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European Society of Gynaecological Oncology quality indicators for surgical treatment of cervical cancer

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ABSTRACT

Background Optimizing and ensuring the quality of surgical care is essential to improve the management and outcome of patients with cervical cancer.

OBJECTIVE

To develop a list of quality indicators for surgical treatment of cervical cancer that can be used to audit and improve clinical practice.

Methods Quality indicators were developed using a four-step evaluation process that included a systematic literature search to identify potential quality indicators, in-person meetings of an ad hoc group of international experts, an internal validation process, and external review by a large panel of European clinicians and patient representatives.

Results Fifteen structural, process, and outcome indicators were selected. Using a structured format, each quality indicator has a description specifying what the indicator is measuring. Measurability specifications are also detailed to define how the indicator will be measured in practice. Each indicator has a target which gives practitioners and health administrators a quantitative basis for improving care and organizational processes.

Discussion Implementation of institutional quality assurance programs can improve quality of care, even in high-volume centers. This set of quality indicators from the European Society of Gynaecological Cancer may be a major instrument to improve the quality of surgical treatment of cervical cancer.

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INTRODUCTION

Cervical cancer has become less common in Europe but is still a major public health problem. The estimated number of new cases of cervical cancer in Europe in 2018 was 61 000, with 25 800 deaths.[1] Five-year relative survival for European women diagnosed with cervical cancer in 2000–2007 was 62%, ranging from 57% in Eastern Europe to 67% in Northern Europe. Survival was particularly low (<55%) in Bulgaria, Latvia, and Poland and highest in Norway (71%).[2] The large geographic variation in rates of cervical cancer reflects differences in the availability of screening and in the prevalence of human papillomavirus (HPV) infection. The quality of surgical care as a component of comprehensive multi-disciplinary management has been shown to improve outcomes in patients with other types of malignancies.[3 4] Implementation of a quality improvement program helped to reduce both morbidity and costs in other tumors where surgical interventions are also high risk. Thus, it is likely that implementation of a quality management program could improve survival of patients with cervical cancer.

The aim of this project was to develop a list of quality indicators for surgical treatment of cervical cancer that can be used to audit and improve clinical practice in an easy and practicable way. These quality indicators are intended to give practitioners and administrators a quantitative basis to improve 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 in European countries. The key characteristics of an ideal indicator are clear definition, clinical relevance, measurability, and feasibility in clinical practice.

The quality indicators and proposed targets are based on the standards of practice determined from available scientific evidence and/or expert consensus. The indicators are defined according to the tumor node metastasis classification, as a recommended tool for staging patients with cervical cancer in the current version of clinical guidelines jointly developed by the European Society of Gynaecological Oncology (ESGO), the European Society for Radiotherapy and Oncology (ESTRO), and the European Society of Pathology (ESP).[5–7] Incorporation of the 2018 revised FIGO staging for carcinoma of the cervix uteri[8] in the joint ESGO-ESTRO-ESP guidelines[5–7] will be evaluated in an upcoming update. The idea behind the project is to improve the standard of surgical care by providing a set of quality criteria that can be used for self-assessment, for an institutional quality assurance program, for governmental quality assessment, and eventually, to build a network of certified centers for cervical cancer surgery. The intention is incentive, not punitive.

