# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Interventional procedures consultation document

# Maximal effort cytoreductive surgery for advanced ovarian cancer

Ovarian cancer has usually reached an advanced stage when it is detected. Maximal effort cytoreductive surgery (also known as extensive or ultra-radical surgery) for advanced ovarian cancer aims to improve outcomes for people with advanced ovarian cancer by removing all or almost all visible cancerous tissue. More tissue is removed than with standard surgery. As well as removing the ovaries, fallopian tubes and womb, tissue from the spleen, liver, diaphragm, peritoneum and bowel may also be removed.

NICE is looking at maximal effort cytoreductive surgery for advanced ovarian cancer. This is a review of NICE's interventional procedures guidance on ultra-radical (extensive) surgery for advanced ovarian cancer.

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This document contains the draft guidance for consultation.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 The draft guidance may change after this consultation.**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- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance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.



Issue date: October 2022

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: 17 November 2022

Target date for publication of guidance: April 2023

# 1 Draft recommendations

1.1 Evidence on the safety and efficacy of maximal effort cytoreductive surgery for advanced ovarian cancer is adequate to support using this procedure provided that standard arrangements are in place for clinical governance, consent and audit. Find out what standard arrangements mean on the NICE interventional procedures guidance page.

1.2 Patient selection should be done by a specialist gynaecological cancer multidisciplinary team, which may include surgeons from other specialities.

1.3 The procedure should be done by a team of surgeons with appropriate expertise. The procedure should only be done in accredited specialised units.

1.4 For auditing the outcomes of this procedure, the main efficacy and safety outcomes identified in this guidance can be entered into NICE's interventional procedure outcomes audit tool (for use at local discretion).

# 2 The condition, current treatments and procedure

## The condition

2.1 Early symptoms of ovarian cancer can be similar to those of other pelvic or abdominal conditions and include persistent bloating, pain in the pelvis and lower abdomen, urinary frequency and urinary urgency. Ovarian cancer is usually at stage 3 or 4 when it is diagnosed and the outcome is generally poor. The overall 5-year survival rate for ovarian cancer is about 43%, and is lower for people with more advanced disease. The stage of the disease at diagnosis is the most important factor affecting outcome and is

defined by the International Federation of Gynecology and Obstetrics (FIGO) system:

- Stage 1 (A to C) – the tumour is confined to the ovary.
- Stage 2 (A, B) – the tumour involves 1 or both ovaries and has extended into the pelvis.
- Stage 3 (A to C) – the tumour involves 1 or both ovaries with microscopically confirmed peritoneal metastasis outside the pelvis or regional lymph node metastasis (if cancer cells are found only in fluid taken from inside the abdomen the cancer is stage 2).
- Stage 4 (A, B) – there is distant metastasis beyond the peritoneal cavity (if ovarian cancer is only found on the surface of the liver and not within the liver itself, then the cancer is stage 3).

2.2 The FIGO stage does not take into account the distribution of disease within the abdomen or the volume of the disease. Therefore FIGO stage 3C can range from a single cancer deposit of more than 2 cm on the omentum to widespread intra-abdominal disease where cancer is present on the surface of the large bowel, small bowel, spleen, diaphragm, liver and across the peritoneum.

## Current treatments

2.3 NICE's guideline on ovarian cancer describes the initial management options. The main treatments for advanced ovarian cancer are surgery to remove all macroscopic residual disease (also known as debulking) and chemotherapy. Standard surgery usually involves, as a minimum, bilateral salpingo-oophorectomy, total abdominal hysterectomy and omentectomy. Maximal effort cytoreductive surgery uses additional surgical procedures including upper abdominal surgery, with the aim of achieving no residual disease. The most important factors affecting outcomes after treatment are responsiveness to platinum-based chemotherapy

and the amount of cancer left behind at the end of cytoreductive surgery (residual disease).

2.4 Conventional imaging techniques cannot accurately predict the distribution or volume of disease before surgery. Therefore, the only definitive assessment of the distribution or volume of disease found in the abdomen and pelvis is done at the time of surgery. Currently, no objective tools exist to select people for surgery and a decision for surgery will depend on many factors including fitness, patient choice, availability of surgeons with appropriate expertise, and resource levels.

## The procedure

2.5 The aim of maximal effort cytoreductive surgery for advanced ovarian cancer is to remove all identifiable disease, to improve survival compared with standard surgery. It is a development and extension of surgery for ovarian cancer.

2.6 The precise differences between standard, radical and maximal effort cytoreduction procedures are not well defined. Surgical complexity scores, such as the Aletti system, have been developed to try to quantify the complexity of surgery. Each procedure that is done during the surgery is allocated a score:

- Total hysterectomy and bilateral salpingo-oophorectomy=1
- Omentectomy=1
- Pelvic lymphadenectomy=1
- Paraaortic lymphadenectomy=1
- Pelvic peritoneum stripping=1
- Abdominal peritoneum stripping=1
- Rectosigmoidectomy anastomosis=3
- Large bowel resection=2
- Diaphragm stripping or resection=2
- Splenectomy=2

- Liver resection=2
- Small bowel resection=1

The total score can then be used to categorise the surgery into low complexity (1 to 3), intermediate complexity (4 to 7) or high complexity (8 and above).

# 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 13 sources, which was discussed by the committee. The evidence included 2 systematic reviews, 9 cohort studies, 1 non-randomised comparative study and 1 case series. It is presented in the summary of key evidence section in the interventional procedures overview. Other relevant literature is in the appendix of the overview.

3.2 The professional experts and the committee considered the key efficacy outcomes to be: overall survival, progression free survival, residual tumour after surgery and quality of life after surgery.

3.3 The professional experts and the committee considered the key safety outcomes to be: perioperative death, organ failure, thromboembolism, wound complications and unanticipated need for stoma.

3.4 Fourteen commentaries from people who have had this procedure were discussed by the committee.

## Committee comments

3.5 The committee noted that in the published literature different terms have been used to describe this procedure, such as ultra-radical, extensive and maximal effort cytoreductive surgery.

3.6 The procedure involves extensive surgery with a risk of significant complications including death.

3.7 There needs to be detailed preoperative assessment of the person's fitness to have maximal effort cytoreductive surgery and postoperative arrangements should include the availability of intensive care.

3.8 The extent of disease may not be apparent until surgery has started and it may be that maximal effort cytoreductive surgery is not possible.

3.9 The committee noted that the surgical techniques used in this procedure have evolved since the last NICE interventional procedures guidance on this procedure was issued.

3.10 There have been developments in chemotherapy and other systemic treatments for ovarian cancer since the last NICE interventional procedures guidance on this procedure was issued.

3.11 The committee encourages centres doing this procedure to submit data to an appropriate register.

3.12 The committee was pleased to receive patient commentary and to have a representative from a patient organisation at the meeting.

Tom Clutton-Brock
Chair, interventional procedures advisory committee
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