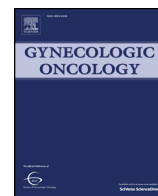




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## Evaluation of the quality of the management of cancer of the corpus uteri – Selection of relevant quality indicators and implementation in Belgium

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### HIGHLIGHTS

- We describe the selection methodology and results of indicators for uterine cancer.
- A list of variables was created and tested by physicians and experienced datamanagers.
- The indicators can be used by other groups and adapted for the endpoints of interest.

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### ABSTRACT

**Objective.** Describe the methodology and selection of quality indicators (QI) to be implemented in the EFFECT (EFFECTiveness of Endometrial Cancer Treatment) project. EFFECT aims to monitor the variability in Quality of Care (QoC) of uterine cancer in Belgium, to compare the effectiveness of different treatment strategies to improve the QoC and to check the internal validity of the QI to validate the impact of process indicators on outcome.

**Methods.** A QI list was retrieved from literature, recent guidelines and QI databases. The Belgian Healthcare Knowledge Center methodology was used for the selection process and involved an expert's panel rating the QI on 4 criteria. The resulting scores and further discussion resulted in a final QI list. An online EFFECT module was developed by the Belgian Cancer Registry including the list of variables required for measuring the QI. Three test phases were performed to evaluate the relevance, feasibility and understanding of the variables and to test the compatibility of the dataset.

**Results.** 138 QI were considered for further discussion and 82 QI were eligible for rating. Based on the rating scores and consensus among the expert's panel, 41 QI were considered measurable and relevant. Testing of the data collection enabled optimization of the content and the user-friendliness of the dataset and online module.

**Conclusions.** This first Belgian initiative for monitoring the QoC of uterine cancer indicates that the previously used QI selection methodology is reproducible for uterine cancer. The QI list could be applied by other research groups for comparison.

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## Introduction

Cancer of the corpus uteri (uterine cancer) is the fourth most common cancer site in North American and European women after breast, lung and colorectal cancers [1]. Cancer of the corpus uteri includes endometrial carcinomas (90%–95%) and uterine sarcomas (less than 10%). Incidence has been shown to rise in the majority of the European countries. This is mainly due to an augmentation in uterine cancer in post-menopausal women (>55 years) and the aging population in general. A decline in fertility rates and an increase in overweight and obesity account for the observed increases among post-menopausal women [2]. In 2010, 1415 new uterine cancer cases were diagnosed in Belgium [3].

In comparison with other female cancers such as breast and ovarian cancers, the evidence for the treatment of uterine cancer is rather limited. For instance, although surgery is well-established as being the cornerstone for the management of uterine cancer, the role of a complete lymphadenectomy is controversial in early-stage cancers. FIGO recommends surgical staging although trials have not shown any benefit of lymphadenectomy [4–6]. This lack of evidence results in discrepancies between guidelines, some recommending systematic lymphadenectomy on the argument that better surgical staging improves survival [7–12]. Other issues exist in the adjuvant setting. Radiotherapy for instance was historically used in the majority of early-stage cancers. To date, it has been proven to be of limited use in patients with low-risk stage I uterine cancer, but still can be considered to prevent local recurrence in patients with intermediate or high-risk stage I uterine cancer [13–15]. Another example is the increasing evidence in favor of chemotherapy for some selected patients with early stage cancers that carry a high risk of recurrence [8,9]. Classification of cancers into high, intermediate and low risk of recurrence is based on pathological features including histological type, grade of differentiation, lymphovascular invasion and on pTNM. Classification therefore requires complete staging including complete lymphadenectomy [9]. These examples underline the importance of adequate initial surgery, complete staging and histopathology and evidence-based decision regarding the choice of adjuvant treatment.

Literature shows a high variability in practices at all steps of the management of uterine cancer [16–22]. This leads to variation in the Quality of Care in comparison with guidelines as demonstrated by a few single-center or regional studies assessing the Quality of Care in comparison with guidelines [23–26]. A German study investigating the adherence to the national surgical guidelines for endometrial carcinoma (EC) showed an improvement for lymphadenectomy (pelvic and para-aortic) and a resulting lower disease-specific survival rate between 2006 and 2009, but still shows a large variance in (systemic) adjuvant treatments for EC [27]. In addition to a lack of evidence to guide treatment, variability in practices is also inherent to the specific characteristics of this patient population, i.e. obesity hindering adequate surgical staging and age related co-morbidity as a barrier for adjuvant therapy. The best way to document variability and its consequence on the outcome is to prospectively measure the Quality of Care with the help of quality indicators (QI), especially outcome and process QI [28].