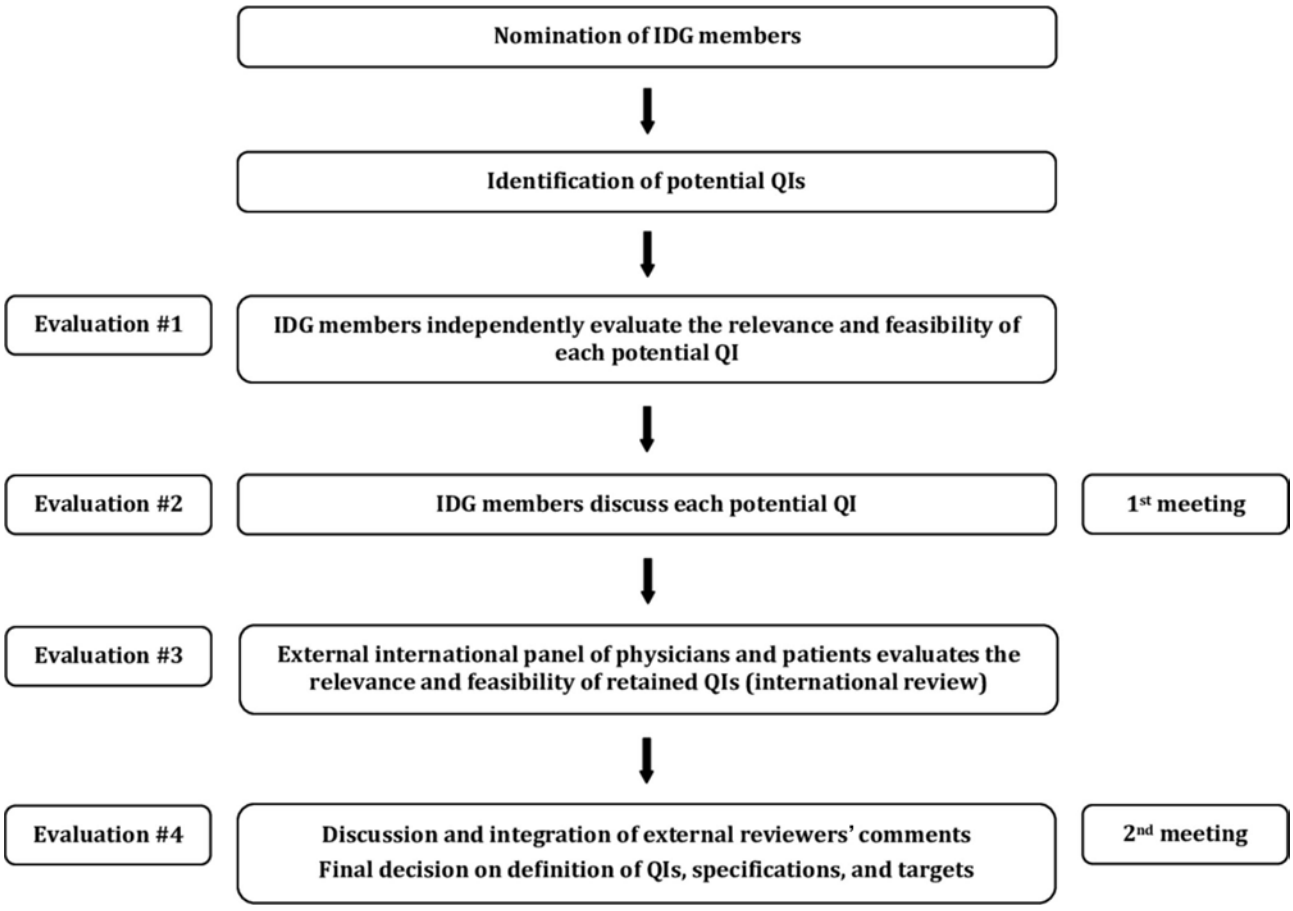

Figure 1 Development process: a four-step evaluation. IDG, international development group; QI, quality indicator.

METHODS

Quality indicators for the surgical treatment of cervical cancer were developed using a four-step evaluation process (Figure 1). This development process involved two physical meetings of an ad hoc international development group, chaired by Professor David Cibula (Gynecologic Oncology Center, First Faculty of Medicine, Charles University and General University Hospital, Prague, Czech Republic), convened on February 8, 2019 and May 24, 2019.

Nomination of an International Development Group

The ESGO Council and the European network for gynecological oncological trial collaborative groups nominated 16 surgeons from among the ESGO members, whose expertise had been previously checked/confirmed by identifying articles, oral presentations, administrative responsibilities, and other works of any type on leadership in improving the quality of care for patients with cervical cancer. Potential conflicts of interests were also checked before the beginning of the development process. Countries across Europe were represented. The experts of the development group were required to inform the ESGO council promptly if any change in the disclosed information occurred during the course of the project. The experts are listed in online supplementary Appendix 1.

Identification of Potential Quality Indicators

All possible quality indicators for cervical cancer surgery were identified from the ESGO-ESTRO-ESP guidelines[5–7] and published indicators. A systematic literature search was conducted in Medline without any restriction of the search period, using the following indexing terms: quality indicators, quality assurance, cervical cancer, uterine cervical neoplasms, surgery, methodology, consensus statements, and evidence-based medicine. References were selected if they described indicators developed by other agencies or synthesized research evidence describing practice contributing to improved patient outcomes (guidelines or consensus statements). Four previous initiatives publishing quality indicators for cervical cancer surgery were identified.[9–12]

Evaluation of Potential Quality Indicators

Possible quality indicators were formatted as a questionnaire and sent to the international development group. Experts were asked to evaluate each indicator according to relevance and feasibility in clinical practice (evaluation No 1). They were also free to propose any additional possible quality indicators they deemed relevant. Responses were pooled and organized according to consensus for relevance, feasibility, and quality of care improvement. The results of this first evaluation was sent to experts who convened during the first 1-day meeting (February 8, 2019). Acceptance, rejection, or the need for further consideration of each indicator was discussed during the meeting (evaluation No 2). Candidate quality indicators were retained if a large consensus among experts was obtained.

