



## ECCO Essential Requirements for Quality Cancer Care: Colorectal Cancer. A critical review



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ABSTRACT

*Background:* ECCO essential requirements for quality cancer care (ERQCC) are checklists and explanations of organisation and actions that are necessary to give high-quality care to patients who have a specific tumour type. They are written by European experts representing all disciplines involved in cancer care.

ERQCC papers give oncology teams, patients, policymakers and managers an overview of the elements needed in any healthcare system to provide high quality of care throughout the patient journey. References are made to clinical guidelines and other resources where appropriate, and the focus is on care in Europe.

**Colorectal cancer: essential requirements for quality care**

- Colorectal cancer (CRC) is the second most common cause of cancer death in Europe and has wide variation in outcomes among countries. Increasing numbers of older people are contracting the disease, and treatments for advanced stages are becoming more complex. A growing number of survivors also require specialist support.
- High-quality care can only be carried out in specialised CRC units or centres which have both a core multidisciplinary team and an extended team of allied professionals, and which are subject to quality and audit procedures. Such units or centres are far from universal in all European countries.
- It is essential that, to meet European aspirations for comprehensive cancer control, healthcare organisations implement the essential requirements in this paper, paying particular attention to multidisciplinary and patient-centred pathways from diagnosis, to treatment, to survivorship.

*Conclusion:* Taken together, the information presented in this paper provides a comprehensive description of the essential requirements for establishing a high-quality CRC service. The ECCO expert group is aware that it is not possible to propose a 'one size fits all' system for all countries, but urges that access to multidisciplinary units or centres must be guaranteed for all those with CRC.

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## Preamble

ECCO essential requirements for quality cancer care (ERQCC) are checklists and explanations of organisation and actions that are necessary to give high-quality care to patients who have a specific tumour type.

They are primarily organisational recommendations, not clinical guidelines, and are intended to give oncology teams, patients, policymakers and managers, an overview of the elements needed in any healthcare system to provide high quality of care throughout the patient journey. References are made to clinical guidelines and other resources where appropriate, and the focus is on care in Europe.

The foundation of this ECCO requirements series is the concept of quality, which has become increasingly important in all aspects of healthcare, as the population has increasing number of older people needing care, as many new and complex treatments come into use, and as more pressure is put on using resources effectively. Policymakers and patients need to know that their healthcare workforce, technology and facilities are configured optimally for each illness. In this context, improving quality of cancer care means delivering care that is timely, safe, effective and efficient; puts the patient at the centre of care; and gives all people equal access to high-quality care.

The structure of the ECCO ERQCC series is the same for each tumour type:

- Introduction: why we need cancer quality frameworks
- Key facts and challenges associated with the tumour type from diagnosis to treatment
- Organisation of care: an overview of the patient pathway and overall requirements to deliver care
- Multidisciplinary working: in more detail, the requirements for core and 'expanded' teams involved in the patient pathway
- Measurement and accountability: quality assurance and audit, patient involvement and access to information.

### *Essential requirements for quality cancer care: colorectal summary points*

- Colorectal cancer (CRC) is the second most common cause of cancer death in Europe and has wide variation in outcomes among countries. Increasing numbers of older people are contracting the disease, and treatments for advanced stages are becoming more complex. A growing number of survivors also require specialist support.
- High-quality care can only be carried out in specialised CRC units or centres which have both a core multidisciplinary team and an extended team of allied professionals, and which are subject to quality and audit procedures. Such units or centres are far from universal in all European countries.
- It is essential that, to meet European aspirations for comprehensive cancer control, healthcare organisations implement the essential requirements in this paper, paying particular attention to multidisciplinary and patient-centred pathways from diagnosis, to treatment, to survivorship.

## 1. Introduction: why we need quality frameworks

There has been a growing emphasis on driving up quality in cancer organisations, given that there is wide agreement that much care is not accessible, not well coordinated and not based on current evidence. This is the starting point of a report by the US Institute of Medicine (IOM) in 2013 (Levit et al., 2013), which is blunt in describing a 'crisis in cancer care delivery', as the growing number

of older people will mean rising cancer incidence and numbers of survivors, while there are pressures on workforces amid rising costs of care and complexity of treatments.

Not least, the IOM notes that the few tools currently available for improving the quality of cancer care – quality metrics, clinical practice guidelines, and information technology – are not widely used and all have serious limitations.

An assessment of the quality of cancer care in Europe was made as part of the first EU Joint Action on Cancer, the European Partnership for Action Against Cancer (EPAAC, <http://www.epaac.eu>), which reported in 2014 that there are important variations in service delivery between and within countries, with repercussions for quality of care. Factors such as waiting times and provision of optimal treatment can explain about a third of the differences in cancer survival, while cancer plans, such as with a national cancer plan that promotes clinical guidelines, professional training and quality control measures, may be responsible for a quarter of the survival differences.

EPAAC paid particular attention to the importance of providing multidisciplinary care for each tumour type, going as far as to issue a policy statement (Borras et al., 2014) that emphasised the importance of team working, as cancer care is undergoing a 'paradigm shift' from a disease-based approach to a patient centred one, in which increasingly more attention is paid to psychosocial aspects, quality of life, patients' rights and empowerment, comorbidities and survivorship. EPAAC further focused on the establishment of networks of expertise in regions where it is not possible to establish comprehensive centres.

The EU Joint Action on Cancer Control (CANCON, <http://www.cancercontrol.eu>), which replaced EPAAC from 2014, is also focusing on quality of cancer care and is due to publish in 2017 the *European Guide on Quality Improvement in Comprehensive Cancer Control*.