Measurement of QI in cancer care may be used for different purposes. Several large scale experiences have shown that a benchmarking approach was able to improve Quality of Care in participating hospitals. Its main advantage over coercive and restrictive measures is that it aims to improve the Quality of Care in all participating centers [29]. This approach is therefore usually preferred by clinicians and hospital managers.

PROCARE, for example, is a Belgian project monitoring the quality of the management of patients with rectal cancer. Forty QI were defined based on the literature and the opinion of a multidisciplinary group [30,31]. Every year, each participating hospital receives its own results compared to the other centers which are kept anonymous. Each center therefore can position itself and implement actions to improve its own Quality of Care.

The EFFECT (EFFectiveness of Endometrial Cancer Treatment) project is a national prospective observational registration study that aims to gain more insight into the quality and effectiveness of clinical care of uterine cancer in Belgium. It was launched on the results from a first study using existing databases to investigate clinical practices for uterine cancer [32]. The measurement of QI in this study confirmed the heterogeneity in treatment and outcome for uterine cancer. To our knowledge, no national or international Quality of Care approach dedicated to uterine cancer has yet been launched. The current paper reports the methodology of the selection process and the final list of QI concerning the management of uterine cancer patients.

## Methods

### *Constitution of a working group and agreement on the methodology*

The EFFECT project was initiated by gynecologists from both the Flemish and French speaking Society for Obstetrics and Gynecology who already participated in the data collection on the management of gynecological and breast cancers. Collaboration was set up with the Belgian Cancer Registry (BCR) and Reliable Cancer Therapies (RCT), a non-profit organization.

Based on 3 experiences at a national level in Belgium, the Belgian Healthcare Knowledge Center (KCE) developed a methodology to identify and select QI to be measured in a quality improvement project. The KCE methodology has been applied for rectal cancer with a prospective data collection coordinated by the BCR [30,31]. It has also been used for breast cancer, testis cancer and recently for upper gastrointestinal cancer with the goal of assessing the possibility of measuring QI by linking data already available in several healthcare databases [33–35].

### *Identification and selection of quality indicators*

As described in the KCE methodology, an expert's panel was constituted. This panel included 8 experts who are experienced representatives of the domains that are active in the treatment of uterine cancer and represent the 2 main Belgian regions: gynecology (n = 4), pathology (n = 1), medical oncology (n = 2) and radiation oncology (n = 1). Together with a representative of the RCT and BCR collaborators specialized in registration of clinical data, an EFFECT working group was assembled.

During the first meeting, the KCE methodology was presented to the expert's panel and the principles of QI selection were discussed by the EFFECT working group. A realistic target number of QI was defined (a predefined maximum of 30–40 indicators), based on the abovementioned three Belgian experiences and the similarities between the EFFECT and the PROCARE project [29,33,34]. PROCARE aims to reduce diagnostic and therapeutic variability and to improve outcome of patients with rectal cancer among others by quality assurance through registration and feedback as will be performed for EFFECT. The goal was postulated to approach all the aspects of the care process for uterine cancer within the list of QI. The literature search was defined and the main guidelines were listed (Table 1).

A first MEDLINE search had already been performed by one researcher (GB). It was completed by two additional MEDLINE searches. Two independent researchers (GB and FA) selected abstracts of articles written in English, Dutch or French and proposed QI were retrieved. FA is senior researcher for the Research Fund Flanders (F.W.O.). Two types of additional sources were used: guidelines and known databases of QI in English and French (Table 1). One researcher (GB) retrieved QI based on the recommendations of the guidelines and selected any cancer-specific QI through screening of the QI databases. Every QI was defined with a clear denominator and numerator as well as the respective characteristics (theoretical target %, type of QI, process of care and dimensions of QoC) (Table 2).