External Evaluation of the Retained Quality Indicators: International Review

The ESGO Council established a large panel of practicing clinicians who provide care to patients with cervical cancer or who had been treated for cervical cancer in the past. These international reviewers are independent of the international development group. Another requirement was balanced representation of countries across Europe. The retained indicators were formatted as a questionnaire and sent to the reviewers for quantitative evaluation of each indicator according to relevance, feasibility in clinical practice, and quality of care improvement (physicians only). Open comments were encouraged (qualitative evaluation). Patients were asked to qualitatively evaluate each quality indicator (according to their experience, preferences, feelings, etc). Evaluations of the indicators were returned by 94 independent physicians and by three patients with cervical cancer (the list of international reviewers is available in online supplementary Appendix 2). Responses were pooled and sent to experts who convened during the second 1-day meeting (May 24, 2019). The results of the external quantitative and qualitative evaluations were examined, and confirmed the choice of the retained quality indicators. All comments were reviewed and discussed by the international development group members. Of note, although the strengths of the process include an international development group, an international expert consensus to support the quality indicators, an international external review process (physicians and patients), a structured format to present the quality indicators, and management of potential conflicts of interests, the quality indicators result from a consensus of experts, with inherent bias in this type of method. They may have to be modified in the future, based on publication of new data and upcoming update of the ESGO-ESTRO-ESP guidelines.

RESULTS

Each retained quality index is categorized as a structural indicator, process indicator, or outcome indicator[13] and has a description which specifies what the indicator is measuring. The measurability specifications are then detailed. The latter highlight the way in which the indicator will be measured in practice to allow audits. The time frame for assessment of criteria is the last calendar year (unless otherwise indicated). Further to measurement of the indicator, a target is indicated. This specifies the level which each unit/center should be aiming to achieve. 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. Whenever available, corresponding published data are described. If not, the targets are based on database analysis of international development group members or on expert consensus. Quality indicators 1 and 2 are related to caseload in the center, training, and experience of the surgeon (Table 1). Quality indicators 3 to 5 are related to the overall management, including active participation in clinical research, decision-making process within a structured multi-disciplinary team, and pre-operative investigation (Table 2). Quality indicators 6 to 8 highlight the need to record relevant information in order to improve quality (Table 3). Quality indicators 9 to 12 are related to the quality of surgical procedures (Table 4). Quality indicators 13 to 15 are related to the compliance of management with the standards of care (Table 5).

Table 1 Quality indicators related to caseload in the center, and training and experience of the surgeon

QI 1 - Number of radical procedures (parametrectomies) in cervical cancer performed per center per year	
Type	Structural indicator
Description	A radical procedure is defined as one that includes parametrectomy (eg, radical hysterectomy, radical trachelectomy, parametrectomy)
Specifications	*Numerator*: number of radical procedures as defined above performed per center per year *Denominator*: not applicable
Targets	Optimal target:≥30 Minimum required target:≥15
QI 2 - Surgery performed or supervised by a certified gynecologic oncologist or a trained surgeon dedicated to gynecological cancer	
Type	Process indicator
Description	Surgery is performed or supervised by a certified gynecologic oncologist or by a trained surgeon dedicated to gynecological cancer (accounting for over 80% of his or her practice) or having completed an ESGO-accredited fellowship
Specifications	*Numerator*: number of patients with cervical cancer operated by a surgical specialist (as defined above) *Denominator*: number of patients undergoing surgery for cervical cancer
Target	100%

Center Case Load, Training, and Experience of the Surgeon

Although hospital volume alone does not guarantee surgical quality, it is a prerequisite. The effect of hospital volume on outcomes of surgery for patients with cancer is related to a surgeon's skill and experience defined notably by surgical volumes, and by hospital infrastructure and the supporting team dedicated to surgical care. Data support a positive relationship between surgical volume and outcomes (eg, survival, increased technical expertise, adherence to evidence-based treatment recommendations, appropriate management of complications) for different types of cancer,[14–37] indicating a benefit for centralization of care pathways. In a systematic review and meta-analysis by Lee et al[38] of the impact of hospital volume of laparoscopic radical hysterectomy on treatment outcomes of 4367 patients with cervical cancer, high volume was a favorable prognostic factor for operative outcomes and peri-operative complication rates. Hospitals were classified as high volume (≥15 cases/year) or low volume (<15 cases/year). In this study, in which high-volume hospitals included cases with relatively more advanced stages, survival outcome was favorable in high-volume hospitals, although the difference did not reach statistical significance.

A large nation-wide retrospective observational study in institutions of the Japanese Gynecologic Oncology Group examined 5964 consecutive women with clinical stage Ib1–IIb cervical cancer undergoing radical hysterectomy and pelvic lymphadenectomy.[39]

Table 2 Quality indicators related to the overall management

QI 3 - Center participating in ongoing clinical trials in gynecological cancer	
Type	Structural indicator
Description	The center actively accrues patients in ongoing clinical trials (not restricted to surgery) in gynecological cancer
Specifications	*Numerator*: number of ongoing clinical trials in gynecological cancer (not restricted to surgery only) *Denominator*: not applicable
Target	≥1
QI 4 - Treatment discussed at a multi-disciplinary team meeting	
Type	Process indicator
Description	The decision for any therapeutic intervention (excluding any diagnostic procedure—that is, biopsies or conization performed with a diagnostic intent) has been taken by a multi-disciplinary team including at least a gynecologic oncologist or a trained surgeon specifically dedicated to gynecological cancer as defined above (quality indicator 2), a radiologist, a radiation oncologist, a medical or clinical oncologist, and a pathologist
Specifications	*Numerator*: number of patients with cervical cancer for whom the decision for any therapeutic intervention has been made by a multi-disciplinary team *Denominator*: all patients presenting with cervical cancer
Target	100%
QI 5 - Required pre-operative investigation	
Type	Process indicator
Description	The required pre-operative investigation is defined according to the ESGO-ESTRO-ESP guidelines[5–7]
Specifications	*Numerator*: number of patients with cervical cancer for whom surgery is planned who received pre-operative investigation according to the ESGO-ESTRO-ESP guidelines[5–7] *Denominator*: all patients with cervical cancer for whom surgery is planned
Target	100%*