Countries have been concentrating expertise for certain tumour types in dedicated centres, or units, such as for childhood and rare cancers, and most comprehensive cancer centres have teams for the main cancer types. For common adult tumours, however, at European level there has been widespread effort to establish universal, dedicated units only for breast cancer, following several European declarations that set a target of the year 2016 for such care of all women and men with breast cancer to be treated in specialist multidisciplinary centres. While this target has been far from met (Cardoso et al., 2016), the view of ECCO's essential requirements expert group is that the direction of travel is for all main tumour types to adopt the principles of such dedicated care.

For colorectal cancer (CRC), this means establishing the care pathways and multidisciplinary teams that are described in this document, and also the same approach to auditing, quality assurance and accreditation of a 'unit' than is emerging in breast cancer, and indeed for CRC in some European countries.

## 2. Colorectal cancer (CRC): key facts and challenges

### 2.1. Key facts

- CRC is a common cancer and the second most common cause of cancer death in Europe (after lung cancer). In 2012, about 447,000 new cases and 215,000 deaths from CRC were estimated, which was 12.2% of all deaths from cancer in Europe (Ferlay et al., 2013a).
- CRC is the second most common cancer in women and the third in men, although the number of men who are diagnosed and die each year in Europe is higher than women (in 2012, there were

about 242,000 new cases in men, 205,000 in women; deaths in that year were 113,000 and 101,000). The risk of contracting CRC for people under the age of 75 in 2012 was 3.51% in Europe (4.48% men, 2.73% women) (Ferlay et al., 2013b).

- In 2012, the 5-year prevalence of CRC (those alive 5 years after diagnosis), was about 1.2 million in Europe, showing that there is a large population of survivors. The 5-year survival rate for Europe was 57% for colon and 56% for rectal cancer according to the Eurocare-5 study (Holleczek et al., 2015). The 5-year survival rate is associated with the stage of CRC at diagnosis, broadly: 90% for local stages, 50% for disease that has spread to lymph nodes, and 10–20% for metastatic disease.

### 2.1.1. Risk factors and prevention

- Risk factors include family history, including inherited disorders; a history of polyps in the bowel and inflammatory bowel disease; lifestyle factors; and age: more than 90% of CRC is diagnosed in people in their 50s and older.
- The risk of developing CRC can be reduced by:
  - Avoiding obesity and weight gain around the midsection
  - Not smoking
  - Increasing the intensity and amount of physical activity
  - Limiting intake of red and processed meats
  - Eating more vegetables and fruits
  - Getting the recommended levels of calcium and vitamin D
  - Avoiding excess alcohol
  - See for example: American Cancer Society. Can colorectal cancer be prevented? <http://www.cancer.org/cancer/colonandrectumcancer/detailedguide/colorectal-cancer-prevention>.

### 2.1.2. Screening

- CRC is one of the few cancers that have evidence for population screening (breast and cervical are the others). Most CRC develops from benign polyps, which can be removed during a colonoscopy. In 2003, the Council of the European Union called on member states to implement screening programmes for CRC in all EU countries.
- The ECCO expert group supports the importance of screening in the prevention and early detection of CRC and also calls on EU member states to ensure that appropriate policies are adopted across Europe to ensure that efficient CRC screening programmes are implemented.

### 2.1.3. Diagnosis and treatment

- Symptoms that often lead to a diagnosis of CRC are change in bowel habit, anaemia, fatigue, rectal bleeding and an abdominal mass. However, as most patients are asymptomatic, screening is of great importance.
- Investigations to detect CRC are colonoscopy, sigmoidoscopy (for the lower colon) and computed tomography (CT) colonography (also called virtual colonoscopy). Biopsy and imaging/pathology reports confirm a diagnosis and the stage of the disease – like most cancers, CRC is categorised into four clinical stages according to Union for International Cancer Control (UICC) classification, from localised to the lining of the colon (stage 1) to spread to other organs (stage 4, or metastatic disease).
- Treatment: most patients with localised (early and locally advanced) CRC have surgery to remove the tumour and any affected lymph nodes. Radiotherapy is used pre-operatively in rectal cancer, but not often in colon cancer as too much healthy tissue can be exposed. Chemotherapy is usually offered post-operatively to people with localised disease with lymph node involvement to reduce the risk of a recurrence. Patients with metastatic disease should receive systemic treatment, including

targeted therapies, depending on characteristics of their disease (including molecular biology). In selected cases, treatment for metastatic disease can include local treatment (surgery, radiotherapy, interventional radiology) and can aim to be curative.

## 2.2. Challenges in CRC care

### 2.2.1. Inequalities

- Countries in Eastern and Central Europe have the lowest survival rates for CRC. In the Eurocare-5 study (Ferlay et al., 2013a), the highest 5-year survival for colon cancer was found for patients in Belgium, Germany and Iceland (62%) and lowest for patients in Latvia (43%) (but lower survival than the 57% European average was also observed for patients in Denmark (54%) and Croatia (50%)). For rectal cancer, the highest survival was for patients in Belgium and Switzerland (63%) and lowest for those in Latvia (36%), but low survival was also observed for Croatia (49%) and Slovenia (50%).
- Discrimination by age is significant in CRC because the majority of cases are among older people – about 60% of cases are in those aged 70 and over, with the highest incidence in people in their mid- to late-80s. Providing the current standard of care to older people in all cancers is important and is particularly challenging in CRC, because of the numbers and because there can be several co-morbidities to manage, and consistent partnership with geriatric specialists can be needed.

### 2.2.2. Diagnosis and screening

- Embarrassment and stigma: in some countries and cultures there can be a reluctance to bother doctors, usually primary care GPs, with symptoms of CRC. There is potential to do much more awareness raising on CRC that can involve policymakers, health professionals and patient groups.
- Screening programmes differ widely across Europe. Only a minority of countries have rolled out population screening; others have 'opportunistic', pilot or no programmes.