The list of QI retrieved from the literature, guidelines and databases was discussed during two meetings with the possibility of rephrasing,

**Table 1**  
Sources and literature searches used to identify existing QI.

Literature searches	
Search 1	("Guideline Adherence"[All Fields] OR ("Guidelines"[All Fields] AND "Adherence"[All Fields]) OR ("Quality Assurance, Health Care"[Mesh] OR "Quality Assurance"[All Fields]) OR ("Quality Indicators, Health Care"[Mesh] OR "Quality Indicators"[All Fields])) AND (("Endometrial Neoplasms"[All Fields] OR "Endometrial"[All Fields] OR "Endometrium"[All Fields])) AND ("Neoplasm"[All Fields] OR "Cancer"[All Fields]))
Search 2	("Quality of Health Care"[All Fields] OR "Patient Care Management"[All Fields] OR "Organization and administration"[All Fields] OR "Quality of Health Care"[All Fields] OR "Quality Assurance, Health Care"[All Fields] OR "Quality Indicators, Health Care"[All Fields]) AND ("Endometrial Neoplasm"[All Fields] OR ((Endometrial[All Fields] OR Endometrium[All Fields] OR "Corpus Uteri"[All Fields]) AND (Neoplasm\$[All Fields] OR Cancer\$[All Fields] OR Malign\$[All Fields] OR Carcinoma\$[All Fields] OR Tumor\$[All Fields])))
Search 3	("Physician's Practice Patterns"[All Fields] OR "Guideline Adherence"[All Fields] OR "Diffusion of Innovation"[All Fields] OR "Health Care Surveys"[All Fields]) AND ("Endometrial Neoplasm"[All Fields] OR ((Endometrial[All Fields] OR Endometrium[All Fields] OR "Corpus Uteri"[All Fields]) AND (Neoplasm\$[All Fields] OR Cancer\$[All Fields] OR Malign\$[All Fields] OR Carcinoma\$[All Fields] OR Tumor\$[All Fields])))
<i>Recent guidelines (published in 2010 or 2011)</i>	
	NCCN Guidelines on Uterine Neoplasms [8]
	ESMO Guidelines on Endometrial Cancer [9]
	Evidence-based guidelines for treatment of uterine body neoplasm in Japan: Japan Society of Gynecologic Oncology (JSGO) 2009 edition [10]
	French recommendations [7]
	Society of Gynecologic Oncologists recommendations on post-treatment surveillance [38]
	Protocol for the examination of specimens from patients with carcinoma of the endometrium 2011 of the College of American Pathologists ( <a href="http://www.cap.org/apps/cap.portal?_nfpb=true&amp;cntvwrPtl_actionOverride=%2Fportlet%2FcontentViewer%2Fshow&amp;_windowLabel=cntvwrPtl&amp;cntvwrPtl%7BactionForm.contentReference%7D=committees%2F%2FcontentViewer%2Fshow&amp;_state=maximized&amp;_pageLabel=cntvwr">http://www.cap.org/apps/cap.portal?_nfpb=true&amp;cntvwrPtl_actionOverride=%2Fportlet%2FcontentViewer%2Fshow&amp;_windowLabel=cntvwrPtl&amp;cntvwrPtl%7BactionForm.contentReference%7D=committees%2F%2FcontentViewer%2Fshow&amp;_state=maximized&amp;_pageLabel=cntvwr</a> )
<i>Databases of quality indicators used</i>	
	National Quality Measures Clearinghouse (USA) <a href="http://qualitymeasures.ahrq.gov">http://qualitymeasures.ahrq.gov</a>
	Joint Commission (USA) <a href="http://www.jointcommission.org/">http://www.jointcommission.org/</a>
	Clinical Indicators Support Team (Scotland) <a href="http://www.indicators.scot.nhs.uk/">http://www.indicators.scot.nhs.uk/</a>
	NHS Indicators for Quality Improvement (UK) <a href="https://mqi.ic.nhs.uk/">https://mqi.ic.nhs.uk/</a>
	Haute Autorité de Santé (France) <a href="http://www.has.fr">http://www.has.fr</a>
	COMPAQ-HPST (France) <a href="http://www.compaqhpst.fr">http://www.compaqhpst.fr</a>

adding or deleting a QI. Changes were only made when a consensus was reached among the experts.

Once the list of QI was consolidated, the 8 members of the expert's panel were asked to rate the resulting QI on 4 criteria (scores 1–5): reliability, relevance, interpretability and actionability.

