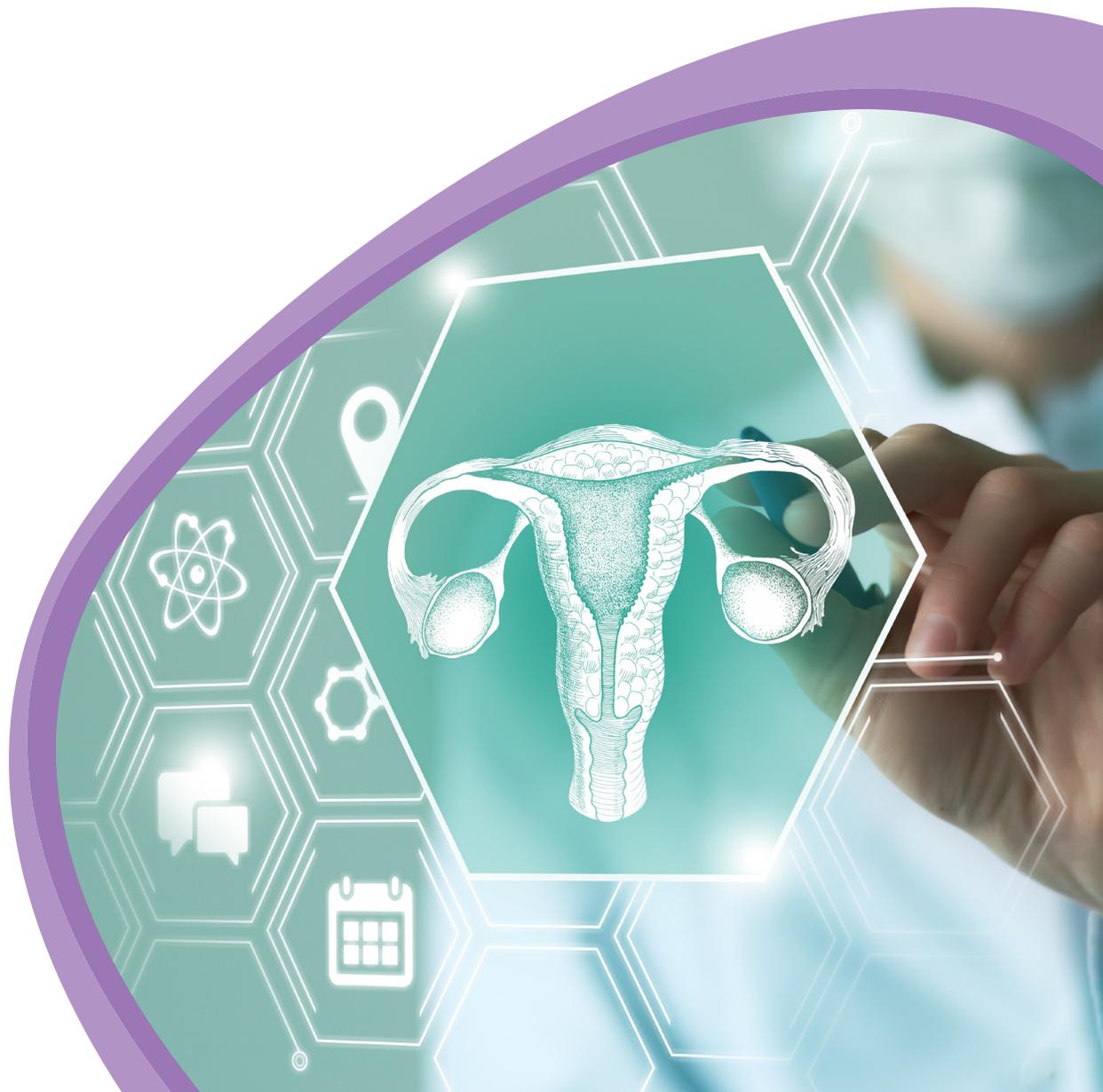




# Essential Requirements for Quality Cancer Care: Ovarian



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## Abstract

European Cancer Organisation Essential Requirements for Quality Cancer Care (ERQCC) are written by experts representing all disciplines involved in cancer care in Europe. They give patients, health professionals, managers and policymakers a guide to essential care.

Ovarian cancer continues to have low cure rates and has wide variation in treatment and care in Europe and beyond. It has a complex treatment that should be carried out in specialised ovarian/gynaecological cancer centres by professionals with the appropriate expertise interacting in a multidisciplinary team (MDT) as described here.

Such centralisation is still not well established in many European countries. A patient-centred pathway from diagnosis through treatment to survivorship, managed in dedicated centres, is key to achieving optimal care and a successful clinical outcome.

European Cancer Organisation essential requirements for quality cancer care (ERQCC) are descriptions and explanations of challenges, organisation and actions that are necessary to give high quality care to patients with a specific tumour type.

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# Introduction

## The Need for Quality Frameworks

There has been a growing emphasis on increasing quality in cancer care given variations in outcomes in Europe. The European Code of Cancer Practice ([european-cancer.org/2-standard/67-about-the-european-code-of-cancer-practice](http://european-cancer.org/2-standard/67-about-the-european-code-of-cancer-practice)), produced in 2021 by a partnership of patients, advocates and oncology professionals, has recognised disparities in the quality of cancer management and sets out 10 rights that patients should expect from their healthcare systems for optimal care throughout their journey.<sup>1</sup>

This has followed an assessment of the quality of cancer care in Europe as part of the first EU Joint Action on Cancer, the European Partnership for Action Against Cancer (EPAAC, <http://www.epaac.eu>), which reported important variations in service delivery between and within countries, with repercussions in quality of care. Quality of cancer services such as short waiting times and provision of optimal treatment can explain about a third of the differences in cancer survival among countries, while variations in cancer policies including the implementation of a national plan and clinical guidelines, professional training and quality control measures, may be responsible for a quarter of the survival differences.<sup>2</sup> EPAAC provided a European Guide for Quality National Cancer Control Programmes published in 2015 for improving each European country cancer outcomes.<sup>3</sup>

The EU Joint Action on Cancer Control (CANCON), which replaced EPAAC, also focused on quality of cancer care and in 2017 published the **European Guide on Quality Improvement in Comprehensive Cancer Control**.<sup>4</sup> This recognised that many cancer patients are treated in general hospitals and not in comprehensive cancer centres (CCCs), and

explored a model of 'comprehensive cancer care networks' that integrate expertise in all areas of treatment under a single governance structure, ensuring specialised cancer care for patients throughout all phases of their disease.

Further, research shows that care provided by MDTs results in better clinical and organisational outcomes for patients<sup>5</sup> and are the core component in cancer care.<sup>6</sup> The latest joint action, Innovative Partnership for Action Against Cancer (iPAAC)<sup>7</sup>, is continuing work on quality and governance in cancer, among other topics.

At European level, there has been widespread effort to establish universal, dedicated units mainly for breast cancer and in 2020 the ERQCC expert group published a paper with the requirements of a specialist breast centre<sup>8</sup> and welcomes the target in the Europe's Beating Cancer Plan for 90% of eligible patients to have access to CCCs by 2030.<sup>9</sup>

## Ovarian Cancer

There is a growing body of evidence on the optimal care provided by centres that treat ovarian cancer, and on the quality and audit measures for assessing care and treatment, particularly by the European Society of Gynaecological Oncology (ESGO) and by national agencies. This ERQCC paper aims to define the essential requirements for ovarian cancer centre to provide cancer treatment and care of quality.

# Epithelial Ovarian Cancer (EOC): Key Facts and Challenges

## Key Facts

### Epidemiology

- EOC is the most common type of malignant ovarian neoplasms, comprising about 90% of cases. Mean age at diagnosis is 63 years and histological subtypes include low and high grade serous, endometrioid, clear cell, mucinous, and others. High grade serous is the most common epithelial subtype and accounts for about 70% of cases.
- Ovarian cancer is the 8th most frequent cancer diagnosis and the 8th leading cause of death by cancer in women. GLOBOCAN 2020 estimates that there were 314000 new diagnosis of ovarian cancer and 207000 ovarian cancer deaths worldwide, the highest incidence being in countries with very high and high Human Development Index (HDI)<sup>10</sup>. There are large disparities in incidence and mortality among European countries, the highest incidence being in Central Eastern Europe (10.7) and Northern Europe (8.8). Mortality rates were similar between countries with different HDI, ranging from 5.6 in Central Eastern Europe to 4.0 in Southern Europe.
- Around 428.000 new ovarian cancer cases and 307.000 deaths are predicted to occur in 2040.
- About 70% of cases of EOC are diagnosed at advanced stages III and IV, which confers a poor prognosis.

