### NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

# Interventional procedures consultation document Implant insertion for prominent ears

Ears naturally stand away from the side of the head, but some people's ears stick out more than others. This does not affect hearing but can cause distress if the person is unhappy with the appearance of their ears. Using local anaesthesia, 1 or 2 small curved implants are inserted under the skin of each ear through small cuts. The implants remain in place permanently. The aim is to pull the ears back so they look less prominent.

NICE is looking at implant insertion for prominent ears.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of specialist advisers, who are consultants with knowledge of the procedure.

This document contains the draft guidance for <u>consultation</u>. Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality, eliminating unlawful discrimination, and actively considering the implications of its guidance for human rights. To help us promote equality through our guidance, please consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

IPCD – Implant insertion for prominent ears

Issue date: [May 2019]

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance
- prepare a second draft, which will go through a <u>resolution</u> process before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 20 June 2019

Target date for publication of guidance: September 2019

#### 1 Draft recommendations

- 1.1 Current evidence on the safety and efficacy of implant insertion for prominent ears is inadequate in quality and quantity. Therefore, this procedure should only be used in the context of research.
- 1.2 Further research should include comparisons of this procedure with current best therapy. It should address issues of patient selection, such as age and type of ear shape, nature of ear implants used, long-term efficacy and safety outcomes, and patient reported outcomes using validated quality-of-life measures.

## 2 The condition, current treatments and procedure

#### The condition

2.1 Protruding or prominent ears result when cartilaginous folds fail to form within the ear.

#### **Current treatments**

2.2 Surgery to correct protruding ears aims to reposition the elastic cartilage permanently while preserving a natural appearance.

IPCD – Implant insertion for prominent ears

Page 2 of 4

Issue date: [May 2019]

Cartilage-sparing techniques such as scoring, drilling and suturing of the cartilage may be used. Most techniques involve a post-auricular skin incision, although an incisionless otoplasty has been described.

#### The procedure

- 2.3 This procedure is done under local anaesthesia and uses one or more implants to create or reshape the antihelical fold of the ear, with the aim of correcting any ear prominence resulting from either poor definition or a lack of this fold.
- 2.4 The position of the implant(s) is discussed and agreed with the patient before the procedure and marked on the ear. The implant (a gold-coated curved nitinol device) is inserted using an introducer and released onto the anterior surface of the cartilage, immediately reshaping it and correcting the ear prominence. The incision is closed using 1 or 2 dissolvable sutures, and the wound is then dressed with sterile tape.
- 2.5 One implant is typically used in each ear, but more may be needed.

  The procedure typically takes about 20 minutes for both ears.

#### 3 Committee considerations

#### The evidence

- 3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 2 sources, which was discussed by the committee. The evidence included 2 case series. It is presented in table 2 of the <a href="interventional procedures overview">interventional procedures overview</a>. Other relevant literature is in the appendix of the overview.
- 3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: quality of life and helical-mastoid distance.

IPCD - Implant insertion for prominent ears

Page 3 of 4

Issue date: [May 2019]

3.3 The specialist advisers and the committee considered the key safety outcomes to be: skin erosion over implants and infection.

#### **Committee comments**

- 3.4 Most of the evidence reviewed came from adults. However, in NHS clinical practice, surgical correction of prominent ears is usually done in children and young people.
- The committee was concerned about the reported frequency of skin erosion over the implants.
- The committee noted that the benefits may disappear when the implants are removed.

Tom Clutton-Brock
Chair, interventional procedures advisory committee
May 2019

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