*Need to specify if the required pre-operative investigation, defined according to the ESGO-ESTRO-ESP guidelines,[5–7] is not followed

In that study, surgery at high-volume centers, defined as ≥21 cases a year, was associated with decreased local recurrence risk and improved survival on multi-variable analysis, suggesting that hospital volume may be a prognostic factor for early-stage cervical cancer. The study examined surgical volume for each institution, not for each surgeon; did not examine the route of radical hysterectomy; and analyzed only oncologic outcome, not peri-operative complications or patient-reported outcomes.

In view of the declining incidence of cervical cancer, notably in Western Europe, there is an argument for centralizing surgical care. The quality of radical procedures could be improved by such centralization. In Europe, organization of gynecologic oncology differs among countries, but there is a trend towards centralization and sub-specialization. The ESGO, in collaboration with the European Board and College of Obstetricians and Gynecologists, has developed a sub-specialty training program in gynecologic oncology. Increasing evidence shows that physicians with different sub-specialty backgrounds affect treatment outcomes of patients with malignant disease.[40–42] Wu et al[43] explored this hypothesis for patients with cervical cancer specifically. They found significant benefits in surgical outcomes and survival for patients undergoing a radical hysterectomy performed by a gynecologic oncologist rather than by a non-gynecologic oncologist. In addition, positive surgical margins were more frequently detected in patients of the non-gynecologic oncologists group, from an oncological perspective. This suggests that gynecologic oncologists would be more likely to ensure the radicality of radical hysterectomy and therefore better disease control. According to the ESGO-ESTRO-ESP guidelines,[5–7] treatment should be undertaken by a dedicated team of specialists in the diagnosis and management of gynecologic cancers. Radical surgery performed by a gynecologic oncologist is the preferred treatment modality in early-stage disease.

Overall Management

Clinical research is crucial to improve the quality of care. Patients with ovarian cancer treated in study hospitals had a higher chance of receiving standard treatment than those treated in hospitals not participating in clinical studies.[44 45] Study centers recruited patients and had the infrastructure required for entering patients into clinical trials. They also might participate more often in quality assurance program. The benefit extended even to patients not enrolled in protocols.[44]

Multi-disciplinary care is internationally recognized as best practice in treatment planning and care. In several types of cancer, evidence shows that decisions made by a multi-disciplinary team are more likely to be in accord with evidence-based guidelines than those made by individual clinicians, and the role of the multi-disciplinary approach in the quality of care is recognized.[46–54] According to the ESGO-ESTRO-ESP guidelines,[5–7] treatment planning should be made on a multi-disciplinary basis (generally at a

Table 3 Quality indicators related to recording pertinent information (surgical reports, pathology reports, recording of post-operative complications)

QI 6 - Minimum required elements in surgical reports	
Type	Process indicator
Description	The required surgical report, based on the ESGO-ESTRO-ESP guidelines,[5–7] includes at least the elements mentioned above
Specifications	*Numerator*: number of patients with cervical cancer undergoing surgery who have a complete surgical report that contains all required elements as defined above *Denominator*: all patients with cervical cancer undergoing surgery
Target	100%
QI 7 - Minimum required elements in pathology and pathology reports	
Type	Process indicator
Description	The minimum required elements in pathology and pathology reports, based on the ESGO-ESTRO-ESP guidelines,[5–7] include at least the elements mentioned above (Box 1)
Specifications	*Numerator*: number of patients with cervical cancer undergoing surgery for whom all minimum required elements as defined above are reported *Denominator*: all patients with cervical cancer undergoing surgery
Target	≥90%*
QI 8 - Structured prospective reporting of the follow-up and 30-day post-operative morbidity	
Type	Outcome indicator
Description	Structured prospective reporting of the follow-up and 30-day post-operative morbidity using a validated surgical complications scoring system
Specifications	*Numerator*: number of patients with cervical cancer who have undergone a surgery and for whom a structured prospective reporting of the follow-up and 30-day post-operative morbidity is available *Denominator*: all patients with cervical cancer undergoing surgery
Targets	Optimal target:≥90%. Minimum required target: selected cases are discussed at morbidity and mortality conferences

*The tolerance with this target reflects situations where it is not possible to report all components owing to poor quality of the specimen.

tumor board meeting) and based on the comprehensive and precise knowledge of prognostic and predictive factors for oncological outcome, morbidity, and quality of life. Treatment requires centralization and involvement of a broad multi-disciplinary team, including at least a gynecologic oncologist or a trained surgeon specifically dedicated to the management of gynecological cancers (see quality indicator 2), a radiologist, a radiation oncologist, a medical or clinical oncologist, and a pathologist. A structured program for multidisciplinary diagnostic investigation, treatment, and follow-up must be present.