Ovarian cancer is the 8th most frequent cancer diagnosis and the 8th leading cause of death by cancer in women.

### Risk factors

- Factors associated with increased risk include older age; genetic mutations such as pathogenic variants in the BRCA1/2 genes; family history; conditions that increase the number of ovulatory cycles, such as nulliparity, early menarche, and late menopause; endometriosis; and lifestyle factors such as obesity.<sup>11</sup>
- The contribution of genetic factors to EOC is substantial and testing to identify mutations in women with cancer is recommended by international guidelines to provide indications for treatment and prognosis (see section Genetics). Testing in relatives at risk is also recommended to quantify the risk and suggest indications for risk reducing procedures.

### Diagnosis and treatment summary

*Key guidelines: ESMO Clinical Practice guidelines (<https://bit.ly/3gr9pix>); ESMO-ESGO consensus conference;<sup>12</sup>*

Initial symptomatology is unspecific and resembles the clinical picture of irritable bowel syndrome; therefore, most patients will be diagnosed at an advanced stage. Typical symptoms include abdominal bloating and/or pain/discomfort, weight loss, changes in bowel habit, fatigue and changes in urinary frequency.

Women with an adnexal mass (a growth in the ovary/fallopian tube) may be initially assessed by ultrasound by expert radiologist. Specialised pelvic ultrasound including transvaginal approach has value in differentiating ovarian masses of unclear entity. Indeterminate or suspicious adnexal tumours on ultrasound should be characterised by diffusion weighted pelvic magnetic resonance imaging (MRI) with an appropriate protocol.

- The most broadly applied tumour marker for EOC is CA125, which is elevated in about 80% of patients with advanced disease. In younger women aged below 40, alpha fetoprotein (AFP), inhibin B and hCG (human chorionic gonadotropin) should also be measured to identify non-epithelial ovarian lesions.

- Diagnostic pathways in patients with presumed ovarian cancer include radiological staging with computed tomography (CT) and/or diffusion weighted MRI to provide information about tumour dissemination patterns and resectability. Positron emission tomography (PET)/CT with 18F-Fluorodeoxyglucose (18F-FDG) may help to differentiate doubtful, mainly extra-abdominal, lesions.
- Surgery and systemic therapies are the main treatment modalities for EOC. Surgery may be by laparotomy (open) or less often by laparoscopy (keyhole) depending on the stage and extent of the disease and has two goals: staging and cytoreduction (removal of all visible tumours). The International Federation of Gynaecology and Obstetrics (FIGO) staging system is usually applied.
- In early stage (stage I) disease, which applies in about 20% of patients, surgery may comprise hysterectomy, bilateral salpingo-oophorectomy (removal of ovaries and fallopian tubes), omentectomy (removal of the fatty sheath), and peritoneal biopsies +/- lymph node assessment. Fertility sparing surgery may be offered to carefully selected patients. Adjuvant (after surgery) chemotherapy is offered to most patients depending on stage and histological subtype.
- In advanced stages (stage II–IV), which comprise the majority of patients, the aim of the primary surgery is the complete removal of all visible disease and is known as maximal cytoreduction which could require the removal of parts of the bowel, spleen, diaphragm and other organs. In some cases, a complete cytoreduction is not feasible and it is necessary to give first at least three cycles of chemotherapy (neoadjuvant) to decrease the tumour extent before proceeding to a secondary cytoreductive surgery.
- Because of the high risk of recurrence, after surgery patients should always receive a combination chemotherapy with platinum and taxane, followed by a maintenance treatment with bevacizumab (antiangiogenics) or PARP inhibitors, the latter being targeted agents indicated in the presence of homologous recombination deficiency (defective DNA repair) caused by BRCA mutations and other genes.
- Intraperitoneal chemotherapy, which is given in heated form in the abdomen during surgery to treat residual disease, is not yet a standard of care.
- Recurrent ovarian cancer, which occur in about 70% of women, is treated with a variety of systemic therapies, including chemotherapy and targeted agents, preceded by surgery in selected cases.
- Radiotherapy is not a standard of care in primary treatment but may be used in selected cases of localised recurrent disease.
- High-quality perioperative, supportive, palliative and psycho-social care are essential components of multidisciplinary care for ovarian cancer.

Recurrent ovarian cancer, which occur in about 70% of women, is treated with a variety of systemic therapies, including chemotherapy and targeted agents, preceded by surgery in selected cases.

## Challenges in Ovarian Cancer Care

### Detection and screening

- The lack of symptoms of early-stage ovarian cancer and the pathogenesis of the disease, often related to undetectable serous tubal intraepithelial carcinoma (STIC) lesions at the fimbrial end of the fallopian tube, are the major challenges for an early detection. It has been reported that 20% of women are too ill to receive treatment by the time they receive a diagnosis.<sup>13</sup> The World Ovarian Cancer Coalition Every Woman Study, which included a survey of ovarian cancer patients, found that 69% of women were not aware of ovarian cancer before their diagnosis, and reported a wide variation in time to diagnosis, and access to specialists and treatments.<sup>14</sup>
- Primary care doctors (general practitioners: GPs) may infrequently see ovarian cancer patients during their careers and should have training to make appropriate referrals to specialised centres.

- Results from large multicentre prospective randomised trials have failed to show any survival benefit of screening methods, including annual ultrasound and tumour markers, therefore no reliable screening methods exist for early diagnosis of ovarian cancer in asymptomatic women.<sup>15</sup>

## Diagnosis, treatment and outcomes

- Diagnosing, staging and treatment of ovarian cancer is complex and should be carried out in specialised centres by an expert MDT.<sup>16</sup>
- Challenges in diagnosis include distinguishing between benign, borderline and malignant tumours, and other types of cancer. Latest consensus on preoperative diagnosis of ovarian tumours emphasises the need of multidisciplinary competence to define the correct diagnosis and procedures.
- Surgery and systemic treatment are the mainstay of treatment in ovarian cancer as both are part of the standard of care for all the histological subtypes.
- Surgery includes staging and cytoreductive procedures, to define the extent and stage of the disease and to achieve maximal tumour clearance of all visible disease. Surgery should be carried out by a gynaecological oncologist or a gynaecologist with expertise in gynaecological cancers, aided when appropriate by specialist surgeons. Poor access to a specialist team results in suboptimal surgical care and staging. Many patients with supposed early-stage disease are surgically upstaged, which has significant implications for their subsequent management.<sup>17</sup> Advanced cytoreductive techniques require specialised training as well as multidisciplinary teams and adequate infrastructure, which should be audited according to quality indicators.<sup>18,19</sup> Complete cytoreduction is strongly associated with improved survival and patients treated in high volume hospitals by gynaecological oncologists have better outcomes.<sup>20</sup>
- Access to centralised surgical expertise appears to be highly variable in Europe and beyond.<sup>21</sup> In many countries in Europe, not all women have access to a high-volume centre that meets all required quality indicators as defined by national and international guidelines. It is recognised that travelling to high-volume centres can be challenging for patients in large countries, especially for older women with co-morbidities, creating inequalities in access to optimal care.<sup>22</sup> In an effort to make high-quality surgery and care accessible to all patients, healthcare systems must work towards training and accrediting more gynaecology oncologists to fill gaps in services.<sup>23,24,25</sup>
- Despite high initial response rates of 70–80% with surgery and systemic treatment, the majority of women recur within the first three years of initial diagnosis, and require multiple subsequent lines of treatment, including maintenance with antiangiogenics and PARP inhibitors.<sup>26</sup>
- Studies have explored differences in ovarian cancer treatment according to clinical guidelines and care patterns,<sup>27</sup> and adherence to guidelines.<sup>28</sup> Findings include variations in rates of primary versus interval debulking, extensive/ultra-radical surgery, and use of targeted therapies. Implementation of quality indicators through a formal quality improvement programme has led to improvements in guideline adherent care. Meeting the standard of care through indicators is an important aim in some European countries, where an audit has found that nearly 25% of women with advanced ovarian cancer do not receive any anti-cancer treatment and only 51% receive standard of care with a combination of surgery and chemotherapy.<sup>83</sup> A set of Quality Performance Indicators (QPI) have been established with a defined minimum optimal target of 95% of patients undergoing primary or interval debulking surgery.<sup>83</sup>
- Although high-resource countries have focused on optimal diagnosis and intensified treatment, there appears to be little progress in improving cure rates in women with EOC. For example, a study in the Netherlands reported no long-term survival benefit in a study period of 25 years, although there were improvements in 5-year survival, attributed to more prolonged disease control rather than better chances for cure.<sup>29</sup>
- Distress for women with ovarian cancer is significant and exacerbated by its frequent late diagnosis, which leaves little time for healthcare professionals to consider psycho-oncological aspects of care; women are most vulnerable to

