European Society of Gynaecologic Oncology Quality Indicators for Advanced Ovarian Cancer Surgery

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Objectives: The surgical management of advanced ovarian cancer involves complex surgery. Implementation of a quality management program has a major impact on survival. The goal of this work was to develop a list of quality indicators (QIs) for advanced ovarian cancer surgery that can be used to audit and improve the clinical practice. This task has been carried out under the auspices of the European Society of Gynaecologic Oncology (ESGO).

Methods: Quality indicators were based on scientific evidence and/or expert consensus. A 4-step evaluation process included a systematic literature search for the identification of potential QIs and the documentation of scientific evidence, physical meetings of an ad hoc multidisciplinarity International Development Group, an internal validation of the targets and scoring system, and an external review process involving physicians and patients.

Results: Ten structural, process, or outcome indicators were selected. Quality indicators 1 to 3 are related to achievement of complete cytoreduction, caseload in the center, training, and experience of the surgeon. Quality indicators 4 to 6 are related to the overall management, including active participation to clinical research, decision-making process within a structured multidisciplinary team, and preoperative workup. Quality indicator 7 addresses the high value of adequate perioperative management. Quality indicators 8 to 10 highlight the need of recording pertinent information relevant to improvement of quality. An ESGO-approved template for the operative report has been designed. Quality indicators were described using a

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The project has been initiated by the European Society of Gynaecologic Oncology (ESGO), which has provided administrative and meeting expenses support. The decision to elaborate a set of quality assurance criteria has been made by the Guidelines and Quality Assurance of the ESGO, with the approval of the ESGO Council. The only external funding source was a grant from the Institut National du Cancer (INCa, Paris, France). The ESGO is a nonprofit knowledgeable society. The INCa is a French government agency.

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Andreas du Bois and Ignace Vergote contributed equally to this work.

The working group (including all authors) is collectively responsible for the decision to submit for publication. Denis Querleu and François Planchamp have chaired the working group as a physician and a methodologist, respectively. They have written the first draft of the manuscript. Systematic literature search was completed by François Planchamp. All other contributors have actively participated to the working group, given personal input, reviewed the manuscript, and have given final approval before submission.

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structured format specifying what the indicator is measuring, measurability specifications, and targets. Each QI was associated with a score, and an assessment form was built.

Conclusions: The ESGO quality criteria can be used for self-assessment, for institutional or governmental quality assurance programs, and for the certification of centers. Quality indicators and corresponding targets give practitioners and health administrators a quantitative basis for improving care and organizational processes in the surgical management of advanced ovarian cancer.

Key Words: Ovarian cancer, Cytoreduction, Quality assurance

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Ovarian cancer is the leading cause of death among all gynecologic cancers, with most patients presenting with advanced stage tumors, as defined by the spread of the disease outside the pelvis.[1,2] As the surgical management of advanced ovarian cancer involves complex surgery, quality of surgical care is a major component of the multidisciplinary management of the disease. Implementation of a quality management program in surgery has a major impact on survival of patients with advanced ovarian cancer.[3,4]

The European Society of Gynaecological Oncology (ESGO) has taken a position to promote the training of gynecological surgeons treating especially advanced stages of gynecologic cancer, incorporating colorectal and upper abdominal resection techniques.[5] In keeping with this policy, the decision to elaborate a set of quality assurance criteria, using a rigorous methodology, has been made by the Guidelines and Quality Assurance Committee of the ESGO, with the approval of the ESGO Council.

The aim of this project was to develop a list of quality indicators (QIs) for advanced ovarian cancer surgery that can be used to audit and improve the clinical practice in a straightforward and practical way. The key characteristics of an ideal indicator are clear definition, clinical relevance, measurability (including targets), feasibility in clinical practice, and a scientific basis. The QIs and proposed targets are based on the standards of practice determined from scientific evidence and/or expert consensus. These QIs 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 of structures, and the establishment of organizational priorities as a basis for accreditation.