An accurate diagnosis guides patient management and informs prognosis. According to the ESGO-ESTRO-ESP guidelines,[5–7] pelvic examination and biopsy, with or without colposcopy, are mandatory components for the diagnosis of cervical cancer. Magnetic resonance imaging is the obligatory initial investigation for assessment of the extent of a pelvic tumor and to guide treatment options. Endovaginal/transrectal ultrasound is an option if performed by a properly trained sonographer. In locally advanced cervical cancer (T1b2 and higher (except T2a1)) or in early-stage disease with suspicious lymph nodes on imaging, positron emission tomography-computed tomography, or chest/abdomen computed tomography is recommended for assessment of nodal and distant disease. Equivocal extra-uterine disease is to be considered for biopsy to confirm or rule out metastatic disease and to avoid inappropriate treatment. Tru-Cut (core-cut) biopsy is preferred rather than fine-needle aspiration biopsy because it allows histological assessment of the tissue.

Recording Pertinent Information for Improving Quality

Evidence shows that standardized operative reports result in more complete and reliably interpretable operative data than non-standardized operative reports.[55] Compliance with the standardized operative report improves over time. Synoptic operative reports have been used in other surgical disciplines such as orthopedics and colorectal surgery, although they have not been evaluated extensively.[56 57] ESGO has approved a template for ovarian cancer operative reports.[58]

In the absence of an international validated standardized surgical report in cervical cancer, some required elements must be reported. As mentioned in the ESGO-ESTRO-ESP guidelines,[5–7] the surgical report must be structured and should include at least the following elements: surgical approach; type of lymph nodes staging; technique of sentinel lymph node (SLN) detection; localization of detected sentinel lymph node; regions of pelvic lymph node dissection; detailed description of type of parametrial resection (Querleu-Morrow classification[59]; type of adnexal procedure; localization of preserved adnexa/ovaries; basic surgical data (duration, blood loss); intra-operative complications (type, grade, and management).

Table 4 Quality indicators related to the quality of surgical procedures

QI 9 - Urological fistula rate within 30-post-operative days after a radical parametrectomy	
Type	Outcome indicator
Description	Any bladder or ureteral fistula diagnosed after a procedure including radical parametrectomy. The fistula rate should be calculated on the basis of data of the preceding 3 years. Radical parametrectomies include radical hysterectomies, radical trachelectomies, and parametrectomies
Specifications	*Numerator*: number of patients treated in the preceding 3 years who develop ureteral or bladder fistulas within 30-post-operative days *Denominator*: all patients with cervical cancer undergoing a procedure including radical parametrectomy in the preceding 3 years
Target	≤3%
QI 10 - Proportion of patients after primary surgical treatment who have clear vaginal (invasive disease) and parametrial margins	
Type	Outcome indicator
Description	Clear surgical margins apply for both the vaginal margins and parametrial margins. Using an adequate clinical staging with modern imaging and careful pre-operative vaginal assessment, as defined in the ESGO-ESTRO-ESP guidelines,[5–7] positive surgical margins after a radical hysterectomy or trachelectomy should be avoided
Specifications	*Numerator*: number of patients after primary surgical treatment who have clear surgical margins for invasive disease in the preceding 3 years *Denominator*: all patients who have undergone primary surgical treatment in the preceding 3 years
Target	≥97%
QI 11 - Proportion of patients with a stage T1b disease T-upstaged after surgery	
Type	Outcome indicator
Description	T-upstaging refers to detection of any involvement of parametria or vagina found on pathology which was unknown before surgery, or a stage shift from T1b1 to T1b2 or higher, from pre-operative assessment to post-operative pathology. Detection of positive LNs is not included
Specifications	*Numerator*: number of patients with stage T1b disease T-upstaged after surgery, as defined above *Denominator*: all patients with a stage T1b who have undergone a surgery
Target	<10%
QI 12 - Recurrence rate at 2 years in patients with a stage pT1b1 with negative lymph nodes (LNs) after primary surgical treatment	
Type	Outcome indicator
Description	This quality indicator applies to the common tumor types (squamous cell and usual types of adenocarcinoma) and both local or distant recurrences, irrespective of adjuvant treatment strategy
Specifications	*Numerator*: lymph nodes-negative pT1b1 patients whose disease recurs within 2 years after primary surgical treatment, irrespective of adjuvant treatment strategy, with a minimum of 2 years' follow-up. *Denominator*: All lymph nodes-negative pT1b1 patients after primary surgical treatment, irrespective of adjuvant treatment strategy, with a minimum of 2 years' follow-up.
Target	<10%