anxiety and depression at the time of diagnosis, with gradual improvement over time. This can impact treatment outcomes as women with poor mental health and patients with depression and anxiety are at a significantly greater risk of mortality and poorer treatment outcomes.<sup>30</sup> Psycho-oncological interventions have shown to reduce anxiety and depression in cancer patients.<sup>31,32</sup>

## Survivorship and palliative care

- Women are affected by a wide range of issues after diagnosis and treatment, with younger women more likely to have psychological suffering and concerns about fertility, and impaired quality of life owing to treatment effects on sexuality and body image.
- Survivorship for most women is not a linear process but one of periods of wellness and recurrences with reintroduction of antitumor treatment, and there are challenges in the best ways to offer support as women experience changing expectations about their outcome.
- Providing better care for the growing population of cancer survivors has been overlooked compared with treatment, but patient advocates see opportunities in the EU's recently launched Cancer Mission and Beating Cancer Plan.<sup>33</sup>
- As women play a pivotal role in family life there are added pressures on family members and carers for psychological distress, and organisational issues such as financial support, especially in traditional communities.
- All women with advanced ovarian cancer require access to high-quality palliative support from the onset of the disease to manage cancer-related symptom and treatment related toxicities. Symptoms of advanced ovarian cancer can be debilitating and serious, such as ascites (abdominal fluid build-up) and bowel obstruction, and studies have shown benefits of early introduction of supportive and palliative care.

## Genetics

- The genetic contribution to ovarian cancer is substantial. Researches on how to improve screening in high-risk subjects, optimal procedures for risk reduction and use of multigene germline panels are ongoing.

- Genetic testing for women with ovarian cancer, has implications for providing targeted therapy, for the definition of the risk of other cancers such as breast cancer, and for the identification of risk in family members.<sup>34</sup> Although good progress has been made in implementing universal genetic testing in EOC, clinical geneticists and genetic counsellors may be under-resourced. There is a risk of uncontrolled tests available on the internet leading to false positives and negatives and lack of informed advice.<sup>35</sup>

## Inequalities

- The variation in outcomes for ovarian cancer in Europe indicates that there may be inequalities in access to high-quality care among countries, although comparisons are hard to make owing to varying incidence and quality of registry information. What is certain is that, as with other cancers, some countries lack access to drugs, equipment and new techniques that may be critical to improve care.<sup>36, 37, 38</sup>
- As a substantial proportion of patients are older women, there are challenges in caring for an increasing population that has more co-morbidities. Treatment decisions are more complex because of the heterogeneity of this population concerning functional status, comorbidity and polypharmacy and lack of clinical implementation of a comprehensive geriatric assessment.<sup>39</sup>

## Research

- The range of research challenges for ovarian cancer is wide, including genomic profile, risk factors, early detection, definition and evaluation of personalised treatment, treatment resistance.

## Cancer registries and data availability

- Cancer registration practice, coverage and quality are highly unequal across Europe<sup>40</sup> and basic epidemiological data on incidence, mortality and survival are not uniformly available. In addition, only a minority of cancer registries provides sufficient data to calculate the parameters needed to assess outcomes and quality of care.<sup>41</sup>

# Organisation of Care

## Care Pathways and Timelines

- Care for people with ovarian cancer should be organised in pathways that cover the patient's journey from diagnosis to follow up including surgical/medical treatment, rehabilitation, psychosocial support, survivorship and palliative care; those pathways should be aligned with current national and European clinical practice guidelines. 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, patient pathways that are also often used. See <http://e-p-a.org/care-pathways>.
- The definition of the characteristics of care pathways include:
  1. an explicit statement of the goals and key elements of care, based on evidence, best practice and patients expectations;
  2. a facilitated communication among the team members and with patients and caregivers;
  3. the coordination of the care process by coordinating the roles and sequencing the activities of the MDT, patients and caregivers;
  4. the documentation, monitoring and evaluation of outcomes;
  5. the identification of the appropriate resources
- Examples of ovarian cancer care pathways are from the Cancer Council Victoria, Australia<sup>42</sup> and Cancer Care Ontario.<sup>43</sup> Integrated care plans (ICPs) have been proposed as a way to improve patient-oriented quality in complex diagnosis and treatment care pathways.<sup>44</sup> They are structured multidisciplinary care plans for a specific clinical condition and describe the tasks to be carried out with timing and sequence and the discipline involved.
- Ovarian cancer should be diagnosed and treated with minimal delays to improve survival and to decrease anxiety.

- According to the Cancer Council Victoria Australia optimal care pathway, surgery should be conducted within four weeks of the suspected or confirmed diagnosis and within 2 weeks from the MDT board. Neoadjuvant chemotherapy should start within two weeks from the MDT board. Adjuvant chemotherapy should start within four weeks from surgery.
- Since emergency presentations are a major problem in ovarian cancer, there must be pathways to ensure patients are seen in gynaecological cancer units as soon as possible.
- After the diagnosis, it should be clear to the patient which professional teams are responsible for each step in the treatment pathway and who is following the patient during the journey (usually called a case manager or patient navigator). In some countries, case managers during the main stages of treatment are cancer nurses.

## Ovarian Cancer Centres and MDTs

- Ovarian cancer diagnosis and treatment should be managed by a core and extended MDT of professionals described below, at an ovarian/gynaecological cancer centre. The ERQCC expert group considers that optimal care is delivered when all members of the core MDT work in a single centre, but it is recognised that some members of the MDT may be based at nearby or other locations. For patients who do not live near specialist units there must be a structure in place to enable referral for complex surgery to an expert centre, with the possibility to discuss in teleconferences with expert centres other aspects of patient management.

Ovarian cancer should be diagnosed and treated with minimal delays to improve survival and to decrease anxiety.

- There has been a wide variety of studies to determine if treatment in specialist centres for gynaecological cancer, and ovarian cancer in particular, is superior compared to general hospitals.
  - A review of centralisation of ovarian cancer care in the US and worldwide reported that patients with EOC stages III-IV are better served by centralised care in high-volume hospitals and by high-volume physicians.
  - In Sweden, care of advanced cases was centralised in 2011 and national guidelines first published in 2012; studies have found an increase in complete cytoreduction, a shorter delay in starting chemotherapy, and better survival.<sup>45, 46</sup>
  - A report from Australia stated that ovarian cancer patients managed by an MDT had improved survival and experienced a high level of satisfaction and improved quality of life.<sup>53</sup>
- A number of indicators for ovarian cancer have been developed at national and international levels with targets for attainment (see also section on National/international quality and audit examples). One is a case volume target for surgery such as ESGO's quality indicators for advanced stage ovarian cancer surgery.
- The ERQCC expert group endorses the ESGO indicators but recognises that countries may develop other types of indicators such as those recommended by the British Gynaecological Cancer Society, which focus on a population dataset rather than individual centres.<sup>47</sup> One of the Quality Performance Indicator (QPI) stated that all patients with ovarian cancer at diagnosis should be discussed by a specialist MDT prior to a decision for treatment, with a target of 95% of patients discussed.