The philosophy behind the project is to improve the average standard of surgical care by providing a set of quality criteria which can be used for self-assessment, for institutional quality assurance programs, for governmental quality assessment, and for the ESGO certification of centers, some of them with the special award of ESGO center of excellence, with the ultimate goal of building a European network of ESGO centers dedicated to ovarian cancer surgery. The mindset is not to be punitive but to incentivize. The targets defined by the workgroup are considered as optimal achievements, not as potential arguments to penalize or litigate physicians or institutions. Certified centers and centers of excellence can make the certification known to physicians, patients, patient advocacy groups, and lay persons.

METHOD

Quality indicators for advanced ovarian cancer surgery were developed using a 4-step evaluation process inspired by published development processes and earlier initiatives, identified from a systematic literature search carried out in MEDLINE and selected Web sites (see Appendix 1, Supplemental Digital Content 1, http://links.lww.com/IGC/A398). This process development included 3 physical meetings of an ad hoc International Development Group (IDG) (Table 1). The strengths of this process are (1) multidisciplinarity of an international experts panel, (2) scientific evidence and/or international expert consensus to support the QIs, (3) patients' involvement in the process, (4) use of an external review process (international validation by physicians and patients), (5) use of a structured format to present the QIs, and (6) management of potential conflicts of interests.

Nomination of an IDG

The ESGO Guidelines and Quality Assurance committee nominated the IDG members, who were approved by the ESGO Council, which placed the project under the leadership of the first author (gynecologic oncologist, chair) and the second author (methodologist, co-chair). One objective was to select active physicians who have demonstrated leadership in quality improvement through research, administrative responsibilities, or committee membership to serve as expert panel. The second objective was to assemble a multidisciplinary group. It was therefore essential to include professionals on the group from relevant disciplines so that their multidisciplinary perspective would influence the validity and acceptability of the chosen indicators (surgery, medical oncology, pathology, radiology, anesthesiology, gynecologic oncology, radiation oncology, clinical science). The third requirement was a balanced representativity of countries across Europe.

The experts of the IDG were required to complete a declaration of interest form, and to promptly inform the ESGO council if any change in the disclosed information occurred during the course of the project. The completed declaration of interest forms were reviewed by the surgical and methodologic co-chair.

TABLE 1. Development process—a 4-step evaluation process

Evaluation Steps	Development Process Framework
	Nomination of multidisciplinary IDG members
	Identification of potential QIs (n = 15)
	Identification of scientific evidence
Evaluation #1	IDG members independently evaluate the relevance and feasibility of each QI
Evaluation #2	IDG members discuss each potential QI (1st meeting). Ten QIs were retained
	Synthesis of scientific evidence
Evaluation #3	External international panel of physicians and patients evaluates the relevance and feasibility of retained QIs (international review)
	IDG members discuss and integrate the comments of international reviewers (2nd meeting). A scoring system is designed
Evaluation #4	Internal validation of the scoring system. The workgroup members fill a self-assessment form. Definition and target of criteria not universally met by expert centers are modified (3rd meeting)

Identification of Potential QIs

A bibliographic search was carried out to identify existing guidelines and published indicators using a systematic literature search in MEDLINE and selected Web sites (see Appendix 2, Supplemental Digital Content 2, http://links.lww.com/IGC/A399). References were selected if they described indicators developed by other agencies or synthesized research evidence describing practice contributing to improve patient outcomes (guidelines or consensus statements). Five previous initiatives publishing QIs for advanced ovarian cancer surgery were identified.[6–10] The surgical and methodologic co-chairs compiled a list of 15 possible quality assurance domains as follows: inclusion in the surgical team of a medical oncologist, surgery performed by a gynecologic oncologist, inclusion of patients in clinical trials, delay between decision to treat and treatment, pelvic and para-aortic lymphadenectomy, pretreatment multidisciplinary decision-making process, perioperative management, prospective reporting of complications, midline laparotomy, volume of ovarian surgery, pathology report, operative report, intraoperative frozen section, complete surgical resection, and preoperative investigations.

Identification of Scientific Evidence

Another systematic literature search was then conducted in MEDLINE to identify available scientific evidence which supports the 15 possible quality domains (see Appendix 3, Supplemental Digital Content 3, http://links.lww.com/IGC/A400). The reference list of each identified article was reviewed for other potentially relevant papers. The bibliography was also supplemented by additional references provided by the IDG members.

