Quality indicators in ovarian cancer surgery: Report from the French Society of Gynecologic Oncology (Société Française d’Oncologie Gynécologique, SFOG)


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Background: Based on registries, the European experience has been that <50% of patients are treated according to protocols and/or benefit from the minimum required surgery for ovarian cancer. The French Cancer Plan 2009–2013 considers the definition of qualitative indicators in ovarian cancer surgery in France. This endeavour was undertaken by the French Society of Gynaecologic Oncology (SFOG) in partnership with the French National College of Obstetricians and Gynecologists and all concerned learned societies in a multidisciplinary mindset.

Methods: The quality indicators for the initial management of patients with ovarian cancer were based on the standards of practice determined from scientific evidence or expert consensus.

Results: The indicators were divided into structural indicators, including material (equipment), human (number and qualification of staff), and organizational resources, process indicators, and outcome indicators.

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Results: The indicators were divided into structural indicators, including material (equipment), human (number and qualification of staff), and organizational resources, process indicators, and outcome indicators.
**Conclusions:** The enforcement of a quality assurance programme in any country would undoubtedly promote improvement in the quality of care for ovarian cancer patients and would result in a dramatic positive impact on their survival. Such a policy is not only beneficial to the patient, but is also profitable for the healthcare system.

**Key words:** gynaecologic oncology, ovarian cancer, surgical oncology, quality assurance

**Introduction**

Quality in medicine is defined as the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and the degree to which they are consistent with current professional knowledge [1]. Based on national and regional registries in Denmark, Switzerland, England, Germany, and the Netherlands, the European experience has been that <50% of patients are treated according to protocols and/or benefit from the minimum required surgery for ovarian cancer, let alone complete cytoreductive surgery [2]. Of the 40 patients referred to a German tertiary centre after primary surgery, only 5 were considered to have received standard management [3]. Even among teams participating in randomized, controlled trials from centres treating more than 20 patients per year, adequate staging for early-stage ovarian cancer occurred in not more than 37%. This was significantly different when compared with centres treating less than five patients per year, where the rate of complete staging was merely 21% [4].

Pursuant to article 23-1 of the current French Cancer Plan 2009–2013, the French Society of Gynaecologic Oncology (SFOG) proposed to establish quality indicators in ovarian cancer surgery in France. The French National Cancer Institute (Institut National du Cancer, INCa), a government agency, agreed to provide logistical support. This endeavour was undertaken in partnership with the French National College of Obstetricians and Gynaecologists (Collège National des Gynécologues et Obstétriciens Français) and the French Society of Anaesthesia and Intensive Care (Société Française d’Anesthésie-Réanimation). The members of the working group were appointed as members of the board of SFOG and representatives of other organizations such as the French Society of Surgical Oncology (Société Française de Chirurgie Oncologique), the French Cancer Society (Société Française du Cancer), the French Society of Gynaecologic and Pelvic Surgery (Société Française de Chirurgie Gynécologique et Pelvienne), and the GINECO group, a National Cooperative Group of investigators involved in the field of clinical trials dedicated to ovarian cancers. Representatives from non-surgical disciplines (medical oncology, radiology, and pathology) involved in the diagnosis and management of ovarian cancers participated and with representatives of all concerned French learned societies.

The mere implementation of a quality management programme impacts survival [5, 6]. Our objective was to define quality indicators for the initial management of patients with ovarian cancer.

**Materials and Methods**

The methodology for the definition of quality indicators relevant to assessing the performance and outcome of care is available [7]. Indicators serve as measurement tools to monitor, assess, and ultimately improve quality of care. They give practitioners and health administrators a quantitative basis for improving care and organizational processes. They also facilitate the documentation of quality of care, the comparison of performance structures, and the establishment of organizational priorities as a basis for accreditation.

The indicators are based on the standards of practice determined from scientific evidence or expert consensus. The key characteristics of an ideal indicator are clear definition, sensitivity and specificity, clinical relevance, the ability to generate comparisons, and a scientific basis.

A literature search limited to publications in French and English was conducted for each indicator according to the following strategy. A query using the Medline® (OVID interface) database was carried out using search equations for the period between January 2000 and August 2011 (see supplementary appendix 1, available at *Annals of Oncology* online) (with the exception of two equations for which no search period was determined due to a lack of data retrieved when applying the limit of the time period).

