availability of Otigo ear drops means a recommendation for use could be made.
- Ear pain is a key reason for children with acute otitis media presenting in primary care, and is a driver for antibiotic prescribing. Having another option (in addition to oral analgesics), which could reduce ear pain and reduce antibiotic prescribing in this population is clinically useful.

Equalities

No equalities issues were identified during the surveillance process.

Overall decision

Based on evidence included in the NICE guideline, new evidence identified during this surveillance review (the CEDAR RCT), a relevant medicine (Otigo ear drops) becoming available in the UK, and expert feedback, the decision is to update the guideline.

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