CANCERS OF THE PERITONEUM – CARCINOMATOSIS

PREFERRED MODEL OF CARE AND CRITERIA FOR REFERENCE CENTRES

Coordinator:	Alex Kartheuser (Colorectal Surgery, Cliniques universitaires St-Luc, UCL)
Authors :	Alex Kartheuser (Colorectal Surgery, Cliniques universitaires St-Luc, UCL), Noella Bletard (Pathology, CHU – ULg), Wim Ceelen (Surgery, UZ Gent), Carla Coimbra (Colorectal Surgery, CHU – ULg), Etienne Danse (Radiology, Cliniques universitaires St-Luc, UCL), André d'Hoore (Colorectal Surgery, UZ Leuven), Alexandra Dili (Surgery, Entité Jolimontoise), Bertrand Filleul (Oncology, Entité Jolimontoise), Gabriel Liberale (Surgery, Bordet – ULB), Anne Mourin (Pathology, Cliniques universitaires St-Luc, UCL), Laura Polastro (Oncology, Bordet – ULB), Eric Van Cutsem (Gastroenterology / Oncology, UZ Leuven), Kurt Van der Speeten (Colorectal Surgery, ZOL Genk), Jaarke Vannoote (Gastroenterology, ZOL Genk).
Reviewers :	Collard Annabelle (Psychologist, Bordet – ULB), Eva Pape (Oncology Nurse Specialist, UZ Gent)

Disclaimer :

- **The coordinators of the working groups and all the authors listed by chapter have worked autonomously under the supervision of the KCE team. The KCE experts are not co-authors of these proposals and did not necessarily validate their content.**
- **Hospitals with which coordinators and authors of these proposals are affiliated are not de facto considered Reference Centres. Similarly, Belgian hospitals that are not represented in these proposals are not de facto considered Peripheral Centres.**
- **These proposals were not submitted to the external validators.**
- **This addendum only exists in English. No French or Dutch translation was done.**
- **Finally, the report to which this addendum refers has been approved by common assent by the Executive Board.**

PREFERRED MODEL OF CARE AND CRITERIA FOR REFERENCE CENTRES

A. Type of cancer

Peritoneal metastases from adenocarcinoma of the colon-rectum. Rare peritoneal tumours.

B. Short description of the cancer

Colorectal cancer (CRC) is one of the commonest causes of cancer related death in developed countries. Peritoneal carcinomatosis of colorectal origin affects 13% of patients with colorectal adenocarcinoma. Systemic chemotherapy offers no long term survival with median survival around 15.2 months in a recent trial (CAIRO II). Prognosis is very poor with poor quality of life of patients in their terminal stages of disease. The combination of cytoreductive surgery and Hyperthermic Intraperitoneal Peroperative Chemotherapy (HIPEC) has resulted in encouraging results both in Phase II and III trials.

C. Model of care pathway suggested for adult patients with colorectal peritoneal carcinomatosis

Model of care pathway	Preferred model
1. Model 1: Reference Centres exclusively (from diagnosis to follow-up). Once there is a suspicion of colorectal peritoneal carcinomatosis or colorectal peritoneal carcinomatosis has been diagnosed, the patient should be referred to a Reference Centre. A network with other Reference centres or with specific experts working in other centres is encouraged.	
2. Model 2: Shared care between Reference Centres and peripheral hospitals. Part of the care pathway is performed in the Reference Centre and for another part of the care pathway, the patient is referred (back) to the peripheral hospital	X

D. Phase(s) of the clinical pathway for which Reference Centres are required

Phase of the Clinical Pathway	Reference Centre	Peripheral centre
MOC	X	X
Diagnostic confirmation (AP and/or medical imaging)	X	X
Comprehensive AP diagnosis	X	
Therapeutic modalities	X	
Follow-up	X	X

Multidisciplinary Oncological Consult

Reference centre. Expert team should establish the indication for surgery or palliative chemotherapy based on diagnostic information provided by the Peripheral or Reference Centre. All patients should be discussed in MOC in a Reference Centre.