The pathology report is a key component in the management of patients with cancer and its accuracy depends on several factors. Pre-analytical steps must be carried out in an optimal way to allow for adequate pathological evaluation. The inclusion of informative clinical and surgical data on the pathology request form, and accurate sampling and processing of the specimens, are the basis for a correct histological diagnosis and the provision of information on tumor staging and prognosis. The pathology report should comprehensively include all the features that enable a patient with cervical carcinoma to be placed into a risk group, which ensures the appropriate management. It should include all the parameters affecting tumor staging and patient management. The histological sub-type is important as some uncommon tumor types are associated with aggressive behavior (eg, high-grade neuroendocrine carcinoma and gastric-type adenocarcinoma) or favorable behavior (eg, adenoid-basal carcinoma) and may be considered for different treatment. Histological tumor grade is generally reported in squamous cell carcinomas and adenocarcinomas but, in general, this does not affect the treatment and the prognosis, especially as there is no validated grading system for these cancers. Accurate tumor measurement, which often requires correlation of the gross and microscopic features, is important for sub-staging of tumors. The presence or absence of lymphovascular space involvement, the lymph nodes status (number of nodes retrieved, number involved, presence of extra-capsular extension, size of metastasis), involvement of extra-cervical tissues, and the margin status, including the

Table 5 Quality indicators related to the compliance of management with the standards of care

QI 13 - Proportion of patients with a stage T1 disease treated by primary surgery who have undergone lymph node (LN) staging according to the ESGO-ESTRO-ESP guidelines	
Type	Outcome indicator
Description	Lymph nodes staging is defined according to the ESGO-ESTRO-ESP guidelines[5–7]
Specifications	*Numerator*: number of patients with a stage T1 disease who have undergone Lymph nodes staging according to the ESGO-ESTRO-ESP guidelines[5–7] *Denominator*: all patients with a stage T1 disease who were treated by primary surgery
Target	≥98%
QI 14 - Counseling about a possibility of FST	
Type	Structural indicator
Description	Counseling of patients with stage T1b1 ≤2 cm disease, potential candidates for fertility-sparing treatment, is described in the ESGO-ESTRO-ESP guidelines.[5–7] All eligible patients should be appropriately counseled about a possibility of FST. FST should be undertaken exclusively in centers with comprehensive expertise in this management
Specifications	*Numerator*: number of patients with stage T1b1 ≤2 cm disease, potential candidates for FST, counseled according to the ESGO-ESTRO-ESP guidelines[5–7] Denominator: all patients with stage T1b1 ≤2 cm disease, potential candidates for FST
Target	100%
QI 15 - Proportion of patients receiving adjuvant chemoradiotherapy after a primary surgical treatment for a stage pT1b1 pN0 disease	
Type	Structural indicator
Description	Management of patients after a surgical treatment for a stage pT1b1 pN0 disease is defined according to the ESGO-ESTRO-ESP guidelines[5–7]
Specifications	*Numerator*: number of patients receiving adjuvant chemoradiotherapy after primary surgical treatment for stage pT1b1 pN0 disease, according to the ESGO-ESTRO-ESP guidelines[5–7] *Denominator*: all patients with primary surgical treatment for stage pT1b1 pN0 disease
Target	<15%

distance of tumor and pre-invasive disease to various margins, are also critical for patient management.T

The international development group considers that widespread use of the requirements for the pathology report for cervical cancer, listed in Box 1 and defined as part of the ESGO-ESTRO-ESP guidelines,[5–7] will improve patient management and is a prerequisite for research and for international benchmarking in healthcare.

The lack of a consensus within the surgical community on how to report surgical complications has hindered progress in surgical research. The therapy used to manage a specific complication remains the cornerstone for ranking a complication. Conclusive assessments of surgical procedures remained limited on how to define and stratify complications. In 1992, Clavien et al[60] proposed a standardized system, modified in 2004 by Dindo et al,[61] based on the intervention needs and health of the patient. This Clavien-Dindo classification, based on the therapeutic consequences of complications, consists of five severity grades and focuses on the medical perspectives, with a major emphasis on the risk and invasiveness of the therapy used to correct a complication. A 5-year evaluation demonstrated its validation, reproducibility, and applicability worldwide, irrespective of the cultural background and in many fields of surgery.[62] Other classifications were proposed in the 1990s[63–65] but are used less frequently. The Common Terminology Criteria for Adverse Events, are oriented more towards medical outcomes than the Clavien-Dindo classification. Identifying 129 studies using the Clavien-Dindo classification as the basis for classifying post-operative complications, Strasberg et al[66] determined how well this classification and its modifications has functioned as a severity grading system. These authors proposed a modified severity grading system, the 'Accordion classification', geared towards making the classification more useful in studies of different size and complexity.