Based on the 8 values that were obtained for each criterion, a mean score was calculated per criterion for each QI. A total mean per QI was then calculated based on the resulting mean scores obtained for the criteria. For calculation of this total mean score, a weight of 1 was attributed to all criteria except for the 'relevance' criterion, which was attributed a weight of 2 (because of its importance according to the KCE methodology). Only QI with a total mean score of more than 4 were selected. From this first selection, the QI that were rated 4 or 5 by all experts on the 4 criteria were immediately retained in the final QI list. All other indicators were discussed based on relevance and feasibility, and indicators could only be selected after consensus, keeping in mind the pre-specified target number. The QI measures were not presented for public comment before implementation.

A level of evidence was assessed for all indicators, based on their relevance on cancer outcome. While outcome indicators are directly related with patients' prognoses, we assume that process indicators also indirectly have an influence on uterine cancer outcome. The process indicators were judged to be important for a correct staging or correct treatment choice and can therefore potentially influence patient outcome, even if those indicators show a low level of evidence within the current guidelines. The EFFECT project provides us the opportunity to validate the relevance of these currently low level indicators.

#### *Definition of variables and test of data collection*

Once a final list of QI indicators was selected, a list of variables required for the calculation of the QI was defined. In addition, patient characteristics including the patients' age, the WHO performance status and the preoperative ASA score will be recorded for EFFECT. Wherever

required, subanalyses will be performed to verify whether results for subgroups differ from the analyses carried out on the whole patient group. When applicable, both results will be reported in view of Quality of Care improvement. Because of the experience with registration of clinical data, the BCR was the most suited to create an online project-specific registration module for data collection. This EFFECT project specific module was coupled to the online application of the BCR for the legally obliged general cancer registration in Belgium. Furthermore, the paper registration forms were placed at the disposal of the testers and a manual was created including additional information about the variables.

A test phase was coordinated by the BCR:

First, each expert from the panel was asked to fill out the paper registration forms for 2 to 5 cases, with the help of the manual. A feedback meeting with the expert's panel was held to discuss the problems and to modify the registration forms and the manual. This first phase aimed to evaluate medical accuracy and relevance of the collected variables.

Second, datamanagers working at the center of the members of the collaborating expert's panels were asked to fill out the modified registration forms for the same cases. The remarks and problems encountered during the second test phase were discussed during a meeting. This second phase aimed to evaluate the feasibility and understanding of the data collection by datamanagers in the hospitals. Third, the online application was created in a test environment and was tested by datamanagers in the hospitals in 3 different settings. A correctly filled out test dataset was asked to be introduced in the online EFFECT module aiming to get used to the application. In a second setting, the registration forms were filled out using anonymized real cases to test the compatibility of the dataset and corresponding validations. The third setting aimed to evaluate the technical aspects of the online data collection and to test the compatibility of the online module with the in-hospital available patient data, using fictive identification data.

**Table 2**  
Final list of indicators selected for monitoring the quality of the management of uterine cancer in Belgium, including respective characteristics.