### 2.2.3. Treatment

- CRC, as one of the major cancers, is treated by a wide range of healthcare providers but not necessarily by multidisciplinary units and according to guidelines and recognised care pathways.
- Some patients with metastatic CRC can be cured but do not always get the multidisciplinary assessment they should. For the majority of metastatic CRC patients, who cannot be cured, treatment is particularly challenging because of the complex and wide range of treatment options, and for which there are varying grades of evidence of effectiveness. Awareness and availability of treatment options such as targeted therapy also varies among and within countries. In CRC, this is exemplified by campaigns that promote greater awareness of metastatic disease options and testing for biomarkers to determine whether certain therapies are beneficial (for example, Get Personal, <http://www.getpersonal.global>).

### 2.2.4. Survivorship

- The number of cancer survivors is rising quickly, and some CRC survivors suffer for many years from ongoing conditions that result from the primary treatment of their cancer, such as a permanent stoma, bowel and urinary problems, and sexual dysfunction (Jansen et al., 2011). Specialist supportive care for a growing population of CRC survivors is becoming a major issue.

### 3. Organisation of care

Essential requirements for the organisation of CRC care encompass:

- Cancer care pathways
- Timelines of care
- Minimum case volumes
- Multidisciplinary teamworking among core and extended groups of professionals, in a dedicated CRC centre or unit
- Audit, performance measurement, quality assurance of outcomes and care
- Professional education, enrolment in clinical trials and delivery of patient information.

These topics are outlined in the following sections, with reference to national and European resources and clinical guidelines, where appropriate.

#### 3.1. Care pathways and timelines

- Care for colorectal cancer patients should be organised in care pathways that chart the patient's journey from their perspective rather than that of the healthcare system. (The European Pathway Association defines a care pathway as "a complex intervention for the mutual decision making and organisation of care processes for a well-defined group of patients during a well-defined period". This broad definition covers terms such as clinical, critical, integrated and patient pathways that are also often used. See <http://e-p-a.org/care-pathways>.) Pathways should incorporate current evidence set out in national and European guidelines. An exemplar of a CRC pathway is the National Institute for Health and Care Excellence (NICE) pathway (NICE Pathways, Colorectal cancer overview. <http://pathways.nice.org.uk/pathways/colorectal-cancer>). As the NICE guidance makes clear, the overall pathway for CRC comprises only a few main subsidiary pathways – suspected CRC and referral, information and support for patients, diagnosis, staging, and cancer treatment management.
- Primary care practitioners are the usual referrers of those with suspected CRC and need timely access to hospital specialists and typically a diagnosis is established by endoscopy. In England and Wales, the maximum time for an appointment to check suspected symptoms of all cancers is 2 weeks (NICE Pathways. Suspected cancer recognition and referral: Gastrointestinal tract (lower) cancers. <http://bit.ly/2gzGU58>). Suspected CRC identified through faecal occult screening programmes is referred in the same time (2 weeks). Other countries have shorter targets: in the Netherlands, the maximum time for an appointment when a malignancy is suspected is 1 week. The ECCO expert group strongly recommends that countries ensure that waiting times are below these times as is the case in several European countries that make urgent referrals within 48 h.
- A comprehensive examination of screening and diagnosis is available in 'European guidelines for quality assurance in colorectal cancer screening and diagnosis' (European Commission, 2010). In England and Wales, about 10% of patients with CRC are currently diagnosed through screening, and 55% following GP referral (Healthcare Quality Improvement Partnership, 2015).
- Times to report a diagnosis of CRC and the opportunity to start treatment are crucial to the wellbeing of patients to avoid as much anxiety as possible. Guidelines in the Netherlands, for example, state that the maximum time for diagnostic and staging procedures is 3 weeks, and the maximum time from first appointment to first treatment is 6 weeks.
- After a diagnosis, it must be clear to the patient which professional is responsible for each step in the treatment pathways and

who is following the patient during the journey (usually called a case manager or patient navigator). In many countries, case managers during the main stages of treatment are cancer nurses (Borras et al., 2014), with some being specialists in CRC. There must also be a medical professional responsible for coordinating treatment modalities and specialties, namely the lead oncology specialist. This is usually a surgeon or medical oncologist, depending on local agreements and the stage of the disease.

- Some patients with CRC present as emergencies with an intestinal obstruction or perforation (this can be a significant number in some countries – about 20% of CRC patients in England and Wales). While it is preferable for these patients to be treated by the colorectal team from the start, this is often not possible but care must be transferred to the colorectal team straight after the emergency procedure.
- Follow-up and survivorship are major issues in CRC. Typically, care pathways include surveillance for cancer recurrence but patients often have to seek help elsewhere for long term side-effects of treatment, by going to both acute and community facilities. Continuity and integration of all care must be implemented as gaps in long-term care can cause much distress (Jansen et al., 2010).

#### 3.2. CRC centres/units: requirements

- It is essential for all patients to be treated in a multidisciplinary centre; that members of the multidisciplinary team see a certain annual number of cases; and that members of the core team dedicate significant time to treating patients with CRC, although requirements vary according to the various disciplines. Based on the existing evidence, the ECCO expert group recommends that for a hospital to be considered as a CRC centre it should manage at least 100 new CRC cases a year.
- There are three patient categories that usually require different levels of expertise and infrastructure:
  - Uncomplicated primary colorectal cancer
- Locally advanced or recurrent disease
- Metastatic disease.
- The expertise required for advanced cases often concerns certain surgery, radiotherapy and specialist interventions, and a CRC unit that does not have this expertise or facilities should have close referral cooperation with centres that provide them.
- All CRC units must have a follow-up programme in place in accordance with guidelines.

#### 3.3. The multidisciplinary team

Treatment strategies for all patients must be decided on, planned and delivered as a result of consensus among a core multidisciplinary team (MDT) that comprises the most appropriate members for the particular diagnosis and stage of cancer, patient characteristics and preferences, and with input from the extended community of professionals. The heart of this decision making process is normally a weekly or more frequent MDT meeting where patients are discussed with the objective of balancing the recommendations of clinical guidelines with the 'reality' of the individual patient.