In 2013, Slankamenac et al[67] developed a comprehensive complication index that takes into account all complications after a procedure and their respective severity. The development of this index was based on the adapted Clavien-Dindo classification system. The complications were weighted with different severities by adopting an 'operation risk index' approach. The value of the comprehensive complication index has been explored in three randomized controlled trials.[68] These trials showed a greater ability to detect differences between treatment effects than classic endpoints such as 'any complication' or 'major complication' defined according to the Clavien-Dindo classification. The index has been used in large multi-centric studies,[69–77] notably as a benchmark endpoint for major surgery.[70] Exploring the potential added value of the comprehensive comprehensive index to standard assessment of post-operative morbidity, and to clarify potential controversies for its application, Clavien et al[78] reported that it yielded substantial additional value to the Clavien-Dindo classification in patients with more than one complication. In particular, its value increases after major surgery and with inclusion of the observation time after surgery. This, however, does not justify the replacement of one system by

Box 1 Minimum requirements for pathology report for cervical cancer

1. Description of the specimen(s) submitted for histological evaluation
2. Macroscopic description of specimen(s) (biopsy, loop/cone, trachelectomy, hysterectomy), including specimen dimensions (three dimensions), number of tissue pieces for loop/cones, and maximum and minimum length of vaginal cuff and the parametria in two dimensions
3. Macroscopic tumor site(s), if the tumor is visible grossly, in trachelectomy and hysterectomy specimens
4. Tumor dimensions, including two measurements of horizontal extent and depth of invasion or thickness (tumor dimension should be based on a correlation of the gross and histological features). When multi-focal separate tumors are present, each should be described and measured separately, and the largest used for tumor staging. Specimens from prior conization and subsequent conization, trachelectomy, or hysterectomy should be correlated for estimation of the tumor size. This is important because different specimens might have been reported at different institutions. It should also be recognized that simply adding up the maximum size of tumors in separate specimens may significantly overestimate the maximum tumor dimension
5. Histological tumor type and tumor grade
6. The presence or absence of lymphovascular space involvement
7. Co-existing pathology (squamous intra-epithelial lesion/cervical intra-epithelial neoplasia, adenocarcinoma in situ, stratified mucin-producing intra-epithelial lesion)
8. Minimum distance of uninvolved cervical stroma
9. Margin status (invasive and pre-invasive disease, specify the margin(s))
10. Lymph node (LN) status, including sentinel lymph node (SLN) status, the total number of nodes found, the number and location of positive LNs, and the presence of extra-nodal extension. Micrometastasis (>0.2 mm and up to 2 mm) are reported as pN1 (mi). Isolated tumor cells no greater than 0.2 mm in regional nodes should be reported as pN0 (i+). The number of positive LNs for each anatomical group should be reported separately
11. Pathologically confirmed distant metastases
12. Provisional pathological staging (tumor node metastasis, eighth edition[110]; a pathological FIGO stage[8] may also be provided if dictated by local protocols
13. The results of any frozen section specimen evaluation

the other as the Clavien-Dindo classification discloses the highest grade of complications and the type of complications.

Using the Clavien-Dindo classification as a guide, the Department of Surgery at the Memorial Sloan Kettering Cancer Center developed a surgical secondary events database based on grade of event and required intervention to begin prospectively recording and analyzing all surgical secondary events. In 2008, a blinded external audit of 1498 operations, randomly selected to examine the quality and reliability of the data, was conducted and demonstrated the accuracy of data collection.[79] A limitation of this database is that it does not capture all grade I and II events.

The international development group considers that the widespread use of a simple, objective, and reproducible approach to comprehensive surgical outcome assessment will improve patient management. It should be easily applicable by surgeons who are less experienced.

Quality of Surgical Procedures

The extensive dissection of the ureters and bladder required during radical procedures for cervical cancer leads to a risk of intra-operative injuries of the ureter and the bladder and the development of post-operative fistulas.[80] The total incidence of urologic fistulas after radical surgery for cervical cancer surgery does not exceed 5.1% but can vary, depending notably on the proportion of patients with advanced disease included in the series.[81–88] Most fistulas are secondary to extensive dissection, leading to ischemic damage rather than unrecognized intra-operative full-thickness visceral injury.[89] Urogenital fistulas significantly increase post-operative morbidity.[90]

The quality of radical surgery has a great impact on local control, underlining the importance of optimal surgical care. The achievement of clear margins is a major prognostic factor. No ideal tumor-free margin distance has been defined which should be achieved after radical trachelectomy or hysterectomy. Positive surgical margins after radical hysterectomy or trachelectomy in patients with a stage T1 disease should be avoided. Similarly, a high proportion of T-upstaged patients after surgery reflects poor quality of pre-operative imaging and surgery planning. Pre-treatment staging is crucial for decisions on choice of treatment and tailoring of surgical radicality. Both the uterine procedure (performance of parametrectomy) and lymph nodes staging should be tailored to the main prognostic factors disclosed (or assessed or evaluated) pre-operatively, including tumor size and the involvement of parametria. Adequate clinical staging with modern imaging and careful pre-operative vaginal assessment should be performed, and radicality of surgery should be tailored as defined in the ESGO-ESTRO-ESP guidelines.[5–7]

According to the available prospective and retrospective studies,[91–106] less than 15% of patients with stage pT1b1 disease and negative lymph nodes develop recurrent disease within 2 years of primary surgical treatment, irrespective of the neo-adjuvant or adjuvant treatment strategy. More recently, Ramirez et al[107] reported, as part of the Laparoscopic Approach to Cervical Cancer trial, disease-free survival and loco-regional recurrence-free survival rates at 3 years of higher than 90% for patients with a stage IB1 disease, irrespective of the lymph nodes status and surgical approach. Thus, a recurrence-free survival rate at 2 years of less than 90% in patients with a stage IB1 disease with negative lymph nodess after primary surgery treated in gynecologic oncology centers should be considered as a failure of management.