## The MDT for Ovarian Cancer

Treatment strategies for ovarian cancer patients must be decided on, planned and delivered as a result of consensus among a core MDT with the most appropriate members for this disease. MDT meets at least weekly to discuss all the cases with the aim to balance the recommendations of the clinical guidelines with the needs of the individual patient.

The core MDT should comprise health professionals from the following disciplines, trained in and dedicated to gynaecological oncology:

- Gynaecologic pathology.
- Gynaecologic radiology.
- Gynaecologic oncology (surgery).
- Gynaecologic medical oncology.
- Radiation oncology.
- Nursing.

Gynaecological specialists are usually the lead of the MDT and may be qualified to deliver medical therapy and/or carry out surgery depending on the country and their training.

The core MDT meets to discuss:

- All suspicious ovarian masses with the presumed diagnosis of ovarian cancer.
- All cases after diagnosis to define staging and appropriate treatment.
- Patients with a recurrence, or where changes to treatment programmes are indicated and have multidisciplinary relevance and/or when there are planned deviations from clinical practice guidelines.
- All cases on treatment when surgery can be considered.

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

- Perioperative care.
- Nuclear medicine.
- Psycho-oncology.
- Palliative care.
- Interventional radiology.
- Geriatric oncology.
- Oncology pharmacy.

- Genetics.
- Fertility and menopause

The expert group also recognises the contributions of department heads, data managers, documentation specialists, patient representatives, caregivers, clinical trials coordinators and others (see also ‘Other essential requirements’).

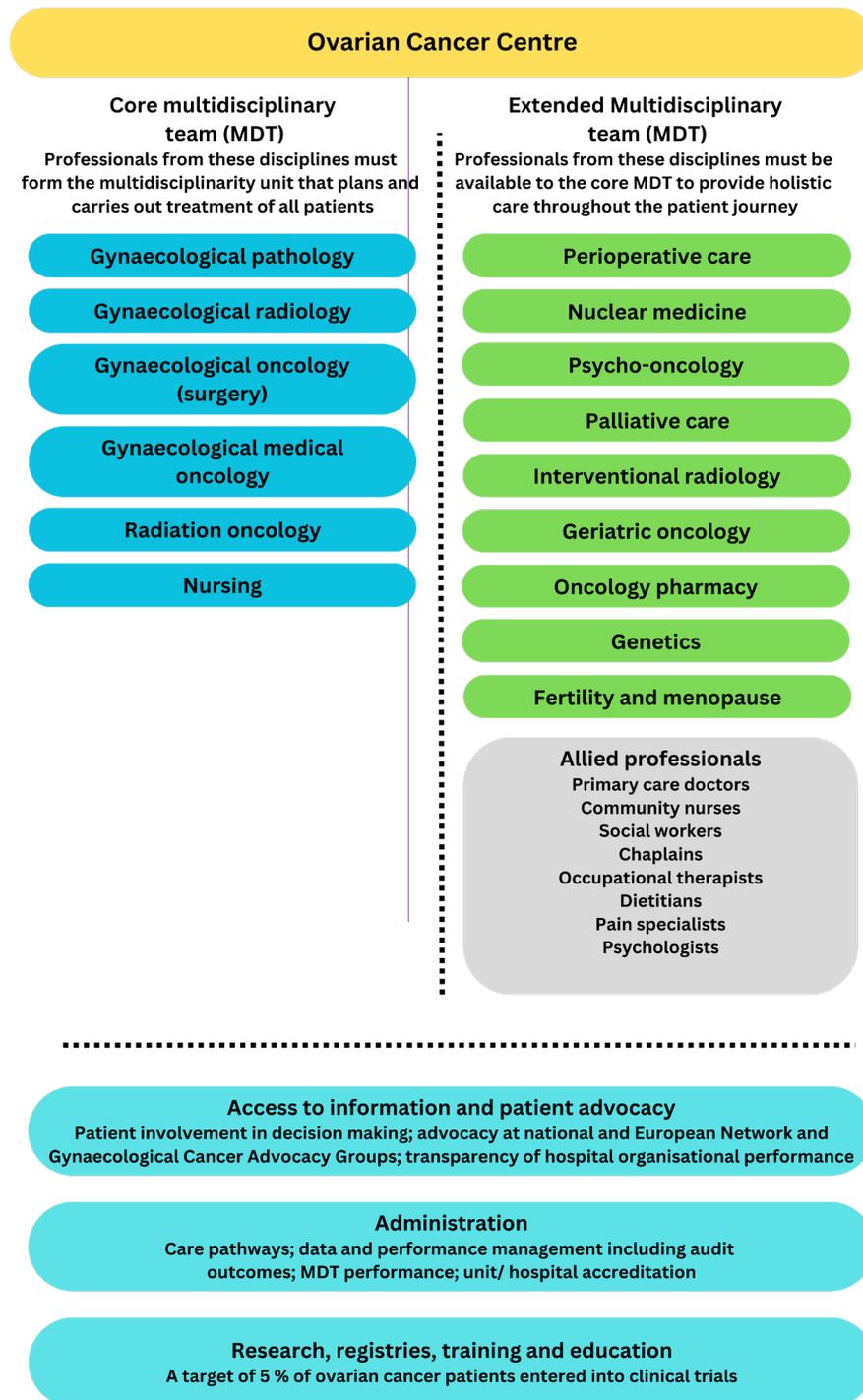


Figure 1. Schematic of ovarian cancer centre

## Disciplines in the Core MDT

### General statements

- The ERQCC experts recognise that specialists may have multiple skills and certifications and that sometimes job titles may not convey this. The core and extended MDTs are described as specialists with certain skills and knowledge.
- Core MDT members who meet patients must have excellent communications skills to discuss benefits and risks of therapies with patients, families and caregivers to ensure that appropriate treatment options are explained and to take shared decisions on the subsequent treatments.

### Gynaecological pathology

The role of pathologists is to establish the correct diagnosis and stage for this complex group of tumours, which is essential for the management of patients. The WHO classification of ovarian cancer 2020 proposed major changes regarding this group of tumours<sup>48</sup> and the AJCC/TNM system eighth edition has incorporated these changes and proposed a new staging system to encompass tumours arising in the three sites (ovary, fallopian tube and peritoneum).<sup>49</sup> The fallopian tubes, or at least their fimbriated ends, should be totally sampled in all cases of high grade serous by a Sectioning and Extensively Examining the FIMbriated End (SEE-FIM)-like protocol to avoid missing this important site of disease which probably represents the tumour origin in the majority of cases.<sup>50, 51</sup>

Pathologists provide reports that include the origin of the tumour, histological type and grade and additional prognostic/predictive morphological parameters. Techniques include grossing of the tumour (visual inspection of surgical specimens), and evaluation of haematoxylin/eosin-stained slides, including quickly frozen specimens during the staging operation to inform the surgeon. Immunohistochemical (IHC) examinations are now part of standard pathological examinations with definition of IHC markers.

Somatic tumour genetic testing is becoming an important service. See section on Genetics for details of testing and applications.

#### Essential requirements: gynaecological pathology

- Pathologists must have experience in gynaecological pathology and detailed knowledge of ovarian cancer.

- Tissue fragments obtained for histopathologic analysis from biopsy must be accompanied by personal data and clinical history of the patient as well as detailed clinical and radiologic information and must be properly fixed in formalin.
- As grossing is a very important step for a correct diagnosis, all surgical specimens of the organs removed must be specified by a gynaecological oncologist or expert surgeon, and pathologists must work with them to provide information on the orientation of the specimen.
- Pathology reports must provide the final diagnosis according to the most recent FIGO and TNM classifications and a list of prognostic/predictive parameters. The use of a structured (or synoptic) report must be encouraged.
- Access to an accredited laboratory for molecular techniques must be provided for diagnosis and/or prognosis in difficult cases.
- Second opinion (including external second opinion to international experts) must be considered for all difficult cases or rare tumours in which pathologists have limited experience, or for cases that have been diagnosed outside the centre.
- In cases of recurrence, pathologists must consider reviewing the initial slides sent by the centre where the first diagnosis was established together with a paraffin block from the tumour for additional stains.
- Somatic tumour genetic testing must be available as detailed in section on Genetics.

