

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

**Interventional procedures consultation document**

**Cytoreduction surgery with hyperthermic intraoperative peritoneal chemotherapy for peritoneal carcinomatosis**

Peritoneal carcinomatosis is cancer that has spread from other parts of the body to the lining of the abdominal cavity (peritoneum). This may lead to bowel obstruction, accumulation of fluid and pain.

There are 2 parts to this procedure which is done under general anaesthesia. The first part is cytoreductive surgery, which removes all the visible cancer. The second part is chemotherapy during the surgery (intraoperative). The abdominal cavity is bathed with heated (hyperthermic) chemotherapy fluid to reach any cancer cells the surgery may have missed. This fluid is drained at the end of the procedure. The aim is to reduce symptoms and improve quality of life.

This is a review of NICE's interventional procedures guidance on [cytoreduction surgery followed by hyperthermic intraoperative peritoneal chemotherapy for peritoneal carcinomatosis](#).

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts, who are consultants 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This document contains the [draft guidance for consultation](#).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 The draft guidance may change after this consultation.**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- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance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 September 2020

Target date for publication of guidance: February 2021

## 1 Draft recommendations

- 1.1 Evidence on the safety of cytoreduction surgery with hyperthermic intraoperative peritoneal chemotherapy for peritoneal carcinomatosis shows frequent and serious but well-recognised complications. Evidence on its efficacy is limited in quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. Find out [what special arrangements mean on the NICE website](#).
- 1.2 Clinicians wishing to do cytoreduction surgery with hyperthermic intraoperative peritoneal chemotherapy for peritoneal carcinomatosis should:
- Inform the clinical governance leads in their NHS trusts.
  - Give patients and their carers clear written information to support [shared decision making](#), including [NICE's information for the public](#).

- Ensure that patients and their carers understand the risk of complications and death, the need for intensive care after the procedure, the long recovery period, and the uncertainty about the procedure's efficacy, which need to be balanced against the perceived benefit.
- Audit and review clinical outcomes of all patients having the procedure. NICE has identified relevant audit criteria and is developing an audit tool (which is for use at local discretion), which will be available when the guidance is published.

- 1.3 Patient selection should be done by an experienced multidisciplinary team.
- 1.4 The procedure should only be done in highly specialised centres by clinicians with specialist expertise and specific training in cytoreduction surgery and hyperthermic intraoperative peritoneal chemotherapy.
- 1.5 NICE encourages further research in the form of randomised controlled trials. These should clearly describe the patient selection criteria, the types of cancer being treated and the chemotherapy regimens used. Outcomes should include survival, reduction in tumour burden and quality of life.
- 1.6 NICE may update the guidance on publication of further evidence.

## **2 The condition, current treatments and procedure**

### **The condition**

- 2.1 Peritoneal carcinomatosis is an advanced form of cancer resulting from the regional spread of gastrointestinal, gynaecological and other malignancies and is associated with short survival and poor quality of life. It may lead to bowel obstruction, ascites and pain.

## Current treatments

- 2.2 There is no curative treatment. Current standard treatment is short-term palliation of complications such as bowel obstruction using systemic chemotherapy (alone or with surgery), closed peritoneal instillation of chemotherapy or surgery alone.

## The procedure

- 2.3 Cytoreduction surgery is done to remove all macroscopic tumours within the abdominal cavity. Hyperthermic intraoperative peritoneal chemotherapy is then used to distribute a chemotherapeutic drug uniformly to all surfaces within the abdominal cavity and to increase drug penetration. This is done to treat any remaining microscopic traces of the cancer. The aim is to reduce symptoms, extend survival and improve quality of life.
- 2.4 Using general anaesthesia, a laparotomy is done and all macroscopic tumour is removed, with resection of involved organs and stripping of the tumour from the surface of some organs and peritoneum. The surgery, which is extensive and complex is followed by perfusion of the abdominal cavity with a heated (between 40 and 48°C) chemotherapy solution for 30 to 120 minutes. The fluid is drained from the abdominal cavity before closure. A further course of systemic or early postoperative intraperitoneal chemotherapy (EPIC) may be administered.

## 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 10 sources, which was discussed by the committee. The evidence included 5 meta-analyses, 4 systematic reviews and 1 randomised

controlled trial. It is presented in [table 2 of 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: survival and improvement in quality of life (physical and emotional).
- 3.3 The professional experts and the committee considered the key safety outcomes to be: post-operative haemorrhage, peri-operative mortality, anastomotic leaks, sepsis, pain, re-admission to an intensive care unit and the need for further surgery.
- 3.4 Two commentaries from patients who have had this procedure were discussed by the committee.

### **Committee comments**

- 3.5 The committee noted that this procedure is unlikely to be curative and may be offered to patients for whom cure is not the intention. Therefore, it is important that patients are clearly informed that the procedure is associated with significant peri-procedural morbidity including often prolonged treatment in an intensive care unit and long-term postoperative recovery.
- 3.6 The committee was informed that the degree of resectability of disease is important in determining the outcome but criteria for this have not been clearly established.
- 3.7 The committee noted that hyperthermic intraoperative peritoneal chemotherapy has no standardised protocol and protocols are continuing to evolve. Variations in the drug regimens include temperature, dose, duration of infusion time, and whether a drug is used on its own or in combination with other drugs.

- 3.8 The committee noted that there have been large improvements in survival and quality of life for patients with metastatic cancer in recent years because of advances in systemic chemotherapy. This made it difficult to assess the benefits of hyperthermic intraoperative peritoneal chemotherapy.
- 3.9 The committee noted that outcomes are different depending on the type of tumour being treated.

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