Evaluation of the Potential QIs

A description of 15 possible QIs was then formatted as a questionnaire which was submitted by e-mail to the IDG members. Experts were asked to evaluate each indicator according to relevance and feasibility in clinical practice. Responses were pooled and organized according to consensus about relevance and feasibility. The results of this first evaluation were sent to experts who convened during the first 1-day meeting. Acceptance, rejection, or the need for further consideration of each indicator was discussed during the meeting. Candidate QIs were retained if they were supported by scientific evidence and/or when a consensus among experts was obtained.

Ten QIs were retained by the IDG members. The 5 remaining indicators which were not retained as a result of lack of supporting evidence, or of duplication of quality information were (1) inclusion in the medical team of a medical oncologist (addressed in the multidisciplinary management), (2) delay between the decision to treat and treatment (lack of evidence and no large consensus among experts), (3) midline laparotomy (addressed in the complete resection and operative report item), (4) intraoperative frozen sections (however, availability of frozen section examination by a specialized pathologist is strongly encouraged), and (5) pelvic and para-aortic lymphadenectomy (removal of enlarged nodes is part of complete cytoreduction and is the standard in patients with stage III based on lymph node involvement only; however, there is no evidence of increased overall survival when routine comprehensive node dissection is performed after complete intraperitoneal cytoreduction).

Synthesis of Scientific Evidence

For the 10 retained QIs, the systematic literature search as described in Appendix 3 (Supplemental Digital Content 3, http://links.lww.com/IGC/A400), has been extended until July 1, 2015, to update the documentation for the second 1-day meeting. All retrieved articles have been methodologically and clinically appraised. After the selection and critical appraisal of the articles, a summary of the scientific evidence has been developed. To classify the risk of bias or confounding in the identified studies, we used the Oxford Center for Evidence-Based Medicine level of evidence.[11]

External Evaluation of the Retained QIs (International Review)

The ESGO Council established a large panel of 232 practicing ESGO members and 31 patient-representatives.

These international reviewers were independent from the IDG. Another requirement was a balanced representativity of countries across Europe. The 10 retained QIs were formatted as a questionnaire and were sent by e-mail to the international reviewers who were asked to evaluate each indicator according to relevance and feasibility in clinical practice (physicians only). Open comments were encouraged. Quantitative and qualitative evaluations were returned by 84 independent physicians and by 8 patients with ovarian cancer (the list of international reviewers is available online at ESGO Web site, http://www.esgo.org/). Responses were pooled and sent to experts who convened during the second 1-day meeting. The pooled results of the external quantitative evaluation were examined, and confirmed the choice of the 10 QIs (see Appendix 4, Supplemental Digital Content 4, http://links.lww.com/IGC/A401). All comments were reviewed and discussed by the IDG members. A first version of the QIs was then printed and circulated at the time of the 19th meeting of the ESGO in Nice.

On the basis of the first version of the QIs, the targets, along with a tentative scoring system, were then tested in the institutions of the workgroup members. The members were asked to fill a self-assessment form. All 13 surgical members of the workgroup responded. As expected, all experts' institutions fulfilled the criteria, but contrasted findings cast doubts on the wording of the first version of the criterion 1.2, regarding the rate of primary debulking surgery. The definition of the criterion 1.2 was consequently modified at the time of a third meeting. The second version of the list and the scoring system are presented in this article.

RESULTS

Each retained QI is categorized as structural, process, or outcome indicator.[12] Each retained QI description specifies what the indicator is measuring. The measurability specifications are then detailed (Table 2). The latter highlights how the indicator will actually be measured in practice to allow audits. In this regard, the timeframe for assessment of criteria is the last calendar year. Further to measurement of the indicator, a target indicates the level which each unit/center should be aiming at to meet quality requirements. When appropriate, 2 or 3 targets were defined: an optimal target, expressing the best possible option for patients; a minimal target, expressing the minimal requirement when practical feasibility factors are taken into account; and intermediate target, if necessary. Targets were based on evidence whenever available, on the personal experience or database of development group members, on expert consensus, and on feedback from the physician's external reviewers. Full description of supporting evidence is available on the ESGO Web site (http://www.esgo.org/).