To properly treat CRC it is essential to have a core MDT of dedicated health professionals from the following disciplines:

- Gastroenterology/endoscopy
- Pathology
- Radiology/imaging
- Surgery

- Radiotherapy
- Medical oncology
- Interventional radiology
- Nursing.

This core MDT must discuss:

- All new patients after diagnosis and staging to decide on optimal treatment
- Patients after major treatment, usually surgery, to decide on further treatment (such as adjuvant chemotherapy) and follow-up
- Patients with a recurrence during follow-up to decide on optimal treatment.

In CRC, there are certain patients who do not need to be discussed at a full MDT meeting:

- Cases with a clear decision algorithm, such as early tumours (T1 stage disease), and advanced adenomas (benign polyps in the colon) usually require only gastroenterologists, pathologists and surgeons
- Those with widespread and incurable metastatic disease may need only radiologists, radiation oncologists, surgeons, medical oncologists and palliative care specialists.

The pre-requisite is a clinical pathway for each category that also determines when patients must be discussed at a full multi-disciplinary tumour board.

Healthcare professionals from the following disciplines must be available whenever their expertise is required (the 'expanded' MDT):

- Nuclear medicine
- Oncology pharmacy
- Geriatric oncology
- Psycho-oncology
- Diet and nutrition
- Palliative care
- Rehabilitation and survivorship
- Neuro-oncology.

All discussions have to be minuted and decisions documented in a comprehensive and understandable manner, and should become part of patient records. Weekly MDT meetings must be minuted and the annual internal audit must be incorporated into quality learning systems as they develop.

It is essential that all relevant patient data, such as pathology reports, meet quality standards and are available at the time of the MDT meeting.

#### 4. Disciplines within the core MDT

##### 4.1. Gastroenterology and endoscopy

The role of the gastroenterologist/endoscopist is to:

- Advise on all means of primary and secondary prevention of CRC
- Perform relevant colonoscopies (including after surgery if needed) and palliative procedures when required, such as colonic stents
- Treat polyps and early lesions
- Identify and follow up patients at high risk for of developing CRC
- Manage long- and short-term gastrointestinal side-effects of treatment

- In some countries and settings, gastroenterologists are also responsible for systemic therapy (see also section on medical oncology).
- A gastroenterologist/endoscopist must have a qualification in diagnostic and interventional colonoscopy (e.g. according to number of procedures performed a year, completeness of procedures, adenoma detection rate, number of polyps removed, as specified by country regulations) (Kamiński et al., 2014; Rees et al., 2016; Bretthauer et al., 2016).
- In countries where systemic treatment of gastrointestinal cancer is carried out by gastroenterologists, they must have a qualification and expertise in the systemic treatment of CRC and the management of side-effects (e.g. as demonstrated by a certain number of chemotherapeutic cycles and targeted agents given each year). They must also follow up after surgery to make sure that adjuvant treatment, for example, is applied whenever it is indicated.

##### 4.2. Pathology

Pathology, including molecular pathology, is playing an increasingly critical role in the diagnosis of CRC. The role of the pathologist is to conduct a detailed study of the tumour based on the sample taken from the biopsy and to prepare a pathology report for discussion at the MDT.

Essential requirements:

- The pathologist must have expertise in reporting on CRC preoperative biopsies and surgical specimens: they must know recently published guidelines and reviews on pathological CRC reporting (Nagtegaal, 2015) and their pathology reports must contain a list of items as recommended by professional organisations (Quirke et al., 2011). The use of structured (or synoptic) reports is strongly encouraged (see examples from the Royal College of Pathology in the UK and the Royal College of Pathologists of Australasia) (Loughrey et al., 2014; Royal College of Pathologists of Australasia, 2013).
- With the increasing importance of molecular data in therapeutic decisions, access to an accredited molecular pathology laboratory must be guaranteed, although it may not be on site.

##### 4.3. Radiology/imaging

Radiology/imaging plays a critical role in diagnosing (including screening), staging and follow-up of CRC, and personalised treatment. The role of the radiologist is to perform radiology procedures for screening, diagnosis, staging and follow-up of CRC using the most appropriate imaging test depending on the clinical scenario (including cancer location and clinical presentation, i.e., emergency, elective).

Essential requirements:

- The radiologist must have expertise in gastrointestinal imaging
- For rectal cancer, they must know the advantages and limitations of -trans-rectal ultrasound and magnetic resonance (MR) imaging in primary staging and must be able to integrate imaging data with colonoscopy data. They must also know how to assess response after neoadjuvant rectal cancer therapy. This is an evolving area where integration of radiologic, clinical and endoscopic data is mandatory (Beets-Tan et al., 2013)
- As colon cancer staging is based mainly on computed tomography (CT) findings, knowledge of state-of-the-art CT protocols, including CT colonography (also called virtual colonoscopy) (Neri et al., 2013) is required. Expertise in liver contrast-enhanced ultrasound (CEUS) and MR imaging, with the use of hepato-specific contrast agents, is also needed as these methods may be neces-

sary to characterise a focal liver lesion and to provide a disease balance before surgery for liver metastases (van Kessel et al., 2012)

- The radiologist must know when to refer a patient to nuclear medicine for positron emission tomography (PET)-CT. In that case, nuclear medicine physicians and radiologists must liaise to allow joint patient management, reading and reporting.

#### 4.4. Surgery

Treatment of primary presentation of CRC requires surgery in 80–90% of patients. For patients with metastatic disease and local recurrence, surgery can also be an important part of the treatment. The role of the surgeon is to coordinate the surgical procedure and perioperative care and to perform appropriate surgery as decided in the MDT. In addition, the surgeon can also be the lead oncology specialist who coordinates treatment modalities, mostly in patients who are treated with curative intent.