### Gynaecological radiology

Imaging is the domain of clinical radiologists, who are experts in using imaging to diagnose, treat and manage medical conditions and diseases, and work in teams with radiographers and sonographers. Imaging plays a major role in diagnosis, staging, postoperative assessment and follow-up of ovarian cancer patients. It may also serve as a roadmap for surgery. Ultrasound, MRI and CT are the main modalities used to characterise ovarian masses and define extent of the disease.<sup>52 53</sup>

## Essential requirements: gynaecological radiology

- Radiologists who report on ovarian cancer patients must have training in gynaecological cancer imaging.
- When performing/interpreting imaging studies, radiologists must be aware of patient history, clinical presentation, ultrasound findings and tumour markers<sup>54</sup> the final clinical interpretation must be discussed with treating clinicians.
- Ovarian cancer staging must be based on abdominal and pelvic contrast-enhanced CT findings for assessment of primary tumours, nodal spread, intraperitoneal disease and metastatic spread, with inclusion of chest CT.<sup>50</sup>
- CT protocols must include reformatted images, using 3 to 5 mm slice thickness at 3 to 4 mm intervals in transaxial, coronal and sagittal planes, to allow assessment of morphology and local extent of ovarian cancer and of peritoneal carcinomatosis.<sup>51</sup>
- High magnetic field MRI ( $\geq 1.5T$ ) must be used for staging ovarian cancer in situations where CT is contraindicated (contraindications to contrast media, renal insufficiency, young patients, pregnancy)<sup>67,68</sup>
- MRI sequences must include a T1-weighted (T1W) sequence, T2W sequences of the pelvis in axial and sagittal planes, and axial T1W FS with gadolinium. Slice thickness must not exceed 4 mm in the pelvis and 6 mm in the upper abdomen. Axial diffusion-weighted imaging of the abdomen and pelvis is indicated, with an optimal b value range from 1000–1100s/mm<sup>2</sup>.<sup>51</sup> Non-enhanced MRI must be considered when contrast enhanced MRI is contraindicated.
- 8F FDG-PET/SCAN may be considered as an adjunct modality in unclear cases, for example when CT is indeterminate or on suspicion of recurrence and must be carried out and reported by a nuclear medicine physician.

## Gynaecological oncology (surgery)

Surgery for ovarian cancer should be carried out by gynaecological oncologists who are accredited in gynaecological oncology, or by gynaecology surgeons who are experts in gynaecological cancers in those countries where no specialist registers and accreditation system is established. Gynaecological oncologists are usually the lead members of the ovarian cancer MDT and may also

be certified to deliver medical therapy depending on the healthcare system.

The surgical expertise of gynaecological oncologists goes beyond pelvic procedures and includes upper abdominal, gastrointestinal and retroperitoneal resection techniques to achieve complete abdominal macroscopic tumour clearance. Other specialist surgeons may assist in operations to achieve optimal cytoreduction in extra-abdominal sites.

In the past 20 years, major centres have implemented surgical programmes to carry out advanced abdominal surgery with improved outcomes despite a more challenging patient caseload.

Gynaecological oncologists should be aware of the importance of research and of the latest clinical and scientific directions in ovarian cancer.

Participation of a centre in clinical trials is included as a quality indicator in many national and international guidelines.

Accreditation of centres and gynaecological oncologists by national bodies and by ESGO is ongoing.

The requirements below include ESGO's quality indicators for advanced ovarian cancer surgery.

## Essential requirements: gynaecological oncology (surgery)

- Ovarian cancer patients must be operated on by a gynaecological oncologist or by a surgeon who spends more than 50% of his/her time on gynaecological cancers.
- 95% of advanced ovarian cancer patients should be treated by a surgeon who carries out at least 20 operations a year or is supervised by a surgeon who has this minimum requirement.
- A minimum of 20 surgeries with the aim of complete cytoreductive for advanced ovarian cancer should be carried out at the centre (intermediate target 50, optimal target 100).
- Centres should aim for a minimum of >50% complete resection rate (optimal >65%) in all stage III-IV ovarian cancer patients. At least >50% of advanced ovarian cancer patients should be in the upfront (first treatment) setting.

- Surgeons with complementary skills in gastrointestinal and upper abdominal surgery must be available to join the operating team where needed for cytoreduction procedures.
- Younger women with early-stage disease must be offered fertility preservation surgery where applicable.
- An intensive care unit must be available and comprehensive perioperative care provided.
- Operative reports should be structured and contain at a minimum: size and location of disease at the beginning and residual disease at end of the operation; all the areas of the abdominal and pelvic cavity evaluated and described; reasons for not achieving complete cytoreduction.
- Audits must be carried out to ensure compliance with quality indicators.
- Centres carrying out advanced surgery must participate in clinical trials.
- Healthcare systems must consider national and/or ESGO accreditation for gynaecological oncologists and centres.
- Patients can have recourse to second opinions from expert centres concerning the feasibility of surgery and other treatment options.

## Gynaecological medical oncology

Medical oncologists play a key role in the management of ovarian cancer patients because the majority of them will need medical therapies for a long period of time. Surgical gynaecological oncologists can be qualified to deliver medical therapies according to country health regulatory and organisational system.

The past decade has seen great progresses in the development of systemic treatment. While platinum-taxane based chemotherapy remains the mainstay of the first line systemic therapy for early and advanced stages, the subsequent treatment has become more modulated in the advanced setting, according to histological subtypes, grading and genomic profile with the addition of maintenance with bevacizumab and or PARP inhibitors to the treatment in frontline or in the recurrent settings.<sup>55</sup>

The main aim of the combination of cytoreduction and medical treatment with maintenance in the frontline treatment is to achieve a prolonged complete remission, thus increasing the chance of cure and delaying the development of resistance to platinum. Main field of investigations are the mechanism and the causes of the platinum resistance and how to overcome it, either in frontline and in the recurrent disease, how to prolong the progression-free interval among the subsequent recurrences and the optimal sequencing of therapy.

### Essential requirements: gynaecological medical oncology

Medical oncologists need to know and apply the latest national and European recommendations on the medical treatment for first line and recurrent disease, and the importance of assessing genomic profile, such as BRCA mutations and homologous recombination dysfunction (HRD) to personalize treatment.

Medical oncologists should be aware of the acute and chronic toxicities of the chemotherapeutic and biological agents used, of the toxicity profile of their combination and how to adapt dosing and schedules of treatment to avoid severe toxicities and to maintain efficacy.

Medical oncologists should be aware of the expected outcomes, in terms of objective response, progression free survival and toxicities, of the different regimens when applied at the different stages of the clinical course of disease and of the potential benefits of the new drugs available within early clinical studies.

Medical oncologists should decide, together with the health care team and the patients, when it is time to switch from an active antitumor therapy to a supportive symptom control only approach.

It is essential that medical oncologists can participate to clinical studies and develop activities and provides structures and resources to be involved in translational studies.

Medical oncologists also play key roles in geriatric, supportive and palliative care, and can lead gynaecological MDTs together with gynaecological oncologists.

## Radiation Oncology

There is no current role for radiation in the first line

treatment of ovarian cancer. Disease recurrences of limited dimensions and anatomical sites can be managed by radiation. Radiation oncologists determine the volume to be irradiated, the most suitable dose, fractionation and technique.

#### **Essential requirements: radiation therapy**

- Access to radiation therapy must be provided in the centre or through a formal, collaborative agreement.
- Radiation oncologists must be involved in follow-up of radiation related toxicity. Protocols must be in place for the management of late toxicity including bowel, urinary and sexual dysfunction.

### **Nursing**

Nurses provide information, care and support to patients and their families throughout the patient pathway. They are a key contact for patients, they provide information to facilitate informed decision-making for treatment options, undertake holistic needs assessment, help managing symptoms and treatment side-effects, provide support at all key points of the patient journey.

Due to the increasing complexity of care, there is a requirement for specialised gynaecological cancer nursing carried out by advanced nurse practitioners or specialists.