Quality indicators 1 to 3 are related to caseload in the center, training, skills, and experience of the surgeon and the surgical team. The panel decided that there is overwhelming evidence to support the use of complete cytoreduction in advanced stages of the disease as the best QI of the surgical procedure. Complete cytoreduction seems to be the best surrogate marker for the final overall outcome, defined as overall survival. Because overall survival can be measured only years after the completion of surgery, surrogacy was felt necessary. However, structuration of a survival database is strongly recommended. Caseload per center has been found to have a prognostic impact. The cutoff derived from relevant studies is in the order of 20 cases per year, including any surgery for ovarian cancer, and does not take into account the number of involved surgeons. As a result, the panel decided to set a more stringent minimum requirement of 20 surgeries for advanced ovarian cancer surgery per center. Furthermore, the panel felt that the cutoff of 20 surgeries is probably not adapted to account for the need of a relevant team experience. As a result, an intermediate and an optimal target of 50 and 100, respectively, were set. In addition, the panel wanted to make clear that the umbrella of a center with sufficient caseload cannot replace sufficient individual surgical expertise, and therefore defined that more than 95% of the surgeries should be performed or supervised by surgeons operating at least 10 patients with ovarian cancer a year. Finally, the panel identified and highlighted the high need to appropriately structure the training of gynecologic oncologists to ascertain that future patients with ovarian cancer will be operated on by a certified gynecological oncologist or, in countries where certification is not organized, by a trained surgeon dedicated to the management of gynecologic cancer (accounting for more than 50% of his or her practice) or having completed an ESGO-accredited fellowship. Again, skills to successfully complete complex abdominal and pelvic surgery procedures necessary to achieve complete cytoreduction must be available. Finally, it is emphasized that caseload and certification per se does not guarantee quality if updated skills are not available.

Quality indicators 4 to 6 are related to the overall management of the patients with ovarian cancer. Although the association between the active participation of each individual center to clinical research and survival is probably multifactorial, there is evidence that survival is better in centers participating to clinical trials.[13] The panel concluded that, for a number of reasons, including the need for assessment of novel therapies, participation in clinical trials should be formally encouraged. The decision-making process within a structured multidisciplinary team including a gynecological oncologist as defined in QIs 2 and 3, a radiologist with a special interest in gynecologic oncology, a pathologist (if a biopsy is available) with a special interest in gynecologic cancer, and a physician certified to deliver chemotherapy is considered mandatory for the management planning of every individual patient, before any surgery or neoadjuvant chemotherapy. Of great importance is that preoperative imaging excludes from cytoreductive surgery those patients with unresectable distant parenchymal metastases, and secondary ovarian neoplasms—such as deriving from the gastrointestinal tract or lymphomas—by suitable methods such as up-to-date abdominal and thoracic imaging, the ratio of plasma CA 125 and CEA levels, and/or by biopsy under radiologic or laparoscopic guidance.

Quality indicator 7 addresses the high value of adequate anesthesiology and perioperative care to ensure an optimal surgical outcome, with not only reduction of surgical morbidity but also the facilities and personnel, to properly manage the complications when they occur.[13] The panel concluded that maximal cytoreductive surgery for advanced