After management of duplicates, this search strategy identified 307 references. When consecutive publications were identified, only the last publication describing the largest number of patients was chosen.

The indicators were divided into structural indicators, process indicators, and outcome indicators [7]. Structural indicators correspond to healthcare facility resources, including material (equipment), human (number and qualification of staff), and organizational resources. Process indicators explore the means implemented to achieve an optimal result. Outcome indicators describe the objectives of the treatment—or a surrogate outcome, the impact of the treatment on quality of life, and the risk-benefit balance. Considering the multidisciplinary nature of ovarian cancer management, criteria related to medical oncology environment were included.

The final outcome criterion, such as cancer survival, may have to be replaced by a surrogate outcome that can be assessed in a timely fashion. The surrogate indicator must be predictive of the final outcome. Once an indicator has been determined to be directly related to the final result, it then becomes an indirect measure of it. For example, complete cytoreduction in advanced-stage ovarian cancer is an indirect measure of the chances of survival.

Quality of evidence was rated as moderate when based on expert consensus. The indicators will be presented as indicated in Table 1 and rated as indicated in Table 2.

**Results**

**Structural Indicators**

*Indicator 1.1:* A team consisting of at least two surgeons who are trained in abdominal and pelvic surgery is necessary to achieve...
Table 1. Rating of quality indicators

<table>
<thead>
<tr>
<th>Quality indicator</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specific usage</td>
<td>Situations, context of use, etc.</td>
</tr>
<tr>
<td>Importance</td>
<td>High, moderate, or weak</td>
</tr>
<tr>
<td>Expected impact</td>
<td>Impact on survival, comorbidities, or management</td>
</tr>
<tr>
<td>Confidence level</td>
<td>Quality and consistency of the data</td>
</tr>
<tr>
<td>Source documentation</td>
<td>Information on the number, type, etc.</td>
</tr>
</tbody>
</table>

Complete cytoreduction; a minimum of ten cytoreductive surgeries per surgeon per year is required

Field of application: Advanced ovarian cancers (stages IIIc–IV)
Impact: High
Quality of evidence: Moderate to high
Definition: This represents the number of stage IIIc or IV ovarian cancers that receive surgical management before (upfront surgery) or after neoadjuvant chemotherapy (interval surgery). Exploratory endoscopies, exploratory laparotomies, or surgeries limited to tissue biopsy, or surgeries that do not include at least a bilateral salpingo-oophorectomy, hysterectomy (if applicable), and a comprehensive peritoneal staging including omentectomy are not included.

Target objective: A number of 10 procedures per surgeon per year and 20 interventions per institutions per year are proposed as an objective. To ensure continuity of care, at least two surgeons are required.

Source documentation: The need for surgical training is derived from recommendations from learned societies [8, 9] and literature data [10]. The relationship between undergoing visceral surgery and survival has been demonstrated [10]. Visceral surgery is necessary in over 50% of patients to achieve complete cytoreduction [11]. Quantitative indicators by surgeon [12–15] and by institution [12–14, 16–21] were derived from the most compelling literature data (see discussion section).

Indicator 1.2: Formalized collaboration of the surgical team with a medical oncologist
Field of application: No restriction

Table 2. Presentation of confidence/impact rating

<table>
<thead>
<tr>
<th>Level of confidence</th>
<th>Expected Impact</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>High</td>
<td>Significant positive impact on survival, comorbidities or management leads to a significant change in practice.</td>
</tr>
<tr>
<td></td>
<td>Moderate</td>
<td>Significant positive impact on survival, comorbidities or management leads a potential change in practice.</td>
</tr>
<tr>
<td></td>
<td>Weak</td>
<td>Significant positive impact on survival, comorbidities or management. A change in practice is unlikely.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Level of confidence</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>New data are unlikely to change the level of confidence.</td>
</tr>
<tr>
<td></td>
<td>New data can have an impact on the level of confidence.</td>
</tr>
<tr>
<td></td>
<td>There is a high degree of uncertainty. New data will most likely have a significant impact on the level of confidence.</td>
</tr>
</tbody>
</table>
Impact: High
Quality of evidence: Moderate
Definition: Institutions managing ovarian cancers include the services of a medical oncologist.
Target objective: 100% of institutions not having a medical oncology service or without the permanent on-site presence of a medical oncologist should establish a formal relationship with a medical oncology team.
Source documentation: The presence of an in-hospital oncology department was investigated in five studies [22]. Only one demonstrated a survival benefit in the field of ovarian cancer [23].