Nurses are the liaison person between patients, families, caregivers and physicians and assure homogeneity of communications among the health care team and the patients. Their role include also providing psychosocial support at all critical phases of the patient's pathway

#### **Essential requirements: nursing**

- Nurses must have training in gynaecological oncology with experience in daily care.
- Nurses must conduct holistic nursing assessments to ensure safe and personalised - nursing care and provide patient information and support to promote self-efficacy throughout the patient journey. They must promote a culture of shared decision-making. 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 ensure systematic screening throughout the disease trajectory to uncover physical symptoms such as pain, psychosocial distress, impairment of physical functioning, malnutrition and frailty. Validated instruments (e.g. the NCCN distress thermometer)<sup>56</sup> must be used where appropriate.
- Nurses must coordinate care with healthcare professionals within and outside the core MDT, including nutrition, rehabilitation, psychosocial, home care and palliative care services.
- Healthcare systems must consider implementing positions for advanced nurse practitioners in gynaecological cancer.

### **Disciplines in the Extended MDT**

#### **Perioperative care**

Anaesthesiologists and intensive care specialists have key roles in the management of patients undergoing surgery for ovarian cancer together with surgeons and other MDT members. Roles include:

- Surgical risk assessment
- Preoperative optimisation of co-existing medical conditions
- Perioperative clinical pathway management (including intraoperative care)
- Postoperative management and management of complications in intensive care facilities
- Acute and chronic pain management.

Enhanced recovery after surgery (ERAS) guidelines for gynaecologic oncology have been published and ESGO has recently released perioperative management guidelines for advanced ovarian cancer surgery that describe essential requirements of perioperative care.

The inclusion of patient reported outcome measures (PROMs) in recovery is important.

#### **Essential requirements: perioperative care**

- A perioperative programme must be in place and patients undergoing ovarian cancer surgery must have appropriate assessment by anaesthesiologists and other perioperative

specialists in partnership with gynaecologic oncologists.

- Centres must consider the ERAS and ESGO perioperative recommendations for patients undergoing surgery.
- The inclusion of patient-reported outcome measures must be considered in developing perioperative pathways.

## Nuclear medicine

Nuclear medicine can complement diagnosis and follow-up of ovarian cancer.<sup>57, 58, 59</sup> There is evidence of the efficacy of 18F-FDG PET/CT in lesion detection and characterisation where there is non-conclusive radiological imaging and negative radiological imaging with increased tumour markers. Studies show that 18F-FDG PET/CT has a better diagnostic accuracy in suspected recurrent disease than radiological imaging, especially in the context of increasing CA-125 serum levels, and ESMO guidelines state that it may indicate locations of disease not detected on CT.

### Essential requirements: nuclear medicine

- Access to PET/CT, conventional nuclear medicine and radionuclide therapy must be available and outsourced if not on site.
- Nuclear medicine departments 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.

## Psycho-oncology

About 30% of women with ovarian cancer experience severe distress with an increased risk of developing more severe conditions such as anxiety and depression in the absence of an adequate psychosocial intervention. Women are most vulnerable to anxiety and depression at the time of diagnosis, with gradual improvement over time.<sup>60</sup> Predictors of psychological distress include:

- Younger age at diagnosis.
- Factors related to fertility and ability to give birth as a diagnosis of ovarian cancer decreases the chances of childbearing.
- Physical complications and side effects that impair quality of life (such as impact on

sexuality, negative perceptions of body image)

- Previous adverse events (unrelated to the cancer) and a history of psychological distress
- Feelings of isolation.

Severe distress and psychological morbidity negatively affect clinical factors and outcomes, such as treatment compliance and quality of life. Reduced cognitive and sexual function, fatigue, are common long-term effects in patients who receive treatment for ovarian cancer, with disruption of psychosocial wellbeing.

Quality of life can improve after diagnosis for some women, who report spiritual growth and strengthened personal relationships. Early identification of women with higher risk for severe distress can be made with screening tools, such as the distress thermometer<sup>63</sup>. Early referral to psychosocial care reduces distress and may mitigate long-term psychological morbidity. Women at risk of developing sexual problems can also be screened with the distress thermometer, its severity being assessed with questionnaires such as the Female Sexual Function Index.<sup>61</sup>

Psychosocial care is still not well-resourced in Europe<sup>62</sup> and cancer policy guidelines recommend improvements to provide services.<sup>63</sup>

The role of psycho-oncologists is to:

- Ensure that psychosocial distress, psychological disorders and psychosocial needs are identified by regularly screening patients for distress, and considered by the MDT
- Provide evidence-based psychosocial care to support patients, spouses/partners, family members and caregivers to reduce and cope with distress and the multifaceted disease effects at all stages of the disease and its treatment.
- Promote effective communication among patients, family members, caregivers and healthcare professionals.
- Evaluate psychosocial care programmes.

### Essential requirements: psycho-oncology

- Psychosocial care should be provided at all stages of the disease to patients, partners and

families by psycho-oncologists.

- Distress should be screened regularly through a self-administered psychological assessment tool (such as the distress thermometer) to which patients should have access to. Reduced levels of distress can be managed by the clinical team through good communication skills that address common concerns and questions; higher levels of distress (above a cut-off level which includes anxiety and/or depression) require referral to specialised professionals in psycho-oncology.
- Psychosocial interventions should be based on evidence in clinical practice guidelines such as the NCCN Guidelines for Distress Management ([https://www.nccn.org/professionals/physician\\_gls/default.aspx](https://www.nccn.org/professionals/physician_gls/default.aspx)).
- Healthcare systems should increase awareness of psychosocial health among women with ovarian cancer, their social support networks, and their healthcare providers, and ensure high-quality psycho-oncology services at places where women are treated.

## Palliative Care

Palliative care, as defined by the World Health Organization, applies throughout all cancer care (<http://www.who.int/cancer/palliative/definition>). Palliative care means patient and family centred care that enhances quality of life by preventing and treating physical, psychosocial and spiritual suffering particularly in advanced stages of the disease.<sup>64, 65</sup>

Supportive care is often used as an alternative term (and can lead to better take-up of interventions),<sup>66</sup> but it is most correctly defined as the prevention and management of the adverse effects of cancer and its treatment' (MASCC, <https://www.mascc.org>). In recent years, supportive/palliative provision has become increasingly integrated and important in meeting major unmet needs, and ESMO has proposed the term 'patient-centred care' to encompass both supportive and palliative care.<sup>67</sup>

There is an increasing need for an early integration of palliative care services with standard cancer treatments for ovarian cancer patients throughout the clinical course of disease. Ovarian cancer can have a fluctuating symptom burden according to response to treatment and tumour recurrence, with an increase in severity and number of symptoms

in the last 6 months of life. Common symptoms are abdominal pain, shortness of breath, ascites, nausea and vomiting, loss of appetite, constipation, bowel obstruction, fatigue and psychological distress.<sup>68</sup> Interventions can include palliative chemotherapy, surgery in selected cases, and procedures such as drainage of abdominal fluid.

It is fundamental for ovarian cancer patients to receive honest communication, advance care planning by the lead clinicians and help to meet unmet physical, informational, psychological and spiritual needs, and help with existential distress. Partners or caregivers should be included.

Palliative care includes palliative and supportive care provided by oncology professionals in the MDT and other clinicians who are responsible for cancer care, and specialised care provided by a multidisciplinary palliative care team.<sup>69, 70</sup>

### Essential requirements: palliative care

- Patients with advanced ovarian cancer should have access to palliative and supportive care from the MDT and from a specialist palliative care team in the outpatient and inpatient setting.
- The palliative care team must include palliative care physicians and specialist nurses, working with an extended team of social workers, psychologists, physiotherapists, occupational therapists, nutritionists, pain specialists and chaplains.
- The palliative care team must have experience of taking care of frail older patients and their families.
- To ensure the continuity of care at home, the palliative care team must work with community/primary care providers.
- Palliative care specialists and oncologists must aspire to meet the standards of the ESMO Designated Centres of Integrated Oncology and Palliative Care (<https://www.esmo.org/for-patients/esmo-designated-centres-of-integrated-oncology-palliative-care>).

## Interventional radiology

Interventional radiology plays a crucial role in the diagnosis, perioperative, clinical and palliative care of ovarian cancer patients.

Image-guided percutaneous targeted core needle biopsy can confirm the diagnosis before treatment. In perioperative and clinical/palliative care procedures include drainage of collections, embolisation for bleeding control, stent insertion for pancreatic leaks, duodenal or gastric outlet stenosis and biliary leaks.