TABLE 2. Presentation of QIs

QI 1—Rate of Complete Surgical Resection	
Type	Outcome indicator
Description	Complete abdominal surgical resection is defined by the absence of remaining macroscopic lesions after careful exploration of the abdomen. Whenever feasible, localized thoracic disease is resected. Surgery can be decided upfront, or planned after neoadjuvant chemotherapy. However, the quality assurance program must take into account that patients who can be operated upfront with a reasonable complication rate benefit most from primary debulking surgery.
Specifications	(i) Complete resection rate (all patients): • Numerator: no. patients with advanced ovarian cancer undergoing complete surgical resection • Denominator: all incoming patients with advanced ovarian cancer (ii) Proportion of stage III–IV patients who are operated upfront: • Numerator: stage III–IV patients undergoing primary cytoreductive surgery • Denominator: all incoming patients with untreated advanced ovarian cancer
Target(s)	(i) Complete resection rate (all patients): • Optimal target: >65% • Minimum required target: >50% (ii) Proportion of primary debulking surgeries (stage III–IV patients): ≥50%
Scoring rule	(i) 5 if the optimal target is met, 3 if the minimum required target is met (ii) 3 if the target is met
QI 2—No. Cytoreductive Surgeries Performed Per Center and Per Surgeon Per Year	
Type	Structural indicator (no. upfront or interval cytoreductive surgeries performed per center) Process indicator (no. surgeries per surgeon per year)
Description	Only surgeries with an initial objective of complete cytoreduction are recorded. Exploratory endoscopies, exploratory laparotomies, or surgeries limited to tissue biopsy that do not include at least a bilateral salpingo-oophorectomy (if applicable), hysterectomy (if applicable), and a comprehensive peritoneal staging including omentectomy are not included.
Specifications	Numerator: (i) no. cytoreductive surgeries as defined previously performed per center per year; (ii) no. cytoreductive surgeries as defined previously performed per surgeon per year. Secondary and tertiary procedures are accepted. Denominator: not applicable
Target(s)	(i) No. surgeries performed per center per year: • Optimal target: n ≥ 100 • Intermediate target: n ≥ 50 • Minimum required target: n ≥ 20 (ii) ≥95% of surgeries are performed or supervised by surgeons operating at least 10 patients a year
Scoring rule	(i) 5 if the optimal target is met, 3 if the intermediate target is met, 1 if the minimum required target is met (ii) 3 if the target is met
QI 3—Surgery Performed by a Gynecologic Oncologist or a Trained Surgeon Specifically Dedicated to Gynecological Cancers Management	
Type	Process indicator
Description	Surgery is performed by a certified gynecologic oncologist or, in countries where certification is not organized, by a trained surgeon dedicated to the management of gynecologic cancer (accounting for more than 50% of his practice) or having completed an ESGO-accredited fellowship. Skills to successfully complete abdominal and pelvic surgery procedures necessary to achieve complete cytoreduction must be available.
Specifications	Numerator: no. patients with advanced ovarian cancer operated by a specialist (as defined previously) Denominator: all patients undergoing surgery for advanced ovarian cancer

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TABLE 2. *(Continued)*

Target(s)	≥90%
Scoring rule	3 if the target is met
QI 4—Center Participating in Clinical Trials in Gynecologic Oncology	
Type	Structural indicator
Description	The center actively accrues patients in clinical trials in gynecologic oncology
Specifications	Numerator: not applicable
	Denominator: not applicable
Target(s)	Not applicable
Scoring rule	3 if the center actively accrues patients in clinical trials in gynecologic oncology
QI 5—Treatment Planned and Reviewed at a Multidisciplinary Team Meeting	
Type	Process indicator
Description	The decision for any major therapeutic intervention has been taken by a multidisciplinary team (MDT) including at least a surgical specialist as defined previously (QI 2 and QI 3), a radiologist, a pathologist (if a biopsy is available), and a physician certified to deliver chemotherapy (a gynecologic oncologist in countries where the subspecialty is structured and/or a medical oncologist with special interest in gynecologic oncology).
Specifications	Numerator: no. patients with advanced ovarian cancer for whom the decision for therapeutic intervention(s) has been taken by an MDT
	Denominator: all patients with advanced ovarian cancer undergoing therapeutic intervention(s)
Target(s)	≥95%
Scoring rule	3 if the target is met
QI 6—Required Preoperative Workup	
Type	Process indicator
Description	Unresectable parenchymal metastases have been ruled out by imaging. Ovarian and peritoneal malignancy secondary to gastrointestinal cancer has been ruled out by suitable methods, for example, plasma CA 125 and CEA levels, and/or by biopsy under radiologic or laparoscopic guidance.
Specifications	Numerator: no. patients with advanced ovarian cancer who had undergone cytoreductive surgery and who were offered minimum preoperative workup as defined previously
	Denominator: all patients with suspected advanced ovarian cancer who underwent cytoreductive surgery
Target(s)	≥95%
Scoring rule	3 if the target is met
QI 7—Preoperative, Intraoperative, and Postoperative Management	
Type	Structural indicator
Description	The minimal requirements are (1) intermediate care facility, and access to an intensive care unit in the center are available; and (2) an active perioperative management program is established*
Specifications	Numerator: not applicable
	Denominator: not applicable
Target(s)	Not applicable
Scoring rule	3 if the minimal requirements are met.
QI 8—Minimum Required Elements in Operative Reports	
Type	Process indicator
Description	Operative report is structured. Size and location of disease at the beginning of the operation must be described. All the areas of the abdominal cavity† must be described. If applicable, the size and location of residual disease at the end of the operation, and the reasons for not achieving complete cytoreduction must be reported.