Indicator 1.3: Institutional contributions to ovarian cancer clinical trials
Field of application: No restrictions
Impact: High
Quality of evidence: High
Definition: The institution is involved in at least one clinical trial programme.
Target objective: Multidisciplinary Tumour Board makes the proposal to participate in a registered trial to at least 10% of patients. This is the target set by The Cancer Plan 2009–2013.
Source documentation: Two converging studies identify the contribution to clinical trials in a given centre as an independent prognostic factor [24, 25].

Process indicators
Process indicators refer to the establishment of management protocol (indicators 2.1–2.2), to the anaesthetic management (2.3), to the surgical management (2.4–2.6), and to the pathology (2.7–2.8)

Indicator 2.1: Preoperative investigations should include, at minimum, a computed tomography scan, and measurement of marker Ca 125
Field of application: No restrictions
Impact: High
Quality of evidence: Moderate
Definition: A preoperative scan assessing the pelvic, abdominal, and chest regions must be carried out according to the recommendations of the European Society of Radiologists [26]. Tumour marker assays must include at least the determination of Ca 125. Assessment may also include laparoscopy.
Target objective: 100% of patient records will contain this information.
Source documentation: International recommendations of diagnostic practices (ESMO guidelines for diagnostic treatment and follow-up [27]).

Indicator 2.2: Formal pretreatment multidisciplinary approach before any decision for laparotomy or neoadjuvant chemotherapy. If neoadjuvant chemotherapy is proposed, a biopsy under radiologic or laparoscopic guidance is mandatory
Field of application: No restrictions
Impact: High
Quality of evidence: Moderate
Definition: The initial decision for immediate surgery or neoadjuvant chemotherapy should be taken jointly by at least a surgeon and a medical oncologist during a formal multidisciplinary Tumour Board meeting. If primary surgery is carried out, a second Tumour Board is indicated with the knowledge of pathological diagnosis and final staging. One of these meetings must also involve a pathologist and radiologist.
Target objective: 100% of patients will be discussed before a decision is made.
Source documentation: The role of the multidisciplinary approach in the quality of care is widely recognized in the management of ovarian and other cancers [28–30].

Indicator 2.3: Pre-, intra-, and post-operative anaesthetic management
Field of application: Stage IIIc and IV ovarian cancers
Impact: High
Quality of evidence: High
Definition: This criterion is defined in compliance with the recommendations adopted by the French Society of Anaesthesia Intensive Care (SFAR), the French Society of Digestive Surgery, and the French Society of Parenteral and Enteral Nutrition. Eight indicators were selected and classified specifically from AR 1 to AR 8. In preoperative management, two indicators are used: presence of a nutritional assessment and nutritional optimization with a minimum of seven days of enteral nutritional supplementation in cases of peritoneal carcinomatosis. Intraoperative management must include antibiotic prophylaxis before skin incision, hemodynamic monitoring, and the administration of at least two different classes of antiemetics. In the postoperative period, thromboprophylaxis with low molecular weight heparin for at least 4 weeks is required. The use of epidural analgesia preoperatively is suggested to contribute to the optimization of pain control as an integral part of postoperative rehabilitation, including physiotherapy, early deambulation, and rapid oral feeding, aiming at promoting a decrease in postoperative morbidity and duration of hospital stay (see supplementary appendix 2, available at Annals of Oncology online).
Target objective: 100% of surgical care for stage IIIc and IV ovarian cancers will conform to these recommendations.
Source documentation: Formalized recommendations drawn up by the SFAR using the Grade of Recommendation Assessment, Development, and Evaluation [31] adopted by the SFAR committee. In areas where no recommendation was made by SFAR, recommendations were developed based on evidence provided by meta-analysis of the current literature. The recommendations are not specific to surgery for ovarian cancer, but the underlying evidence can be applied in this context.

