

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Removal, preservation and subsequent reimplantation of ovarian tissue to prevent symptoms from the menopause

Reduced oestrogen levels after the menopause can cause symptoms such as hot flushes, altered mood and fatigue, and can weaken the bones (osteoporosis) and increase the risk of heart disease and stroke. In this procedure, under general anaesthesia, a small piece of ovarian tissue is removed before the menopause using keyhole surgery (laparoscopic). This is then frozen and stored. When menopause starts, the tissue is thawed and transplanted under the skin of the armpit, abdomen, or forearm. The aim is for the transplanted ovarian tissue to produce oestrogen to prevent menopause symptoms.

NICE is looking at removal, preservation and subsequent reimplantation of ovarian tissue to prevent symptoms from the menopause.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts with knowledge of the procedure.

This document contains the [draft guidance for consultation](#). 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 of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics 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 The draft guidance may change after this consultation.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:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance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 [resolution 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: 25 April 2022

Target date for publication of guidance: September 2022

1 Draft recommendations

- 1.1 Evidence on the safety and efficacy of removal, preservation and subsequent reimplantation of ovarian tissue to prevent symptoms from the menopause is inadequate in quality and quantity. Therefore, this procedure should not be done unless it is part of a formal research study, with appropriate governance and ethics approval. Find out [what only in research means on the NICE interventional procedures guidance page](#).
- 1.2 Research should include randomised controlled trials and should report details of:
- patient selection
 - the procedure, including the techniques used for harvesting tissue and cryopreservation, the timing and the frequency of reimplantation of ovarian tissue, the association between the amount of tissue removed and reimplanted and subsequent endocrine function
 - a comparator group who have pharmacological hormone replacement therapy (HRT).
- 1.3 Patient selection should be done by a multidisciplinary team including clinicians with specialist expertise in managing the menopause.
- 1.4 The procedure should only be done by surgeons with specialist expertise in the procedure.

2 The condition, current treatments and procedure

The condition

- 2.1 Menopause occurs with the final menstrual period and is usually diagnosed clinically after 12 months of amenorrhoea. It usually happens when someone is between 45 and 55, although around 1% of people have early (premature) menopause before 40.
- 2.2 As oestrogen levels reduce, most people have some symptoms, which can affect quality of life. Most commonly, these are hot flushes and night sweats. Other symptoms are mood changes, memory and concentration loss, vaginal dryness, a lack of interest in sex, headaches, and joint and muscle stiffness. Menopause can also increase the risk of osteoporosis and cardiovascular disease.

Current treatments

- 2.3 Symptoms can be treated with pharmacological hormone replacement therapy (HRT). For someone with a uterus, HRT usually consists of an oestrogen and a progestogen. For someone who has had their uterus removed, it is usually oestrogen only. HRT aims to replace the hormones that are no longer produced by the ovaries because of menopause. Non-hormonal treatments can also be used.

The procedure

- 2.4 The level of reproductive hormones and ovarian reserve is assessed first. If this is adequate, one-third to one-half of the outer cortex of 1 ovary is removed laparoscopically under general anaesthesia and cryopreserved in thin slices. When menopause starts, a slice of the ovarian tissue is thawed and regrafted under the skin in a heterotopic site (for example, the forearm or axilla) with the aim of restoring normal ovarian endocrine function. The

IPCD – Removal, preservation and subsequent reimplantation of ovarian tissue to prevent symptoms from the menopause Page 4 of 6

transplantation process is reversible and may be repeated to maintain endocrine function. The aim is to prevent the symptoms associated with the menopause.

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 rapid review did not identify any relevant studies.
- 3.2 The professional experts and the committee considered the key efficacy outcomes to be: quality of life outcomes including menopause-specific questionnaires and endocrine function of the implant (including the levels of oestrogen, progesterone and follicle stimulating hormone) in the short and long term.
- 3.3 The professional experts and the committee considered the key safety outcomes to be: laparoscopy-related complications (including pain, bleeding, and infection), reduced fertility (in the period between ovarian tissue removal and reimplantation), and premature menopause.
- 3.4 Patient commentary was sought but none was received.

Committee comments

- 3.5 There was no published evidence for the use of this procedure in otherwise healthy people who wanted to prevent menopause symptoms.
- 3.6 This guidance is specifically to prevent menopause symptoms in otherwise healthy people. It does not cover the use of this procedure to preserve fertility or to prevent menopausal symptoms or premature menopause from iatrogenic (such as cancer

treatment) or non-iatrogenic (such as hereditary or disease) causes.

- 3.7 The committee was informed that pharmacological hormone replacement therapy (HRT) has an established efficacy and safety profile for preventing the symptoms of menopause.
- 3.8 The committee was informed that there is a small risk of significant complications associated with laparoscopy.

Colin Howie

Vice-chair, interventional procedures advisory committee

March 2022