Essential requirements:

- Surgeons must have expertise in the type of CRC operations they carry out, as there are different requirements for surgical treatment according to the tumour. There are no current guidelines on the minimum number of procedures for each surgeon, but some countries recommend minimum numbers per centre, for example Dutch guidelines state that 50 colonic resections and 20 rectal resections per year per institution should be a minimum requirement for surgery. Locally advanced rectal cancer and metastatic CRC procedures on the liver, lung and peritoneum must be carried out in centres that have the required infrastructure, with a minimum volume of 20 surgical procedures for each procedure (Van Leersum et al., 2013; SONCOS (Dutch foundation for oncological collaboration), 2016; National Institute for Health and Care Excellence, 2014; Are et al., 2016)
- There must be at least two experienced colorectal surgeons who dedicate a significant proportion of their time to colorectal procedures, including cancer surgery
- There must be perioperative care programmes that include anaesthesiologists, nurses and dieticians
- An intensive care unit must be available on-site.

#### 4.5. Radiotherapy

Radiotherapy is often used before surgery in rectal cancer to facilitate curative resection with clear margins and to reduce the risk of local recurrence. It can be selectively used after surgery in a small minority of patients with high risk factors for local recurrence who did not receive pre-operative treatment. Decision-making is multidisciplinary and takes many factors into account (Valentini et al., 2014; Glimelius et al., 2013; National Institute for Health and Care Excellence, 2014). Radiotherapy can also help control cancers in people who are not healthy enough for surgery or to ease (palliate) symptoms in people with advanced cancer that has caused an intestinal blockage, bleeding or pain.

Radiation oncologists are responsible for patients' ongoing care and wellbeing, according to these clinical situations. They also determine and prescribe the most suitable dose fractionation of radiation in keeping with national and international guidelines.

Essential requirements:

- Access to radiotherapy must be provided in the centre or through a formal, collaborative agreement
- The radiotherapy centre must have agreed protocols for radiotherapy and concurrent chemo-radiotherapy for rectal cancer

and clearly describe their image guidance policy and quality assurance guidelines

- Access to 3D conformal RT and IMRT, where clinically indicated, must be available and delivered according to clearly defined protocols. Centres must have access to stereotactic ablative radiotherapy (SABR) where clinically indicated and according to agreed referral and treatment guidelines
- Radiation oncologists must be responsible for follow-up and management of late toxicity and survivorship issues. Protocols must be in place for the management of late toxicity including bowel, urinary and sexual dysfunction.

#### 4.6. Medical oncology

Medical oncology plays an important role in the general management of CRC patients – and specifically of CRC patients with advanced and metastatic disease (stages 3 and 4) and in selected high-risk patients with stage 2 disease. In these situations, the medical oncologist is the lead oncology specialist. The role of the medical oncologist is to:

- Coordinate all aspects of multimodal drug treatment, which may include coordination of clinical and molecular diagnostics, and indication setting and distribution of treatment with systemic therapies (such as chemotherapy, monoclonal antibodies, signal-transduction inhibitors and, potentially in the future, immunotherapies) and to carry out indication setting for multimodal treatment and discuss treatment goals with the patient and other professionals
- Initiate and coordinate symptom-related management in cooperation with specialists who manage tumour or disease-related symptoms (palliative and symptomatic treatment), and rehabilitation and survivorship.

Essential requirements:

- Medical oncologists treating CRC must have in-depth understanding of the prognostic and predictive clinical and molecular factors that contribute to indication setting and treatment intensity and duration of drug therapies. These factors comprise both clinical risk factors and molecular factors and must be considered with clinical goals and other, non-disease related factors and patient preferences. Medical oncology for CRC is increasingly complex, as evidenced in the latest clinical guidelines for metastatic disease (Labianca et al., 2013; Glimelius et al., 2013; Van Cutsem et al., 2016)
- They must have in-depth knowledge of the interaction of cancer specific treatments with other conditions (such as comorbidities and their management). This includes supportive treatment for management of pain, gastrointestinal symptoms and side-effects of systemic therapy.

#### 4.7. Interventional radiology

Interventional radiology plays a central role in the treatment of patients with metastatic CRC. The role of the interventional radiologist is to:

- When indicated, perform biopsies on unclear hepatic, pulmonary or musculoskeletal lesions
- Participate in the MDT to support combined therapies in patients with metastatic disease, e.g. surgery and ablation or systemic treatment and radioembolisation (for the latter, with the nuclear medicine physician)

- Perform minimally-invasive therapies according to the MDT's decision.

Essential requirements:

- The interventional radiologist must discuss the role and propose use of local ablative techniques for treating liver or lung or bone metastases not amenable to, or combined with, surgery or radiotherapy
- They must be able to perform not only percutaneous thermal ablation (e.g. radiofrequency, microwave), but also transarterial bland or transarterial chemoembolisation (including drug-loaded particles), radioembolisation (e.g. yttrium-90 labelled particles) and cementoplasty (Gillams et al., 2015; Tanis et al., 2012; de Baère et al., 2015). A minimum of 100 interventions a year is required for the German Certificate of Interventional Radiology.

#### 4.8. Nursing

Nursing a person with CRC requires a range of roles. Nurses use communication, technical and observation skills to conduct a holistic assessment to identify and then address physical, psychological and social needs throughout the care pathway. They promote patient autonomy and self-management where possible, through personalised information and support. Due to the increasing complexity of care, there is a requirement for highly-specialised cancer nursing (National Cancer Action Team, 2010; Macmillan Cancer Support, 2011). Extended nursing roles for CRC (often known as nurse practitioners) are now common in some countries and they include performing endoscopy, stoma care, and delivering systemic treatments and survivorship care, including organising surveillance on consequences of treatment.