Denominator	Numerator	Theoretical target % <sup>a</sup>	Type of QI	Process of care	Dimension(s) of Quality of Care
<i>All histologies</i>					
Overall proportion of patients	Who had at least one tumor board review/multidisciplinary opinion during the management of their disease	100%	Process	1—treatment decision	Effectiveness
Overall proportion of operated patients	Who had a pre-operative biopsy	100%	Process	1—treatment decision	Effectiveness Safety Timeliness
Overall proportion of patients	Whose ASA and/or WHO score is reported	100%	Process	1—treatment decision	Effectiveness/Safety
Proportion of patients with clinical stage I undergoing surgery	For whom the surgical intervention is a TH/BSO	100%	Process	2—Surgery	Effectiveness
Proportion of patients undergoing surgery	For whom adnexal invasion (Yes/No) is reported/available (pathology report) for treatment decision	100%	Process	3—pathology-Staging	Effectiveness
Proportion of patients who had para-aortic lymphadenectomy during surgery	For whom number of para-aortic lymph nodes with metastasis is specified	100%	Process	3—pathology-Staging	Effectiveness
Proportion of patients undergoing surgery	For whom histological type according to WHO classification is reported/available (from resection specimen) for treatment decision	100%	Process	3—pathology-Staging	Effectiveness
Proportion of patients who had lymphadenectomy during surgery	For whom localization (pelvic and/or para-aortic) of lymph nodes removed is specified	100%	Process	3—pathology-Staging	Effectiveness
Proportion of patients who had pelvic lymphadenectomy during surgery	For whom number of pelvic lymph nodes harvested is specified	100%	Process	3—pathology-Staging	Effectiveness
Proportion of patients who had para-aortic lymphadenectomy during surgery	For whom number of para-aortic lymph nodes harvested is specified	100%	Process	3—pathology-Staging	Effectiveness
Proportion of patients who had pelvic lymphadenectomy during surgery	For whom number of pelvic lymph nodes with metastasis and extracapsular extension is specified	100%	Process	3—pathology-Staging	Effectiveness
Proportion of operated patients receiving subsequent/adjuvant anticancer treatment, if any	Within a maximum waiting time of 60 days (between date of surgery and date of 1st session of radiotherapy or chemotherapy)	100%	Process	4—adjuvant treatment	Effectiveness Timeliness
Proportion of patients who received external radiotherapy as adjuvant treatment	For whom the technique was IMRT or 3DCRT	100%	Process	4—adjuvant treatment	Effectiveness Safety
Proportion of patients with clinical stage I and II cancer who were not operated	Who received radiotherapy (intra-uterine brachytherapy +/- pelvic radiotherapy)	100%	Process	4—adjuvant treatment	Effectiveness
Proportion of patients who received postoperative adjuvant chemotherapy	For whom regimen included platinum-based drugs	100%	Process	4—adjuvant treatment	Effectiveness
Proportion of patients operated	Who died within the 30 days after the operation (30-days mortality rate)	0%	Outcome	5—outcome	Effectiveness Safety
Proportion of patients	Who are alive 5 years after their diagnosis (5-year overall survival)	100%	Outcome	5—outcome	Effectiveness
Proportion of patients	Who are alive without uterine cancer 5 years after their diagnosis (5-year disease-free survival)	100%	Outcome	5—outcome	Effectiveness

Table 2 (continued)

Denominator	Numerator	Theoretical target % <sup>a</sup>	Type of QI	Process of care	Dimension(s) of Quality of Care
<i>All endometrial carcinomas</i>					
Proportion of patients with clinical stage I cancer	Who were operated by minimally invasive surgery (laparoscopy or robot)	100%	Process	2–surgery	Safety
Proportion of patients with stage II disease	Who had TH/BSO and at least pelvic lymph node dissection	100%	Process	2–surgery	Effectiveness
Proportion of patients with clinical stage I and grade 3 tumors	Who had at least pelvic lymphadenectomy	100%	Process	2–surgery	Effectiveness
Proportion of clinical stage IIIA patients undergoing surgery	Who had TH/BSO and pelvic and para-aortic lymphadenectomy	100%	Process	2–surgery	Effectiveness
Proportion of patients undergoing surgery	For whom myometrial invasion is semi-quantitatively or quantitatively reported/available for treatment decision	100%	Process	3–pathology-staging	Effectiveness
Proportion of patients undergoing surgery	For whom tumor grade (1/2/3 or type II) is reported/available (from biopsy) for treatment decision	100%	Process	3–pathology-staging	Effectiveness
Proportion of patients undergoing surgery	For whom cervical stromal invasion (Yes/No) is reported/available (post-operatively) for treatment decision	100%	Process	3–pathology-staging	Effectiveness
Proportion of pathological stage I patients with at least 2 of the following 3 risk factors (age ≥60 years, >50% invasion of myometrium or grade 3) who were operated but did not have lymphadenectomy	Who received adjuvant radiotherapy	100%	Process	4–adjuvant treatment	Effectiveness
Proportion of pathological stage I patients with at least 2 of the following 3 risk factors (age ≥60 years, >50% invasion of myometrium or grade 3) who received adjuvant radiotherapy	For whom radiotherapy was vaginal brachytherapy	100%	Process	4–adjuvant treatment	Safety
Proportion of patients with advanced cancer (pathological stages III and IVa) who underwent surgery	Who received chemotherapy	100%	Process	4–adjuvant treatment	Effectiveness
Proportion of pathological stage I patients with at least 2 of the following 3 risk factors (age ≥60 years, >50% invasion of myometrium or grade 3) who were operated but did not have lymphadenectomy	Who received adjuvant chemotherapy	100%	Process	4–adjuvant treatment	Effectiveness
<i>Type I endometrial carcinomas</i>					
Proportion of patients with tumor invading less than 50% of the myometrium and grade 1 tumors	Who had lymphadenectomy	0%	Process	2–surgery	Effectiveness Safety
Proportion of patients with metastatic or recurrent endometrioid adenocarcinoma	For whom hormone receptors were assessed in the pathology report	100%	Process	3–pathology-staging	Effectiveness Safety
Proportion of operated patients without risk factors for recurrence (stage IA and Grade 1 or 2)	Who received any form of post-operative radiotherapy	0%	Process	4–adjuvant treatment	Effectiveness Safety

