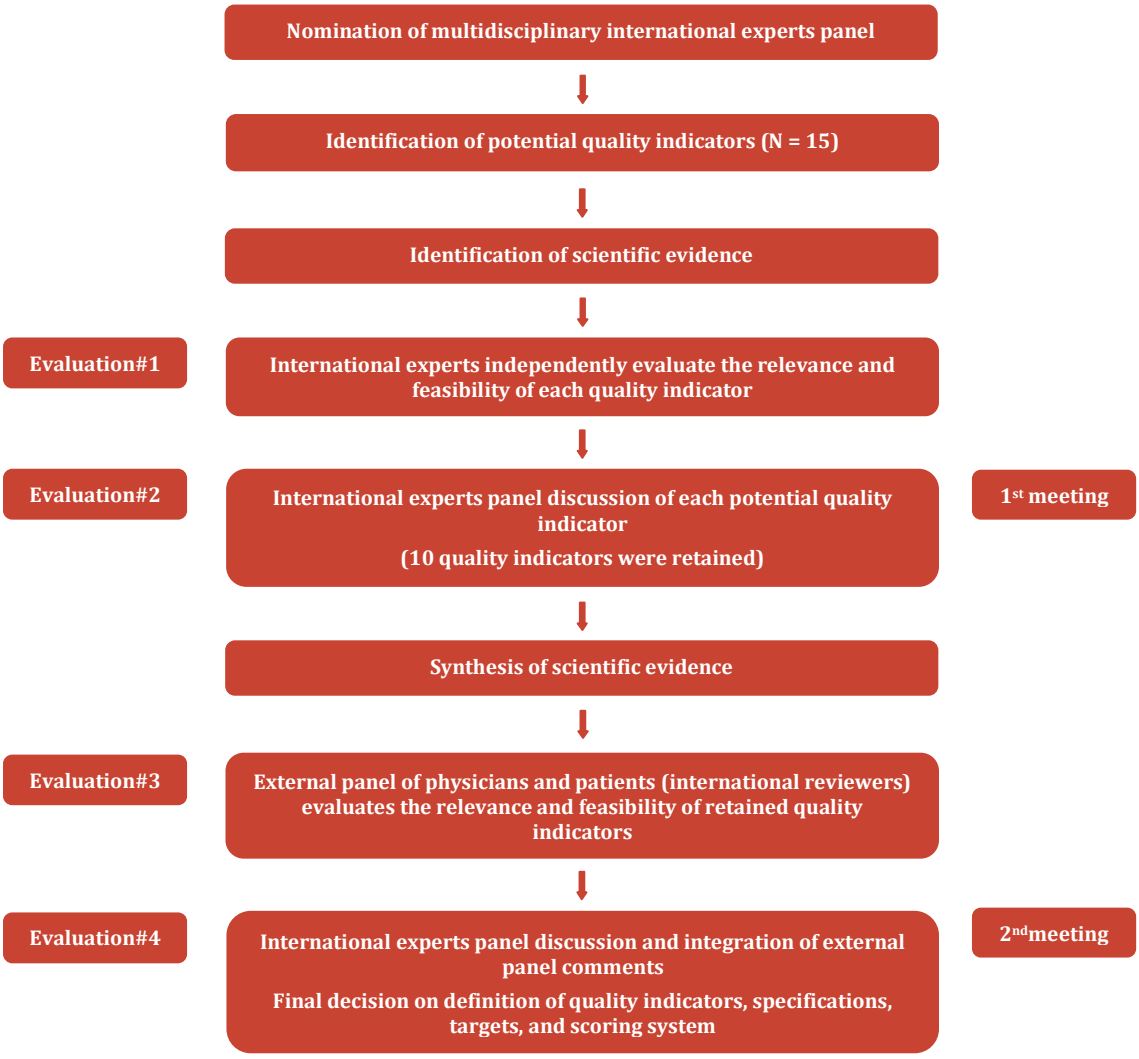
ADVANCED (STAGE III-IV) OVARIAN CANCER SURGERY QUALITY INDICATORS

Ovarian cancer is the leading cause of death among all gynecologic cancers and remains the most common cause of death for 15 years after diagnosis in women with stage III-IV tumours[1]. Surgery is the cornerstone in treatement of advanced ovarian cancer. Quality of surgical care as a component of a comprehensive regimen of multidisciplinary management has been shown to benefit the patient in other types of malignancies. Implementation of a quality management programme could impact survival of patients with advanced ovarian cancer[2,3].

The European Society of Gynaecological Oncology (ESGO) has developed a list of quality indicators for advanced ovarian cancer surgery that can be used to audit and improve the clinical practice in an easy and practical way. After a comprehensive literature search, each retained quality indicator was categorized as structural indicator, process indicator, and outcome indicator[4].

A four-step evaluation process was followed :



[1]Ferlay, J., et al. Cancer incidence and mortality pattens in Europe : estimates for 40 countries in 2012. Eur J Cancer 49, 1374-1403 (2013).

[2]Harter, P., et al. Impact of a structured quality management program on surgical outcome in primary advanced ovarian cancer. Gynecol Oncol 121, 615-619 (2011).

[3]Aletti, G.D., et al. Quality improvement in the surgical approach to advanced ovarian cancer : the Mayo Clinic experience. J Am Coll Surg, 614-620 (2009).

[4]Mainz, J. Defining and classifying clinical indicators for quality improvement. *Int J Qual Health Care***15**, 523-530 (2003).

Each quality indicator has a description which specifies what the indicator is measuring. The measurability specifications are then detailed. The latter highlight 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 is indicated. This dictates the level which each unit/center should be aiming to achieve against each indicator. When appropriate, two targets were defined: an optimal target, expressing the best possible option for patients, and a minimal target, expressing the minimal requirement when practical feasibility factors are taken into account. An intermediate target was defined if necessary. Targets were based on evidence whenever available, on the personal experience or database of workgroup members, on expert consensus, and on feedback from the physicians external reviewers. They may have to be modified in the future.