Essential requirements:

- Nurses working in CRC centres must have insight into each patient's experience of their disease, treatment and side-effects
- They must provide information and education to the patient and family and be the point of contact for them where they act as case managers
- Nurses must act in the best interest of the patient and their family to help coordinate the diagnosis, treatment and after-care of a person with CRC
- They must represent the patient's psychosocial needs and preferences within the MDT
- Nurses must help make referrals to other services, such as to a psychologist if there is a concern about distress.

### 5. Disciplines in the expanded MDT

#### 5.1. Nuclear medicine

There is evidence for the efficacy of FDG-PET and FDG-PET/CT in selected clinical indications in CRC for restaging (detection of local recurrence (Maas et al., 2011), metastases (Maffione et al., 2015), local recurrence or metastases in the case of rising tumour markers with negative first-line imaging with CT/MRT); and treatment response evaluation (assessment of response of metastases after chemotherapy, early assessment of metastases during chemotherapy, assessment of efficacy of neoadjuvant therapy for advanced rectal carcinoma, assessment of efficacy of localised minimally invasive therapy).

The role of the nuclear medicine physician is to oversee all aspects of PET/CT for patients who require this procedure, including

indications, multidisciplinary algorithms and management protocols (Boellaard et al., 2015).

Essential requirements:

- Nuclear medicine physicians with expertise in PET must be available to the MDT. In 2016, most European hospitals have access to PET/CT technology but it should preferably be on-site, be less than 10 years old and ready for radiation treatment planning, and have integrated PACS/RIS and updated workstations
- Conventional nuclear medicine must also be available
- Nuclear medicine must be able to perform daily verification protocols and to react accordingly. Quality-assurance protocols must be in place. An option for ensuring the high quality of PET/CT scanners is provided by the European Association of Nuclear Medicine (EANM) through EARL accreditation.

#### 5.2. Geriatric oncology

As 60% of CRC patients are more than 70 years old and 43% over 75 and given that older individuals may require adapted care and prioritisation of health issues, geriatric oncology plays an important role in care. The role of the geriatric oncologist is to:

- Ensure that older patients are screened for frailty
- Coordinate recommendations to other specialists about the need for personalised treatment for frail patients.

Essential requirements:

- Geriatric oncologists must ensure all older patients are screened with a simple risk-assessment frailty screening tool (Decoster et al., 2015) with whenever possible an estimation of life expectancy to allow prioritisation of medical interventions (for example with the ePrognosis colorectal screening survey. <http://cancerscreening.eprognosis.org/screening>)
- A 'geriatric oncology team' (including geriatricians and other specialists) must be available for all frail patients and their evaluation discussed in MDT meetings to offer personalised treatment (Papamichael et al., 2015)
- Geriatric oncologists must ensure the early integration of palliative care plans or 'geriatric interventions', especially for frail patients
- Organ preservation strategies for frail rectal cancer patients must be discussed and implemented at the MDT. This includes a number of strategies with reduced invasiveness such as transanal surgical techniques, 'watchful waiting' approach after chemoradiation or locally applied endocavity contact radiation therapy.

#### 5.3. Oncology pharmacy

Oncology pharmacy plays a critical role in the care of CRC patients, given the importance of systemic treatment. The role of the oncology pharmacist is to:

- Liaise with the medical oncologist to discuss pharmaceutical treatment
- Supervise the preparation of oncology drugs.

Essential requirements:

- Oncology pharmacists must work closely with medical oncologists. They must have experience with interactions with other drugs (CRC patients are often older people and so are likely to have comorbidities); experience with dose adjustments based on liver and kidney function; and knowledge of complementary and alternative medicines. Oncology pharmacists must comply with



the European QuapoS guidelines (European Society of Oncology Pharmacy, 2014)

- Oncology drugs must be prepared in the pharmacy and dispensing must take place under the supervision of the oncology pharmacist

#### 5.4. Psycho-oncology

About 30% of colorectal cancer patients suffer from severe psychosocial distress: 60% reported mild to severe levels of depression, and 52% mild to severe levels of anxiety (Mehnert et al., 2014). These conditions can negatively affect clinical factors such as treatment compliance, quality of life and survival. Reduced cognitive and sexual function, and fatigue, can be long-term effects in patients with colorectal cancer even years after diagnosis and treatment, disrupting psychosocial wellbeing (El-Shami et al., 2015).

The role of the psycho-oncologist is to:

- Ensure that psychosocial distress, psychological disorders and psychosocial needs are identified by screening, and considered by the MDT
- Promote effective communication between patients, family members and healthcare professionals
- Support patients and family members to cope with multifaceted disease effects
- Evaluate psychosocial care programmes.

Essential requirements:

- Access to a self-administered psychological assessment tool ('distress thermometer') and psychosocial care must be guaranteed at all stages of the disease and its treatment
- Psycho-social care for patients and their families must be provided by psycho-oncologists to ensure comprehensive cancer care.

#### 5.5. Diet and nutrition

Qualified nutritional specialists are required in the pre-, peri- and postoperative settings of CRC, and also during adjuvant treatment of advanced CRC. The role of the nutritional specialist is to prevent or treat malnutrition, improve or stabilise the nutritional state, maintain performance status, support the tolerability of therapeutic measures, and so positively influence the course of disease (Arends et al., 2016; Bozzetti et al., 2009).

Essential requirements:

- Nutritional advice must be given to minimise side-effects after surgery such as intestinal discomfort, lack of appetite and risk of malnutrition
- The nutritionist must perform regular nutritional screenings, starting with the first presentation of the patient, to determine a compromised nutritional state as soon as possible. The screening should use validated instruments such as NRS-2002, MUST or SGA
- In cases of malnutrition, a structured assessment must be performed including assessing food intake, total and lean body mass (e.g. by BIA analysis), performance status and systemic inflammation (e.g. by assessing CRP and/or albumin levels in blood)
- The nutritionist must also determine the reasons for compromised food intake and take appropriate measures to counteract them. This includes enteral and parenteral nutrition in the hospital and at home.