(continued on next page)



Table 2 (continued)

Denominator	Numerator	Theoretical target % <sup>a</sup>	Type of QI	Process of care	Dimension(s) of Quality of Care
Proportion of operated patients at low risk of recurrence (pathological stage IA and Grade 1 or 2)	Who received post-operative adjuvant chemotherapy	0%	Process	4—adjuvant treatment	Effectiveness Safety
Proportion of patients with endometrioid (stage IVB) adenocarcinoma cancer with positive hormonal receptors	Who received hormone therapy (progesterone or AI)	100%	Process	4—adjuvant treatment	Effectiveness
<i>Type II endometrial carcinomas</i>					
Proportion of patients with stage I or II serous or clear cell carcinoma or carcinosarcoma	Who had at least pelvic lymphadenectomy	100%	Process	2—surgery	Effectiveness
Proportion of patients with stage I or II serous or clear cell carcinoma or carcinosarcoma	Who had omentectomy	100%	Process	2—surgery	Effectiveness
<i>Uterine sarcomas</i>					
Proportion of patients with uterine leiomyosarcoma and endometrial stromal sarcoma	Who had TH (+/– BSO)	100%	Process	2—surgery	Effectiveness
Proportion of patients with uterine leiomyosarcoma or endometrial stromal sarcoma (low grade)	Who had lymphadenectomy	0%	Process	2—surgery	Effectiveness Safety
Proportion of patients with endometrial stromal sarcomas undergoing surgery	For whom receptor status (ER and PR) has been assessed and reported/available for treatment decision	100%	Process	3—pathology-staging	Effectiveness Safety
Proportion of operated patients with stage I and low grade endometrial stromal sarcoma or leiomyosarcoma	Who received radiotherapy	0%	Process	4—adjuvant treatment	Effectiveness Safety
Proportion of operated patients with clinical or pathological stage II to IV endometrial stromal sarcomas	Who received post-operative hormone treatment (progesterone or AI)	100%	Process	4—adjuvant treatment	Effectiveness

Abbreviations: QI: quality indicators; ASA: American Society of Anesthesiologists; WHO: World Health Organization; TH: Total hysterectomy; BSO: Bilateral salpingo-oophorectomy; IMRT: Intensity Modulated Radiation Therapy; 3DCRT: 3-Dimensional Conformal Radiation Therapy; ER: Estrogen Receptor; PR: Progesterone Receptor; AI: Aromatase Inhibitor.

<sup>a</sup> The theoretical target is the target which is expected for a standard patient. Although the theoretical target gives an indication of the expected direction, some variation cannot be avoided.

## Results

### Indicators retrieved from literature search and additional sources

The literature searches resulted in a total of 210 articles. Forty-seven papers were judged relevant based on title and abstract of which a total of 77 QI were retained (Fig. 1).

Sixty QI were retained from the pre-specified guidelines. Only 6 additional QI were selected from the QI databases (none of them is specific for uterine cancer) since most QI in those databases are very general, in order to be applicable to all types of patients or diseases.

### QI selection

When presenting the total list of QI (n = 143), 44 indicators were rephrased to improve the level of details or avoid confusion in their interpretation, and 21 indicators were added by consensus by the expert's panel. Since a given indicator could be retrieved from more than 1 source, 138 indicators were considered for further discussion.

A first discussion by the experts resulted in the selection of 82 indicators eligible for rating. Reasons for exclusion of the 56 indicators are presented in Fig. 1 and mainly include redundancy and lack of relevance.

The results of the rating, performed by 8 experts, were presented during a meeting and 16 indicators were excluded due to an insufficient total mean score (<4). To stay in line with our predefined target of 30–40 QI, 25 additional QI were removed after discussion and after reaching a consensus. The final list of 41 indicators with corresponding characteristics is presented in Table 2. The members of the experts' panel independently gave the selected indicators high scores during the rating process, which enhances the credibility of the indicators among the intended users. The QI represent general QI focusing on all histologies as well as QI that more specifically focus on endometrial carcinomas (in general or on type I or II) and uterine sarcomas. The list includes in total 3 outcome indicators and 38 process indicators involved in the process of treatment decision, pathology-staging, surgery or adjuvant treatment.