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TABLE 2. *(Continued)*

Specifications	Numerator: no. patients with advanced ovarian cancer undergoing cytoreductive surgery who have a complete operative report that contains all required elements as defined previously
	Denominator: all patients with advanced ovarian cancer undergoing cytoreductive surgery
Target(s)	90%
Scoring rule	3 if the target is met
QI 9—Minimum Required Elements in Pathology Reports	
Type	Process indicator
Description	Pathology report contains all the required elements listed in the International Collaboration on Cancer Reporting (ICCR) histopathology reporting guide.‡§
Specifications	Numerator: no. patients with advanced ovarian cancer undergoing cytoreductive surgery who have a complete pathology report that contains all required elements as defined in ICCR histopathology reporting guide
	Denominator: all patients with advanced ovarian cancer undergoing cytoreductive surgery
Target(s)	≥90%. The tolerance within this target reflects situations where it is not possible to report all components of the data set due to poor quality of specimen.
Scoring rule	3 if the target is met
QI 10—Existence of a Structured Prospective Reporting of Postoperative Complications	
Type	Outcome indicator
Description	Data to be recorded are reoperations, interventional radiology, readmissions, secondary transfers to intermediate or intensive care units, and deaths.
Specifications	Numerator: no. recorded serious postoperative complications or deaths occurred among patients with advanced ovarian cancer who have undergone cytoreduction
	Denominator: all complications occurred among patients with advanced ovarian cancer who have undergone cytoreduction
Target(s)	Optimal target: 100% of complications are prospectively recorded
	Minimum required target: selected cases are discussed at morbidity and mortality conferences
Scoring rule	3 if the optimal target is met, 1 if the minimum required target is met

*Details of perioperative management include (nonexhaustive list) preoperative hemoglobin optimization and iron deficit correction; correction of denutrition and immunonutrition according the current guidelines; fluid management, involving a Goal-Directed Therapy (GDT) policy rather than liberal fluid therapy without hemodynamic goals. However, the superiority of GDT compared to restrictive fluid strategy remains unclear. There is no recognized standard method of monitoring; pain management, including in the absence of contraindication the use of epidural analgesia to avoid opioids; although routine premedication is no longer recommended, prevention of postoperative nausea and vomiting should be systematic.

†Ovaries, tubes, uterus, pelvic peritoneum, paracolic gutters, anterior parietal peritoneum, mesentery, peritoneal surface of the colon and bowel, liver, spleen, greater and lesser omentum, porta hepatis, stomach, Morrison pouch, lesser sac, undersurface of both hemidiaphragms, pelvic and aortic nodes and if applicable pleural cavity.

‡https://www.rcpa.edu.au/Library/Practising-Pathology/ICCR/Cancer-Datasets.

§McCluggage WG, et al. Data set for reporting of ovary, fallopian tube and primary peritoneal carcinoma: recommendations from the International Collaboration on Cancer Reporting (ICCR). Mod Pathol (2015).

ovarian cancer cannot be undertaken in hospitals without the availability of at least an intermediate care facility, or without access to an intensive care unit. In addition, there is a definite need for a comprehensive perioperative management program including (nonexhaustive list) preoperative hemoglobin optimization and iron deficit correction; correction of malnutrition and immunonutrition according to the current guidelines; fluid and fluid shift management, involving a Goal-Directed Therapy (GDT) policy rather than liberal fluid therapy without hemodynamic goals—even if the superiority of GDT compared to restrictive fluid strategy remains unclear, with no recognized standard method of monitoring available. The panel also emphasized the significant value of adequate pain management, with an epidural service available; routine premedication not being longer recommended, whereas prevention of postoperative nausea and vomiting should be systematic.