Diagnostic confirmation

Diagnostic confirmation is in the scope of general as well as expert radiological centres if there are radiologists having an abdominal subspecialisation

- Complexity and new approaches: Standard diagnostic modalities needed
  - Based first on high quality CT and/or high quality MRI
  - PET-CT strongly recommended
- Facilities and equipment required
  - Imaging (CT, MRI, PET), surgery (laparoscopy, laparotomy), pathology
- Professional expertise required both to perform the diagnostic procedure and to interpret the results
  - Abdominal surgeon, radiologist, nuclear physician, pathologist

Comprehensive AP diagnosis

- Complexity and new approaches
  - Standard pathologic modalities (light microscopy, immunohistology, molecular biology)
- Facilities and equipment required
  - Standard pathology and molecular biology lab
- Expertise required both to perform the cell or tissue sampling and to interpret the results
  - Pathologist with expertise in colorectal cancer

Therapeutic modalities:

- Complexity: Need for trained team in surgical approach
- Facilities and equipment required: Surgical suites, need for HIPEC equipment (CE agreement), ICU, chemotherapy unit
- Expertise required to perform the treatment: Surgeon with established training in cytoreductive surgery and HIPEC, Anesthesiologist and ICU physicians with experience in intra-operative and peri-operative care of HIPEC patients
- Para-medical expertise required:
  - operating room and ICU nurses with experience in HIPEC
  - perfusionist
  - stoma nurses
  - specialists in psycho-oncology
  - physiotherapist
  - nutritionist

Follow-up

- Complexity: Standard follow-up
- Facilities and equipment required: Standard follow-up modalities (lab, CT...)
- Medical expertise required: Medical oncologist or GI oncologist
- Para-medical expertise required: Standard follow-up

E. General and specific criteria for Reference Centres

Human Resources and dedicated team

- Surgical team, anesthesiologist, ICU physician, pathologist, GI oncologist, radiologist
- Nutrition team
- Stoma nurses
- Support team
- HIPEC trained operating room and ICU nurses, perfusionist
- Multidisciplinary management per guidance of the MOC.

Required facilities and equipment

- *Surgery*
  - CE approved chemo-perfusion apparatus; adequate protocols and organization in place to allow intra-operative administration of chemotherapy
  - The team should have access to a CE certified perfusion machine. Use of 'custom made' solutions (without formal certification) should probably be discouraged.
  - The team should implement a formal safety procedure including written guidelines (handbook), training of staff, and communication with local workplace safety representatives regarding safe handling of cytotoxic drugs in the operating room and in the postoperative phase. When using open abdomen perfusion, adequate care should be taken to protect the operating room environment.
- *Radiotherapy*
- *Chemotherapy*
  - HIPEC perfusion machine, pharmacy accredited for chemotherapy preparation
- *Interventional imaging*
  - Both diagnostic and therapeutic interventional radiology
- *Intensive care unit*

Patient centred care

- Waiting and throughout times: Review of referred patient within two weeks (including review of imagery, pathology and MOC). Operating waiting list under 6 weeks.
- Continuity of care: At least one surgeon experienced with peri-operative complications and care of HIPEC patients on call at all time.
- Support services for the patient: HIPEC care coordinator, structured patient information (website, brochures, etc.…)
- National and international networking with other Reference Centres: Dedicated referral pattern and protocol for external (national and international) patients.

Minimal volume of patients

- Number of patients
  - 10 patients per year.
  - at least 50 HIPEC performed in the last 5 years for all types of indications.
- Number of second opinions (annual volume of referrals and second opinions): 10 per year

Quality Assurance

- Compulsory prospective registration of quality indicators (indications, treatment, incidents and complications, re-interventions, 30-day mortality, 1, 3 and 5 year survival, permanent stoma rate)
- Compulsory registration with the Cancer Registry
- Compliance with existing guidelines and documentation of deviations from guidelines: Implementation of KCE guidelines on HIPEC
- Involvement in quality initiatives (e.g. benchmarking)
- Annual activity report ensuring transparency (e.g. number of new patients / type of cancer; diagnostic, treatment and outcome data; specific protocols for reporting and recording complications...)
  - All teams should keep a prospective database of all procedures including indications, complications (Dindo Clavien system), and outcome. Ideally, this should be a shared web based database. For Belgian patients, reimbursement should probably be conditional on delivery of a minimal clinical dataset, or on providing data to a central, government organized database.

Research and other scientific activities

Referral centre should be able to demonstrate participation in international research protocols

- Involvement in clinical studies (RCTs, Cohort studies, translational studies) in the field of carcinomatosis or HIPEC
- Active participation in national and international scientific and educational efforts
- Publications in peer-reviewed journals: At least one peer reviewed, PubMed cited publication in the field of carcinomatosis and/or HIPEC
- Compulsory link with a tumour bank
- Compulsory development of clinical practice guidelines for diagnosis and care

Educational activities: Teaching and dissemination

Established active participation in scientific and educational efforts in the HIPEC field