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 eventually to build a network of certified centres for ovarian cancer surgery. The mindset is not punitive but incentive. Certified centers can make the award known from doctors, patients, patient advocacy groups and lay persons. On the contrary, the targets defined by the workgroup can absolutely not be used to penalize or litigate doctors or institutions.

QI 1 -Rate of complete surgical resection

DESCRIPTION OF THE PROPOSED QUALITY INDICATOR	
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: • *Numerator*: number of patients with advanced ovarian cancer undergoing complete surgical resection. • *Denominator*: all patients with advanced ovarian cancer referred to the center. (ii) Proportion of patients who are operated upfront*(based on evidence from the EORTC 55971 trial, only patients presenting with low metastatic volume (peritoneal metastases less than 5 cm in diameter) are considered;patients with unresectable parenchymal metastases are excluded).* • *Numerator*: patients who are offered upfront surgery. • *Denominator*: all patients not previously treated.
TARGET(S)	(i) Complete resection rate: • *Optimal target*: > 65%. • *Minimum required target:*> 50%. (ii) Proportion of patients who are operated upfront: >80%

QI 2 -Number of cytoreductive surgeries performed per center and per surgeon per year

DESCRIPTION OF THE PROPOSED QUALITY INDICATOR	
TYPE	Structural indicator (number of upfront or interval cytoreductive surgeries performed per center). Process indicator(number of 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) number of cytoreductive surgeries as defined above performed per center per year. (ii) number of cytoreductive surgeries as defined above performed per surgeon per year. Secondary and tertiary procedures are accepted. *Denominator*: not applicable.
TARGET(S)	(i) Number of 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.

QI 3 -Surgery performed by a gynecologic oncologist or a trained surgeon specifically dedicated to gynaecological cancers management

DESCRIPTION OF THE PROPOSED QUALITY INDICATOR	
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 over 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*: number of patients with advanced ovarian cancer operated by a specialist (as defined above). *Denominator*: all patients undergoing surgery for advanced ovarian cancer.
TARGET(S)	≥ 90%.

QI 4 -Center participating in clinical trials in gynecologic oncology

DESCRIPTION OF THE PROPOSED QUALITY INDICATOR	
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.

QI 5 -Treatment planned and reviewed at a multidisciplinary team meeting

DESCRIPTION OF THE PROPOSED QUALITY INDICATOR	
TYPE	Process indicator.
DESCRIPTION	The decision for any major therapeuticinterventionhas been taken by a multidisciplinary team (MDT) including at least a surgical specialist as defined in 4.2 and 4.3,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*: number of patients with advanced ovarian cancer for whom the decision for therapeutic intervention(s) has been taken by a MDT. *Denominator*: all patients with advanced ovarian cancer undergoing therapeutic intervention(s).
TARGET(S)	≥ 95%

QI 6 -Required preoperative workup

DESCRIPTION OF THE PROPOSED QUALITY INDICATOR	
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 e.g. plasma CA 125 and CEA levels, and/or by biopsy under radiologic or laparoscopic guidance.
SPECIFICATIONS	*Numerator*: number of patients with advanced ovarian cancer who had undergone cytoreductive surgery and who were offered minimum preoperative workup as defined above. *Denominator*: all patients with suspected advanced ovarian cancer who underwent cytoreductive surgery.
TARGET(S)	≥ 95%

QI 7 -Pre-, intra-, and post-operative management

DESCRIPTION OF THE PROPOSED QUALITY INDICATOR	
TYPE	Structural indicator.
DESCRIPTION	The minimal requirements are: (1) intermediate care facility, and access to an intensive care unit (ICU) in the center are available, (2)anactive perioperative management program is established[1].
SPECIFICATIONS	*Numerator*: not applicable. *Denominator*: not applicable.
TARGET(S)	Not applicable.

[1]Details of perioperative management includes (non-exhaustive 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 contra-indication the use of epidural analgesia in order to avoid opioids; while routine premedication is no longer recommended, prevention of postoperative nausea and vomiting should be systematic

QI 8 -Minimum required elements in operative reports

DESCRIPTION OF THE PROPOSED QUALITY INDICATOR	
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[1] 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.
SPECIFICATIONS	*Numerator*: number of patients with advanced ovarian cancer undergoing cytoreductive surgery who have a complete operative report that contains all required elements as defined above. *Denominator*: all patients with advanced ovarian cancer undergoing cytoreductive surgery.
TARGET(S)	90%.

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

QI 9 -Minimum required elements in pathology reports

DESCRIPTION OF THE PROPOSED QUALITY INDICATOR	
TYPE	Process indicator.
DESCRIPTION	Pathology report contains all the required elements listed in the International Collaboration on Cancer Reporting (ICCR) histopathology reporting guide[1][2].
SPECIFICATIONS	*Numerator*: number of 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.

[1]https://www.rcpa.edu.au/Library/Practising-Pathology/ICCR/Cancer-Datasets.

[2]McCluggage, W.G., 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).

QI 10 -Existence of a structured prospective reporting of postoperative complications

DESCRIPTION OF THE PROPOSED QUALITY INDICATOR	
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*: number of 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.

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Future developments, which will be made available on the ESGO website, will include:

- A full report on the project, including synthesis of the literature supporting the decisions of the workgroup. In addition, a paper will be submitted for publication in the international literature
- An ESGO approved template for operative report
- A methodology for ESGO certification, including a self-assessment, presentation in front of ESGO experts, and possible audits on site
- An educational project with the contribution of excellence centers

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