Quality indicators 8 to 10 highlight the need for a complete and transparent information flow on the management and surgical outcome of the patient, with the objective of recording information relevant to future patient care, communication with colleagues, assessment of quality, and monitoring of improvement of quality. The operative report must be

structured. Size and location of disease at the beginning of the operation must be described. All the areas of the abdominal and pelvic cavity (ovaries, tubes, uterus, pelvic peritoneum, paracolic gutters, anterior parietal peritoneum, mesentery, peritoneal surface of the colon and bowel, liver, spleen, greater and lesser omentum, hepatic port hepatic, stomach, Morison pouch, lesser sac, surface of both hemi diaphragms, pelvic and para-aortic lymph nodes, and if applicable pleural cavity) must be evaluated and described. If applicable, the size and location of residual disease at the end of the operation, and the reasons for not achieving complete cytoreduction must be reported. An ESGO-approved template will be made available on the ESGO Web site. The pathology report should contain all the required elements listed in the International Collaboration on Cancer Reporting histopathology reporting guide. The tolerance regarding the targets for QIs 8 and 9 reflects emergency situations, or impossibility to correctly assess the abdominal and pelvic cavity, or poor quality of surgical specimens. Finally, although it seems unrealistic to define a number of postoperative complication rates that would seem acceptable, because this depends on the extent of the surgery and patients' condition, it is considered mandatory to properly monitor surgical morbidity and mortality during the first 30 days after surgery within structured morbidity and mortality meetings

TABLE 3. Self-Assessment Form

QIs	Targets (Tick if Applicable)		Scoring Rules
1. Rate of complete surgical resection			
1.1. Rate of complete surgical resection	>65%	□	Score: 5
	51%–65%	□	Score: 3
	≤50%	□	Score: 0
1.1. Rate of primary debulking surgeries	≥50%	□	Score: 3
	<50%	□	Score: 0
2. No. cytoreductive surgeries performed per center and per surgeon per year			
2.1. No. cytoreductive surgeries performed per center per year	≥100	□	Score: 5
	50–99	□	Score: 3
	20–49	□	Score: 1
2.1. Surgeries supervised or performed by surgeons operating at least 10 patients a year	≥95%	□	Score: 3
	<95%	□	Score: 0
3. Surgery performed by a gynecologic oncologist or a trained surgeon specifically dedicated to gynecological cancers management	≥90%	□	Score: 3
	<90%	□	Score: 0
4. Center participating in clinical trials in gynecologic oncology	Yes	□	Score: 3
	No	□	Score: 0
5. Treatment planned and reviewed at a multidisciplinary team meeting	≥95%	□	Score: 3
	<95%	□	Score: 0
6. Required preoperative workup	≥95%	□	Score: 3
	<95%	□	Score: 0
7. Preoperative, intraoperative, and postoperative management	Yes	□	Score: 3
	No	□	Score: 0
8. Minimum required elements in operative reports	≥90%	□	Score: 3
	<90%	□	Score: 0
9. Minimum required elements in pathology reports	≥90%	□	Score: 3
	<90%	□	Score: 0
10. Existence of a structured prospective reporting of postoperative complications	All complications are prospectively recorded	□	Score: 3
	There is no prospective complication database but selected cases are discussed at morbidity and mortality conferences	□	Score: 1
	Other situations	□	Score: 0
→Please register the sum of your scores←			

and through an established mechanism to prospectively assess, report, and describe complications.

Finally, each QI was associated with a score, and an assessment form was built (Table 3). The form is designed to support the self-assessment, or the external assessment of an institution. The sum of the individual scores being 40, it has been decided to consider that an institution meeting 80% of the score (score 32) provides a satisfactory surgical management of advanced ovarian cancers.

DISCUSSION

Complete surgery, compared with any surgery leaving behind any residual tumor, even minimal, is a strong and independent predictor of survival, and consequently the best possible surrogate for survival outcome.[14–17] Consequently, completion of complete surgery, along with the necessary training, surgical skills, experience, and perioperative management, is the centerpiece of the QI set. A debate about the timing of surgery has been ongoing since the pivotal publication of the EORTC 55971 trial comparing primary debulking surgery to interval debulking surgery after neoadjuvant chemotherapy.[18] Although many centers favor a policy of neoadjuvant chemotherapy, primary debulking surgery is still considered as the preferred option whenever possible with reasonable morbidity, taking into account the extent of surgery required to achieve complete resection and the patient's status.[16] A subset of patients with relatively low tumor burden (peritoneal metastasis less than 5 cm in diameter) in the EORTC 55971 trial clearly benefit from primary debulking surgery.[18] Anyway, complete surgery is the main objective of interval debulking surgery as well.[17] Interestingly, the results of the EORTC 55971 are valid in the subset of countries with high optimal resection rate, in line with the current primary objective of ovarian cancer surgery.