Interventional procedures can prevent a relaparotomy when there are surgical complications.

#### Essential requirements: interventional radiology

- An ovarian cancer centre should have onsite access to interventional radiology services; interventional radiology nurses and radiologists must be available at all times to cover routine and emergency situations.
- Infrastructure must be in place for advanced interventional radiology techniques with access to intensive care for post-intervention observation.

#### Geriatric oncology

The MDT should have access to geriatricians with oncology experience or oncologists familiar with the care of elderly women. Studies have shown that older women (>70-year-old) often are undertreated; are less likely to undergo complete cytoreductive surgery or to receive standard chemotherapy. Only recently clinical studies in elderly have been implemented.<sup>71</sup>

Treatment decisions should be based on patient's general health, comorbidities and patient preference. Pre-treatment objective assessment of frailty using validated scales, like the Geriatric Vulnerability Score (GVS) in ovarian cancer, could allow a safe use of standard combination chemotherapy also in frail women, improving their outcome.

#### Essential requirements: geriatric oncology

- All older patients (70+) must be screened with a quick, simple frailty screening tool, such as the adapted Geriatric-8 (G8) screening tool or the validated GVS.<sup>72</sup>
- Frail and disabled patients must undergo a geriatric assessment<sup>73</sup> based on self-report combined with objective assessments by a specialist nurse and a physician (geriatrician/specialist in internal medicine).
- Cognitive impairment affects all aspects of treatment – ability to consent, compliance with

treatment, and risk of delirium – and screening using tools such as Mini-Cog<sup>74</sup> is essential. A geriatrician or a geriatric psychiatrist or neurologist would preferably be involved with impaired patients.

- For frail and disabled patients, the geriatrician or specialist nurse must be present in the MDT meeting to discuss treatment options aligned with the patient's goals of care.

#### Oncology pharmacy

The complexity and often low safety profile of oncology drugs together with the high cost of drugs involved in ovarian cancer treatment require an optimisation of pharmacotherapy. Oncology pharmacy plays a critical role in the extended MDT in the care of ovarian cancer patients, given the importance of systemic treatment.

The role of the oncology pharmacist is to:

- Liaise with the medical oncologist/clinical oncologist to discuss cancer specific treatments, including interactions with other treatments.
- Supervise the preparation of oncology drugs.
- Be aware of both common and rare side effects of chemotherapy, targeted treatments and immunotherapies and the supportive measures to reduce them.

#### Essential requirements: oncology pharmacy

- Oncology pharmacists must have experience with antineoplastic treatments and supportive care, drug-interactions, drug dose adjustments based on age, liver and kidney function, and toxicity profile; utilisation and monitoring of pharmacotherapy; pharmacovigilance; and knowledge of complementary medicine.
- Oncology pharmacists must comply with European QuapoS. Oncology drugs must be prepared in the pharmacy and dispensing must take place under the supervision of the oncology pharmacist.
- Oncology pharmacists must work with medical oncologists to optimise the introduction of new drug regimens and on clinical ovarian cancer trials that are in place.

#### Genetics

Because of the importance of genetic factors in ovarian cancer genetic counselling should be an essential part of the cancer service for all women

with non-mucinous EOC. Genetic testing is done after genetic counselling by clinical geneticists, supported by genetic counsellors. The main aims are to identify relatives who may be at high risk of developing ovarian and other cancers in the hereditary breast ovarian cancer syndrome (HBOC) and guide prognosis and treatment decision-making for patients.

About 25% of EOC cases are associated with BRCA1/2 mutations. The lifetime risk of developing EOC in women with germline BRCA mutations is 40–60%.<sup>75</sup> As about 40% of women with germline variants have no family history of EOC or breast cancer, the other cancer most associated with BRCA, it is important testing regardless of family history. Healthy individuals with significant family history should be offered genetic testing with multigene panels of clinically validated genes (such as those in Lynch syndrome, BRIP1, RAD51C/D, PALB2, ATM).<sup>76</sup>

Carriers can be offered prophylactic surgery given that there is no effective screening. Risk-reducing salpingo-oophorectomy has been estimated to give an 80–90% reduction in ovarian/fallopian tube cancer risk in BRCA carriers and can be proposed to women aged in their early 40s following childbearing.<sup>77</sup> Salpingectomy with delayed oophorectomy is an option only within clinical trials.

For high grade serous ovarian cancer, germline and/or tumour testing for BRCA1/2 mutations determines eligibility to receive PARP inhibitors as maintenance after response to initial platinum-based chemotherapy.<sup>61</sup>

The target mechanism known as homologous recombination deficiency (HRD) involves, besides BRCA mutations, mutations in other DNA repair genes. The presence of HRD is associated with response to PARP inhibitors, also in patients without a BRCA mutation. HRD can be evaluated by different assays and there is ongoing research to improve tests for clinical practice.<sup>78</sup>

Women affected by BRCA should undergo surveillance for the risk of developing other cancers (breast and pancreas) in the HBOC syndrome.

It is important that genetic reassessment is scheduled to capture new family history information and to apply clinical re-evaluation in light of medical advances and identification of significant genetic variants previously classified as variants of unknown significance (VUS). The German Consortium for Hereditary Breast and Ovarian Cancer (GC-HBOC) reviews classifications of genetic variants.

### Essential requirements: genetics

- Ovarian cancer patients with non-mucinous disease should be offered genetic testing and counselling in a clinical genetics service allied to the MDT.
- Both germline and tumour tests should be available for detecting familial predisposition and for therapeutic decision-making.
- Germline testing and counselling should be offered to family members where indicated.
- Genetic risk reassessment should be carried out to capture changes in family history and take account of new medical knowledge.

### Fertility and menopause services

Providing a range of fertility preservation options is essential for certain young cancer patients. The risks of treatment causing infertility should be discussed with women as soon as possible by MDT members and early referral to a fertility service arranged where required.

In pre-menopausal women, cytoreductive surgery induces premature menopause, which may cause symptoms such as hot flushes, sweats and vaginal dryness, and can increase the risk of heart disease and osteoporosis. Hormone replacement therapy (HRT) is a treatment option for some women; lifestyle changes and complementary therapies can help alleviate symptoms; a prospective randomised study has shown the oncologic safety of HRT in patients with ovarian cancer.<sup>79</sup> In hormone receptor positive advanced or relapsed low grade ovarian cancer, HRT carries oncologic risks and should not be prescribed.

Fertility services for cancer patients are usually provided by reproductive health specialists in partnership with MDT members. A reproductive endocrinologist, a specialist gynaecologist who treats hormonal disorders related to reproduction, may be part of the team.

### Essential requirements: fertility and menopause services

- Women of childbearing age should be offered options for conservative treatment to preserve fertility according to the stage and type of early ovarian cancer, and egg and embryo cryopreservation where appropriate.
- Women should be offered treatments and support to manage symptoms of induced menopause.

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## Other Essential Requirements

### Patient involvement

Patients must be involved in every step of the decision-making process on their treatment and care. Patients, families and caregivers should be offered relevant, objective and understandable information and be allowed to take time for additional information and questions. They should be supported and encouraged to interact with their health team to ask questions and obtain feedback on their treatment to facilitate their decision-making process and compliance with treatment.

### Contact with Patient Organisations and patient advocacy

It is essential that ovarian cancer patients and advocacy organisations are involved whenever relevant throughout the patient pathway. These groups work to:

- Provide information about ovarian cancer in a lay language.
- Help patients and families to understand the treatment options.
- Improve patients' knowledge and ability to take decisions.
- Secure access to innovative therapies and improve quality of treatment.
- Support ovarian cancer research, such as by being involved in the better design of clinical trials.
- Encourage patients to participate in clinical trials.
- Contribute to clinical guidelines.
- Support the use of patient reported outcome (PRO) tools.
- Advocate at European and national health policy level.

There are several advocacy groups in Europe dedicated to ovarian and gynaecological cancers.