#### 5.6. Palliative care

More than one third of the CRC patients suffer from incurable disease and need palliative care in conjunction with cancer treatments to manage distressing clinical complications and symptoms, and improve their quality of life and that of their families (Temel et al., 2010; Quill and Abernethy, 2013; Hui et al., 2015). Palliative care, as defined by the World Health Organization, applies not only at end of life but throughout cancer care (see <http://www.who.int/cancer/palliative/definition/en>).

The role of the palliative specialist is to:

- Be responsible for specialist palliative care and make recommendations to other specialists about symptom control and other conditions
- Identify patients who need palliative care through the systematic assessment of distressing physical, psychosocial and spiritual problems
- Treat disease and treatment-related symptoms such as pain, bowel dysfunction and dyspnoea, and offer psychosocial and spiritual care
- Incorporate support for family members
- Provide early integrated palliative care in conjunction with cancer specific treatments
- Provide end-of-life care, working with primary care palliative care providers.

Essential requirements:

- There must be a palliative care unit with a specialist team that includes palliative care physicians and specialist nurses, working with social workers, chaplains, psychotherapists, physiotherapists, occupational therapists, dieticians, pain specialists and psycho-oncologists
- All CRC patients with severe symptoms or suffering, or patients with metastatic disease and short life expectancy (under a year), irrespective of the cancer-specific treatment plan, must be introduced to a specialist palliative care team
- To ensure the continuity of care at home, the palliative care team must work with primary care providers.

#### 5.7. Rehabilitation and survivorship

Survivorship, rehabilitation and supportive care are major issues for CRC patients and are increasing in importance as the number of survivors rises. Some CRC survivors suffer for many years from ongoing conditions that result from the primary treatment of their cancer, such as a permanent stoma, bowel and urinary problems, and sexual dysfunction.

Late-effects from treatments and how patients' lives are affected are not well understood. Cancer rehabilitation is crucial in helping people adapt to their condition and maximise function, independence and quality of life. It is every professional's responsibility to anticipate rehabilitation needs before treatment and offer appropriate rehabilitative care to prevent, restore, support or palliate (Stubblefield et al., 2013; Berg et al., 2016; Scott et al., 2013).

Return-to-work remains an important topic for many cancer patients when they are identified as 'cured' cases. Work is not only an issue with financial implications, but can also help patients to feel better psychologically.

Essential requirements:

- A multidisciplinary team involving clinicians, nurses, psychologists and physiotherapists must discuss with patients how their

functioning will develop as the treatment goes and the types of help available for them, e.g. physical activity.

- Patients and their families must also be informed about potential treatment late-effects and how these can be monitored and tackled, e.g. through good post-treatment care and regular screening
- Rehabilitation and survivorship must be integrated into care pathways to ensure the best possible care continues beyond active curative treatment
- Professionals must use a person-centred, goal-setting approach, empowering the patient and their carers to take control of their rehabilitation
- Professionals need to adjust their psychosocial and other supportive care keeping in mind the problems faced by CRC cancer survivors, including ostomy/bowel problems (McMullen et al., 2016) sexual concerns (Downing et al., 2015) and fatigue (Mota et al., 2012)
- Employers and trade unions must encourage early discussions about the possibilities for employees to return to work after sick leave, such as changing job duties and working hours
- Rehabilitation and survivorship of cancer must be integrated into national cancer plans.

### 5.8. Neuro-oncology

Colorectal cancer can metastasise into the brain, although rarely. Other types of CRC metastasis relevant to neurology are to the spinal cord, and also local spread involving nervous tissue (e.g. the sacral plexus). A frequent nervous system side-effect from certain CRC drugs is peripheral neuropathy (Grisold et al., 2012; Park et al., 2013) which is not always reversible and late effects are increasingly observed in long-term survivors. Sensory symptoms, clumsiness, ataxia and neuropathic pain are other disabling symptoms.

The role of the neurologist is to:

- Advise and guide in metastasis to the nervous system
- Advise on neurotoxic effects of chemotherapy
- Assess and treat neuropathies, and take part in pain analysis and treatment (in several countries these can also be the responsibility of pain specialists).

Essential requirements:

- For patients presenting with neurotoxic effects access to a neurologist must be guaranteed, not necessarily on site
- Neurologists must assess neurologic symptoms and treatment effects in CRC patients, with a focus on toxicity and changes/side-effects on the central nervous system (CNS) and peripheral nervous system. The use of simple composite scores for neuropathies is recommended.

## 6. Other essential requirements

### 6.1. Patient involvement, access to information and transparency

- Patients must be involved in every step of the decision-making process. Their satisfaction with their care must be assessed throughout patient care pathways. It is also essential that patient support organisations are involved whenever relevant. Patients must be offered information to help them understand the treatment process from the point of diagnosis. They must be supported and encouraged to engage with their health team to ask questions and obtain feedback on their treatment wherever possible.

- Conclusions on each case discussion must be made available to patients and their primary care physician. Advice on seeking second opinions must be supported.
- Cancer healthcare providers must publish on a website, or make available to patients on request, data on centre/unit performance, including:
  - Information services they offer
  - Waiting times to first appointment
  - Pathways of cancer care
  - Numbers of patients and treatments at the centre
  - Clinical outcomes
  - Patient experience measurements
  - Incidents/adverse events.

### 6.2. Auditing, performance measurement, quality assurance and accreditation

- The expanded MDT must meet at least once a year to review the activity of the previous year, discuss changes in protocols and procedures, and improve the performance of the unit/centre.
- To properly assess quality of CRC care, three categories of outcomes must be measured and collected in a database at the level of the CRC centre, and regionally and/or nationally:
  - Clinical outcomes
  - Process outcomes
  - Patient-reported outcomes (PROs).