Compliance of Management with the Standards of Care

According to the ESGO-ESTRO-ESP guidelines,[5–7] lymph nodes staging is not indicated in T1a1 patients who have no lymphovascular space involvement but can be considered in those who do have such involvement. For T1a2 patients with no lymphovascular space involvement, lymph nodes staging can be considered but should be performed in those with positive involvement. Sentinel lymph node biopsy alone (without additional pelvic lymph node dissection) appears to be an acceptable method of lymph nodes staging in T1a disease (except in T1a1 patients with no lymphovascular space involvement). For management of a T1b1 disease, the standard lymph nodes staging procedure is systematic pelvic lymphadenectomy. Sentinel lymph node biopsy before pelvic lymphadenectomy is strongly recommended because it increases staging

accuracy—namely, the identification of micrometastases (<2 mm in the largest diameter) and small micrometastases (slightly larger than 2 mm). Combination of blue dye with radio-colloid or use of indocyanine green alone is the recommended technique. Lymph nodes assessment should be performed as the first step of surgical management as it allows intra-operative Sentinel lymph node/lymph nodes assessment and the avoidance of radical parametrectomy in patients with intra-operativelly detected lymph nodes involvement. Intra-operative assessment of lymph nodes status (frozen section) is recommended. All sentinel nodes from both sides of the pelvis and/or any suspicious LNs should be sent for frozen section. If a sentinel node is not detected, intra-operative assessment of the pelvic LNs should be considered. If intra-operative lymph nodes assessment is negative or not carried out, systematic pelvic lymph node dissection should be performed. Sentinel lymph node biopsy alone is not recommended in stage T1b outside of clinical trials. Systematic lymph nodes dissection should include the removal of lymphatic tissue from regions with the most frequent occurrence of positive LNs (Sentinel lymph node), including the obturator fossa, the external iliac regions, the common iliac regions bilaterally, and the pre-sacral region.[108] If lymph nodes involvement is detected intra-operatively, including macrometastases or micrometastases, further pelvic lymph node dissection and radical hysterectomy should be avoided. Para-aortic lymph node dissection, at least up to the inferior mesenteric artery, may be considered for staging purposes. Negative pelvic lymph nodes status is the pre-condition for any fertility-sparing treatment. Therefore, pelvic lymph nodes (Sentinel lymph node) staging should always be the first step in such a procedure. Identification of sentinel lymph nodes and its ultra-staging is highly recommended because it increases staging accuracy. The involvement of suspicious LNs should be confirmed by histology.

For patients who consider fertility-sparing treatment, consultation at a fertility center is recommended. The treatment should exclusively be undertaken in gynecologic-oncological centers with comprehensive expertise in this type of oncologic therapy. Prognostic factors, clinical staging, and pre-operative investigation do not differ from those who do not consider this treatment. Every woman with a desire to spare fertility and histologically proven squamous cell carcinoma or usual-type (HPV-related) adenocarcinoma ≤2 cm of the largest diameter should be counseled about the possibility of fertility-sparing treatment. This consultation should encompass the possibility of abandoning fertility-sparing treatment if there are positive margins or lymph nodes involvement and oncologic and obstetric risks related to this type of management. Fertility-sparing treatment should not be recommended for rare histological sub-types of cervical cancer, including neuroendocrine carcinomas and non-HPV-related adenocarcinomas (except for adenoid basal carcinoma), which tend to exhibit aggressive behavior. Expert sonography and/or pelvic MRI are recommended imaging tests to measure remaining (after cone biopsy) cervical length and non-involved cervical length. However, no imaging system can predict exactly the extent of necessary local resection in order to reach sound margins with adequate safety distance. Fertility-sparing treatment in patients with tumors >2 cm cannot be recommended and is considered as an experimental approach.

According to the ESGO-ESTRO-ESP guidelines,[5–7] treatment for patients with stage T1b1 cervical cancer should aim to avoid combining radical surgery and radiotherapy because of the high morbidity after combined treatment. Adjuvant radiotherapy should be considered in the presence of a combination of risk factors at final pathology, such as tumor size, lymphovascular space involvement, and depth of stromal invasion. If a combination of risk factors is known at diagnosis which would require an adjuvant treatment, definitive chemoradiotherapy and brachytherapy can be considered without previous radical pelvic surgery. When in these situations an adequate type of radical hysterectomy has been performed, observation is an alternative option, especially in teams experienced in this approach.[109]

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