The umbrella body in Europe is the European Network of Gynaecological Advocacy Groups ENGAGe (<https://engage.esgo.org/>) and national groups among others include:

- UK: Target Ovarian Cancer (<https://www.targetovariancancer.org.uk>), Ovarian Cancer

Action (<https://ovarian.org.uk>), Ovacome (<https://www.ovacome.org.uk>)

- Ireland: OvaCare (<http://www.ovacare.com>), Supporting Ovarian Cancer Knowledge (SOCK) (<http://www.sock.ie>)
- German Foundation for Ovarian Cancer (<http://stiftungeierstockkrebs.de>)
- France: Imagyn (<http://arcagy.org>)
- Italy: Acto Onlus (<http://www.actoonlus.it>)
- Denmark: Kræft I Underlivet (KIU) (<https://www.kiuonline.dk>)
- Sweden: Network against Gynaecological Cancer (<http://www.gyncancer.se>)
- Spain: Asociación de Afectados por Cáncer de Ovario (ASACO) (<http://www.asociacionasaco.es>).

A global body, the World Ovarian Cancer Coalition, was established in 2016 and has published the Every Woman Study, which draws on an atlas of global trends, a survey of women and a clinician report (<https://worldovariancancercoalition.org/every-woman>).<sup>80</sup> It has also published the Global Ovarian Cancer Charter.

### Performance and Quality

The ERQCC expert group recommends that the ovarian cancer centre should develop.

- Performance measurement metrics/quality indicators based on the essential requirements in this paper and on clinical guidelines.
- Operational policies to ensure the full benefits of a coordinated clinical pathway based on published guidelines.
- Accountability within the governance processes in individual institutions
- Systems to ensure safe and high-quality patient care and experience throughout the clinical pathway.
- Effective data management and reporting systems
- Engagement with patients, their care-providers and support groups to ensure reporting of patient outcomes and experience.

To assess properly the quality of ovarian cancer care, three categories of outcomes must be measured and collected in databases in the specialist centre, regionally and/or nationally:

- Clinical outcomes.
- Process outcomes.
- Patient reported outcomes.

These approaches can be developed in the context of quality management systems (QMS) depending on the health economy of an individual country. The benefits of such a system include:

- Improving processes to enhance patient safety.
- Setting standards within a clinical pathway.
- Ensuring appropriate resource management including workforce and financial resources.
- Facilitating training opportunities.
- Determining optimal outcomes with appropriate audit.

### Audit of Outcomes

The ERQCC expert group recommends these outcome metrics are systematically measured and collected for audit planned and reviewed at MDT meeting (pre and post operatively).

- Rate of complete surgical resection.
- Number of cytoreduction surgeries per centre and per surgeon per year.
- Surgery performed by a gynaecological oncologist or a surgeon dedicated to gynaecological cancer.
- Required preoperative workup.
- Pre-operative, intra-operative, and post-operative management.
- Required elements in operative reports.
- Required elements in pathology reports.
- Structured prospective reporting of post-operative complications.

- 30-day mortality.
- 30-day readmission.
- Participation in clinical trials.
  - Patients according to clinical stage at time of diagnosis.
  - Patients receiving treatment with curative and palliative intent.
  - 1 and 5-year overall survival rate.
  - Adherence to MDT recommendations.

### MDT Performance

- All MDT decisions should be documented in an understandable manner and must become part of patient records. Decisions taken during MDT meetings must be monitored, and deviations reported back to the MDT. It is essential that all relevant patient data meet quality standards and are available at the time of the MDT meeting.
- The core and extended MDTs must meet at least twice a year to review the activity of the previous period based on the audited metrics, discuss changes in protocols and procedures, and improve the performance of the unit/centre. MDT performance must be quality assured both internally and by external review, and MDT guidance must be promoted nationally and written into national cancer plans.
- A study on MDT decision making in advanced ovarian cancer found that case discussions were structured by four components: clinical presentation, patient factors, chair's direction and input from other specialties. Clinical presentation was the most significant, component comprising patient history, tumour markers, images and radiologist input. Patient factors such as comorbidities, psychosocial and patient views though were often underrepresented.

Further attention must be given to PROs and patient reported outcome measures (PROMs) as part of discussions and evaluation within the MDT.

## Accreditation

The ERQCC expert group strongly recommends participation in national or international accreditation programmes, e.g. Organisation of European Cancer Institutes (OECI) accreditation, ([https://www.oeci.eu/Accreditation/Page.aspx?name=MANUAL\\_3](https://www.oeci.eu/Accreditation/Page.aspx?name=MANUAL_3))<sup>81</sup> the German Cancer Society certification system for cancer centres, which is offered to centres outside Germany (<http://www.ecc-cert.org>); ESGO accreditation (<https://www.esgo.org/explore/esgo-accreditation>).

ESMO Designated Centres of Integrated Oncology and Palliative Care accreditation programme bestows special recognition for effectively integrating medical oncology and palliative care<sup>82</sup>

## National/international quality and audit examples

- The British Gynaecological Cancer Society has recommended a set of draft quality indicators for advanced ovarian cancer following an audit feasibility pilot, which will link databases that capture clinical data in routine practice in NHS hospitals and which aims to increase the number of women receiving the standard of care.<sup>83</sup>
- NHS National Services Scotland has developed quality performance indicators with targets for ovarian cancer.<sup>84</sup>
- The German Cancer Society produces reports on certified cancer centres in Germany and other countries that are part of the scheme. For ovarian cancer there are a set of treatment indicators and targets, including surgical staging for early cancer, complete resection of advanced cancer, chemotherapy, and also a number of generic indicators including presentation at a tumour board, provision of psycho-oncology and social services counselling, inclusion in trials.<sup>85</sup>

## Education and training

- It is essential that each ovarian cancer centre provides professional clinical and scientific education on the disease with at least one person responsible for this programme. Healthcare professionals working in the field must also receive training in psychosocial oncology, palliative care, rehabilitation and communication skills. Such training must also be incorporated into specialist postgraduate

and undergraduate curriculums for physicians, nurses and other professionals. Nurses should undertake post-qualification education and training to provide holistic care to ovarian cancer patients.

- In 2021 ESGO launched a new curriculum for gynaecological oncology trainees, who must have two- or three-years training at an ESGO-accredited gynaecological oncology unit.<sup>86</sup> A few countries have gynaecological oncology subspecialty training, such as the UK (<https://bit.ly/2S6ZF3O>), and the Royal College of Obstetricians and Gynaecologists has also signed a training agreement with ESGO (<https://bit.ly/35mNKSv>).<sup>23</sup>
- The ERQCC expert group highlights the importance of European training standards in medical oncology, available from ESMO, from the European School of Oncology (ESO) and from the European Union of Medical Specialists (UEMS).
- An expert group on cancer control at the European Commission has endorsed a recommendation for multidisciplinary training of cancer specialists to improve the value of MDTs and patient care.<sup>87</sup>

## Clinical research and registries

- Centres treating ovarian cancer 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 academic and industry sponsored clinical trials at the centre or in research networks.
- The German Cancer Society specifies a minimum accrual rate for clinical trials of 5% and the British Gynaecological Cancer Society has recommended 5% participation in a National Cancer Research Institute study as one of its proposed quality indicators for care of advanced ovarian cancer. The OECI requirement for CCCs is >10%. The ERQCC expert group considers that the 5% target is an important recommendation for all ovarian cancer centres.
- Collaborations with European academic

networks are strongly recommended – see the European Network of Gynaecological Oncological Trial Groups (ENGOT– <https://www.esgo.org/network/engot>), gynaecological cancer group of the European Organisation for Research and Treatment of Cancer (EORTC – <http://www.eortc.org>), and the European Clinical Research Infrastructure Network (ECRIN – <http://www.ecri.org>).

- Cancer control plans must include high-quality cancer population and specialist registries to inform clinical research and to improve the quality of care.
  - A gynaecological cancer registry cited as a model in Europe is the Swedish Quality Register for Gynecological Cancer (SQRGC), which was launched in 2008, and captures clinical information, surgical details, oncological variables and follow-up outcomes.<sup>88</sup>

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## Conclusions

Taken together, the information presented in this paper provides the organisational and clinical requirements for establishing a high-quality ovarian cancer service, led by an MDT with specialised expertise, to guarantee adequate standard treatment to all patients with ovarian cancer.

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