Data measured and collected varies from one country to another but it is recommended that the following outcome data are systematically measured and collected (see also 'Further quality and audit resources', below):

- 5-year overall survival rate
- Complications
- % of preoperative patients discussed in the MDT
- % of postoperative patients discussed in the MDT.

The expert group also recommends that centres develop performance measurement metrics based on the essential requirements in this paper.

- The ECCO expert group also recommends that further attention must be given to patient reported outcome measures (PROMs), to not only agree on which tools should be used, but also to use PROs more systematically as part of discussions and evaluation within the MDT.

To ensure appropriate, timely and high-quality care, a quality management system (QMS) must be in place. It must involve clinical care, strategic planning, human resource management, training etc. The QMS must be accountable at an institutional management level and based on written and agreed documentation such as guidelines, protocols, patient pathways, structured referral systems, and standard operating procedures (SOPs).

The QMS must ensure continuity of care for patients, involvement of patients in cancer care pathways, and reporting of patient outcomes and experience. As part of a QMS, an effective data management and reporting system, and an internal audit system, are necessities. Where available, external national audit and certification systems are to be followed. The ECCO expert group also strongly recommends participation in international accreditation programmes (e.g. Organisation of European Cancer Institutes (OECI) accreditation: see <http://oei.selfassessment.nu/cms/>) (Wind et al., 2016).

At European level, a consortium of cancer societies, including ECCO, have started a quality improvement programme, European

Registration of Cancer Care (EURECCA), which has initially focused on colorectal cancer. A paper from 2014 (Breugom et al., 2014) notes that audits have most commonly focused on surgery, and on rectal surgery in particular, owing to poor outcomes in the 1990s. Several country audit programmes are mentioned – the longest standing is the Norwegian Colorectal Cancer Project, which began in 1993. EURECCA has been identifying a core dataset for audit registries, and held a consensus meeting to draw up CRC multidisciplinary guidelines (van de Velde et al., 2014).

It is noted that quality assurance is high in clinical trials of CRC, such as when research was carried out on combining radiotherapy with total mesorectal excision (TME) surgery in rectal cancer, and indeed quality assurance is most advanced in surgery generally. The EURECCA 2014 paper notes that patients treated in trials have better outcomes, and discusses how quality assurance is developing in other disciplines such as radiation oncology, pathology and medical oncology – in the latter, some studies have indicated that about half of patients have received non-evidence based schedules.

And not least, quality assurance applies to the management of MDTs and also to demonstrating cost-effectiveness of quality improvements.

#### 6.2.1. Further quality and audit resources

- The National Bowel Cancer Audit in England and Wales (Healthcare Quality Improvement Partnership, 2015) reports on care pathways, referral sources, how patients are treated, the outcomes of surgery and survival, and will include linkages to chemotherapy, radiotherapy and palliative care databases. It uses quality standards from both NICE and the Association of Coloproctology of Great Britain and Ireland.
- Germany has a voluntary certification system for cancer institutions including those that qualify as a multidisciplinary bowel cancer centre. This system currently covers about half of colon cancers and the majority of rectal cancers treated in Germany. The certification guideline for CRC has 197 qualitative and quantitative requirements, such as minimum surgery volumes, as discussed in a paper that concludes that certification leads to a better concentration of treatment-related issues (Jannasch et al., 2015). There are regular benchmark reports (Wesselman et al., 2014) on the performance of these centres on all items audited annually, and quality indicators are regularly reported and updated. Another requirement for certification is that 5% of CRC patients are included in clinical trials.
- The Dutch Surgical Colorectal Audit in hospitals in the Netherlands increased guideline compliance for diagnostics, pre-operative multidisciplinary meetings and standardised reporting, while complication, re-intervention and postoperative mortality rates decreased significantly (Van Leersum et al., 2013).
- A study that developed evidence-based quality indicators for CRC in a population setting was published by a Swiss group in 2013 (Bianchi et al., 2013). An important message is that older people must be included.
- A systematic review of the literature on patterns of CRC care in Europe, Australia and New Zealand found there is less treatment for older people and for the less well-off, although wide variability in data collection, health systems and populations made comparisons challenging (Chawla et al., 2013).

#### 6.3. Cancer education and training

It is essential that each CRC centre provides professional clinical and scientific education on the disease and that at least one person is responsible for this programme. Healthcare professionals working in CRC must also receive training in psychosocial oncology, palliative care, rehabilitation and communication skills. Such train-

ing must also be incorporated into postgraduate and undergraduate curriculums for physicians, nurses and other professionals.

#### 6.4. Clinical research

Centres treating CRC must have clinical research programmes (either their own research or as a participant in programmes led by other centres). The research portfolio should have both interventional and non-interventional projects and include academic research.

The MDT must assess all new patients for eligibility to take part in clinical trials at the centre or in research networks. For CRC, centres should have at least 10% of all patients included in their research projects or in research performed in other centres. Researchers at other centres should be considered as part of the expanded MDT for at least annual discussion of clinical trial participation. Recent research demonstrates that institutions active in research achieve better outcomes for the entire patient group rather than just the research participants (Downing et al., 2016).

Older adults are currently underrepresented in cancer clinical trials despite having a disproportionate burden of disease (Kaźmierska, 2013). Strategies to increase the participation of older adults in clinical trials must be implemented and trials designed to take into account their needs.

#### 7. Conclusion

Taken together, the information presented in this paper provides a comprehensive description of the essential requirements for establishing a high-quality CRC service. The ECCO expert group is aware that it is not possible to propose a 'one size fits all' system for all countries, but urges that access to multidisciplinary units or centres must be guaranteed for all those with CRC.

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