Indicator 2.4: Median laparotomy (xipo-pubic)
Field of application: No restriction, except occasional early-stage patients who can be managed by laparoscopy
Impact: High
Quality of evidence: High
Definition: Laparotomy extending from the xiphoid process to the pubic region
Target objective: 0% transverse or low midline laparotomies

Indicator 2.5: Performing a pelvic and para-aortic lymphadenectomy in cases of complete cytoreduction
Field of application: All early stages except those of mucinous type, all advanced stages where a complete cytoreduction was achieved and where the general condition of the patient permits) Impact: High
Quality of evidence: High
Definition: Complete dissection extending from the femoral rings to the left renal vein. Sampling is not accepted as standard.
Target objective: 100% complete lymphadenectomy
Source documentation: Same as for indicator 2.4

Indicator 2.6: Analytical description of initial peritoneal lesions and residual lesions in all segments of the abdomen
Field of application: No restriction Impact: High
Quality of evidence: High
Definition: Structured description of the initial and, if applicable, residual lesions. The use of validated scales, such as the Peritoneal Cancer Index and Completeness of cytoreduction (CC), is recommended (see supplementary appendix 3, available at Annals of Oncology online).
Target objective: 100% of reports are organized by anatomical regions and contain a description of the initial and, if any, residual lesions after cytoreductive surgery.
Source documentation: The importance of standardization to achieve improved completeness, reproducibility, and evaluation of data pertaining to peritoneal extension and residual tumour has been documented in several studies [32–35]. The prognostic value of the presence and extent of peritoneal carcinomatosis is documented [36–38]. The scores evaluating the extension of carcinomatosis were ranked at a consensus conference [39]. The Sugarbaker CC-score is the most widely used [40].

Indicator 2.7: Possibility of frozen section at the time of surgical intervention
Field of application: No restriction Impact: High
Quality of evidence: Moderate
Definition: A pathologist can be consulted intraoperatively.
Target objective: All institutions ensure access to facilities for frozen sections.
Source documentation: Most authors advise the practice of frozen section examination during surgery for an ovarian tumour of indeterminate nature [41, 42].

Indicator 2.8: Minimum required elements in pathology reports
Field of application: No restriction Impact: High
Quality of evidence: Moderate
Definition: Standardized reporting [http://www.e-cancer.fr/lantanomopathologie#compte-rendu]
Target objective: 100% of reports will contain the minimally required elements.
Source documentation: A recent European audit on the quality of pathological reports for ovarian cancer found that the origin of the tumour was missing in 20.5% of reports and the histological grade was absent in 10% [43]. This advocates for the use of templates based on data from the literature [44–46].

outcome indicators
Indicator 3.1: Rate of complete surgical resection either at initial surgery or after neoadjuvant chemotherapy
Field of application: No restriction Impact: High
Quality of evidence: High
Definition: Complete surgical resection is defined by the absence of remaining macroscopic lesions in all quadrants after careful exploration of the abdomen.
Target objective: The target of complete resection (CC-O) is set to 100% for stage I to IIIb and 70% for stage IIIC and IV.
Source documentation: Retrospective cohorts show that the overall survival of patients with cancer of the ovary stage III–IV was proportional to the proportion of optimal debulking surgery [47]. An analysis of a single-centre prospective cohort showed the direct impact of the increase in the proportion of patients with complete surgical resection on survival [48]. Analysis of multicentre prospective cohorts from three randomized trials showed that the median overall survival of patients with ovarian cancer stage IIB–III–IV reached 99 months in cases where complete surgical resection was achieved [49].

A recent meta-analysis by the Cochrane group revealed that when compared with microscopic residual disease, the risk of death is two times greater if there is residual disease <1 cm and three times higher in cases where residual disease measures >1 cm [50]. This concept is valid regardless of the timing of surgery and applies to the policy of neoadjuvant chemotherapy, which is not a substitute for complete resection [51]. The 70% target in advanced ovarian cancers has been reached in the most recent report on day-to-day practice of French centres in a multicentre study in the current era of complete cytoreductive surgery [11].

Indicator 3.2: Existence of a structured prospective reporting of complications within 30 days postoperatively
Field of application: None Impact: High
Quality of evidence: High
discussion

The main prognostic factor for ovarian cancer surgery is represented by the possibility of achieving complete cytoreduction. Practically speaking, around 70% of complete resections in advanced ovarian cancers are attainable based on the results obtained from a French multicentre national study collecting cases operated between 2003 and 2007 [11].