Implementation of QIs mentioning caseload of institutions and individual surgeons is a potentially conflictual topic. The definitions of the cutoff targets at 20 surgeries for advanced ovarian cancer per year and per center and at 10 surgeries per year per surgeon are based on available literature, whereas the 50 and 100 targets are the result of expert consensus. Large-scale studies have provided evidence that caseload is associated with better survival outcomes[19–22] and less perioperative mortality.[23] The cutoff previously mentioned, which a significant effect on outcome is found, has been consistently found to be in the range of 20 per year (20 in 2 studies,[19,22] and at 15–25 in another large-scale study[21]). In addition, patients managed in a low-volume hospital are less likely to receive guideline adherent care.[21] The combination of a high-volume hospital and high-volume surgeon has been found to be a favorable prognostic factor, with a 1.31 hazard ratio compared to low-volume hospital and surgeon.[20] The workgroup has decided to use the 20 cases per institution and per year cutoff as a minimal requirement, while observing that a higher caseload is most probably beneficial, if only through the need to structure a proper multidisciplinary team. In addition, although the literature data are based on all types of ovarian cancer, it has been decided to target advanced ovarian cancers only, making the requirement more stringent. Finally, specialty and experience of the surgeon has been highlighted to prevent physicians with very low experience from benefiting from the caseload of the whole institution.

There is evidence that centralization of care at the national level of 2 developed countries, Norway and Denmark, results in an improvement of survival.[24,25] At the same time, the implementation of a quality assurance program in an institution with a high caseload results in substantial improvement in survival outcomes.[3,4] Consequently, it is emphasized that centralization and volume are not the only driver of improvement. As volume is an imprecise measure of quality of health care, quality assurance remains mandatory in referral centers.

Current developments of the European quality assurance program include an ESGO-approved template for operative report which is available in the ESGO Web site and a methodology for ESGO certification, including a scoring system for the purpose of self-assessment or certification. Certification will be based on the completion of application forms on the grounds of database-generated numbers and declaration of adherence to structural, process, and outcome indicators. Only centers performing more than 20 surgeries for advanced ovarian cancer and able to provide exact figures documenting the responses to the assessment form will be considered. The following items must be documented for each case referred and managed in the applicant institution during the last calendar year: age, performance status, FIGO stage and sub-stage, patient offered primary debulking surgery or surgery after neoadjuvant chemotherapy, complete cytoreduction or not. An ESGO certification process, based on the declaration of the institutions, and possibly on audits on-site, is being developed. Institutions reaching the 32 score will be certified for 5 years if the ad hoc ESGO committee validates the application. Institutions scoring less than 32 but over 28 will be asked to resubmit after one year when they reach the 32 certification score. In addition to the standard certification award, centers of excellence will be defined on the basis of high volume (≥50 stage III–IV cytoreductive surgeries per year), a position of national PI of at least one clinical trial on ovarian cancer, one peer-review publication (first or last author) on ovarian cancer in the last three years, and an accredited ESGO fellowship. The centers of excellence award will be a tool to build a network for education—hosting visitors and/or organizing teaching sessions with live surgery demonstrations and/or providing material for ESGO e-academy—and research.

Admittedly, targets and corresponding scores have been largely arbitrarily set. Target figures may depend on the casemix of the center. The system will have to be refined in the future with the feedback provided by the scoring of candidate centers, and by a prospective research on the multivariate correlation between survival outcome, characteristics of the patient, and indicators.

It is hoped that governments and health care administrations will understand that implementing a global quality assurance program is currently a necessary and cost-effective way to improve the outcome of patients with ovarian cancer.[26] Fostering access of patients to high-quality care through organized centralization, coverage of care costs, and funding of institutions is especially needed in countries where there is no structured policy at a national level. In conclusion, the

implementation of institutional quality assurance programs is a universal way to improve quality of care, even in high-volume centers. The ESGO QIs and certification program may be a major tool to facilitate this achievement.

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