The Society of Surgical Oncology (USA) and the European Society of Gynaecological Oncology [8, 9] took a position to promote the training of gynaecological surgeons treating cancer for abdominal procedures including colorectal resection and diaphragm stripping and resection [9]. Surgeons who perform radical surgery in more than 50% of stage IIIc ovarian cancer cases obtain a median survival of 5.9 years compared with 2.5 years for other surgeons [10]. The rate of visceral surgery necessary to achieve complete cytoreduction (see test results) has been confirmed to be more than 50% of cases [11]. The technical ability of the surgeon must be adapted to this context.

The experience and caseload required are diversely estimated. In a systematic review, DuBois et al. [12] were unable to recognize the number of operations per surgeon as prognostic. In a US study based on the population of Maryland, surgeon volume significantly and independently decreased the risk of postoperative mortality by 69%, despite achieving a greater number of cytoreductive surgeries. The threshold was set at 10 cases per year per surgeon [14].

However, the review by DuBois [12] did not take into account the following two publications that gave evidence of a relationship between quality and volume [13, 18]. Finally, other publications after the DuBois systematic review complete the documentation. A US population-based study from Maryland assessing the influence of the number of procedures per institution (threshold of 20 cases per year) found an increase in the rate of cytoreduction (44%) with a paradoxical decrease in the duration of hospitalization, and as a result, a reduction in hospital costs [14]. In an Austrian study, a number of 24 per year established in a previous publication of the same investigators was confirmed as being prognostic [hazard ratio 1.38, confidence interval (CI) 1.2–1.7, P < 0.001] in a multivariate analysis [20]. A US-based study centred on the National Cancer Database for stage IIIC/IV between 1996 and 2005 included 45 929 patients. Survival was correlated with institutional volume. Compared with the reference point ‘1’, which represents institutions with more than 35 cases per year, the relative risk is 1.08 (significant) for institutions in the 9–20 case-per-year bracket, and 1.14 (significant) for those seeing less than nine cases per year. These differences persisted after accounting for treatment modalities. Considering the most recent evidence, the threshold was thus set at 20 interventions per year [21]. A Norwegian study also shows that the threshold of 10 surgeries per year per surgeon is prognostic [15]. An indirect argument was presented through the analysis of treatment results for women with ovarian cancer in East Anglia between 1996 and 2003 (3406 patients) [55]. A multidisciplinary approach and centralization of treatment were accompanied by improved prognosis in this population (hazard ratio 0.71, CI 0.64–0.79).

Quality of surgical care as a component of a comprehensive regimen of multidisciplinary management has been shown to benefit the patient in many types of malignancies. Implementation of a quality improvement programme helped to reduce both morbidity and costs in other tumours where surgical intervention is also high risk [56]. Structured operative reports are associated with a quality assurance programme [33, 34]. There is a consensus that multidisciplinary approach in cancer care benefits the patient [57, 58].

Careful perioperative management and collaboration with the anaesthetic team is critical. The dire prognosis of ovarian cancer is not amenable to current screening techniques and generally presents at an advanced stage, justifies specific measures to improve oncological outcomes while preventing an increase in the complication rate of aggressive surgical management. Among the necessary actions, a quality assurance programme is obviously required for surgery, as there is evidence that most ovarian cancer surgeries in non-specialized centres are suboptimal due to lack of skill and training in visceral surgery and lack of awareness of the need for complete cytoreduction. There is also evidence that the reduction in mortality from complex procedures is more related to the ability to manage complications than to surgical volume [59].

A multidisciplinary group representing the full range of learned societies in a single European country came to a consensus on defining structural, process, and outcome indicators supported by solid bibliographic evidence to assess the quality of surgical management of ovarian cancer. The enforcement of a quality assurance programme using these indicators in France, or their adaptation to practice in any country, would undoubtedly promote improvement in the quality of care for ovarian cancer patients and would result in a dramatic positive impact on their survival. The cost-effectiveness ratio of this policy has been shown to be favourable in experienced compared with less experienced centres. In spite of an obvious need for specific resources and an increase in short-term operational costs, such a policy is then not only beneficial to the patient, but is also profitable for the healthcare system [52, 54, 60].

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disclosure

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