The test phases on paper enabled us to indicate the difficulties in the registration forms and to select variables that required additional

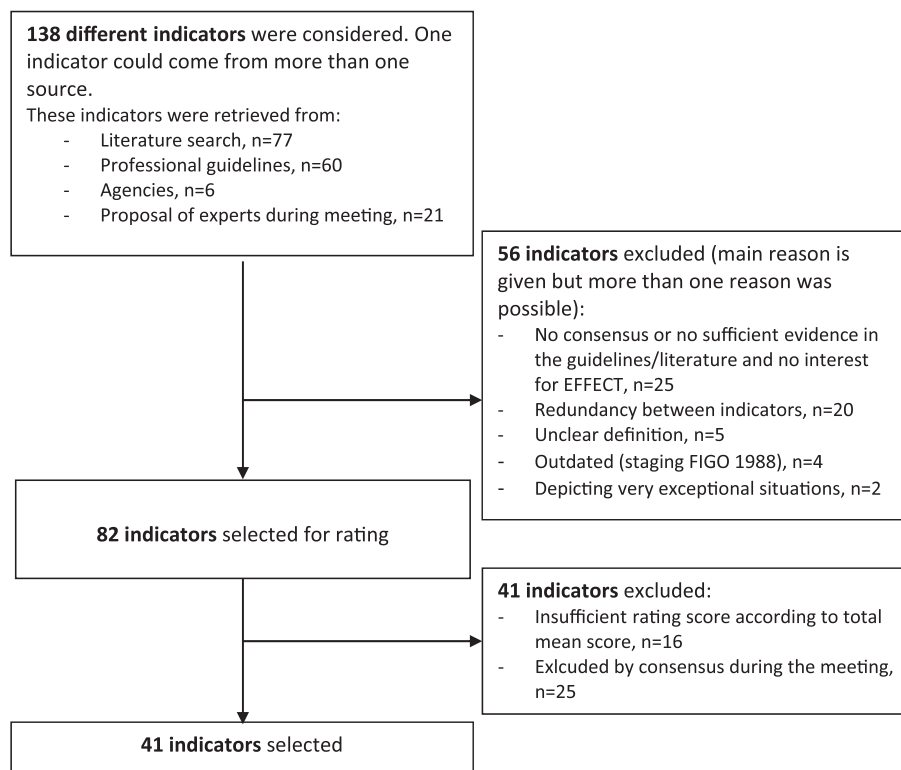


Fig. 1. Selection flowchart of quality indicators.

information for optimal registration. Testing of the dataset on paper thus resulted in 1) the modification of some of the variables to clarify the underlying idea, 2) the combination of some of the variables to restrict the number of project-specific variables, and 3) the removal of some variables that were not available for registration.

Testing of the online module provided useful information to improve the user friendliness and the technical aspects of this application.

## Discussion

To our knowledge, this is the first national initiative on quality of the management of patients with cancer of the uterine corpus. Even though it is the most frequent gynecological cancer, few initiatives have explored the Quality of Care for this cancer type.

A recent US initiative did not succeed in reaching a consensus about the choice of gynecologic oncology quality measures to be used in the Prospective Payment System-Exempt Cancer Hospitals [36]. Contrary to this initiative, we did not experience a high variability in the ranking of QI in our group, which allowed us to come to a consensus of 41 QI for cancer of the uterine corpus. This highlights the critical role that the methodology has played in reaching our goal of coming to a consensus for the QI that will be implemented and further evaluated.

The QI selection should rely on a sound methodology and should include several disciplines involved in the management of the target population. When starting this project, an extensive list of recent and relevant indicators was lacking. The lists of indicators selected by our methodology can therefore be used by other groups allowing comparison. French and Dutch translations of these indicators are available on request.

Very few process QI in the final list have a high level of evidence. This is either due to the difficulty of providing a high level of evidence for some processes, such as pathology, or due to a real lack of clear evidence from randomized trials for some clinical questions, such as the role of lymphadenectomy. The high mean scores attributed to these QI by the

expert's panel clearly indicates their clinical value emphasizing that evidence should not be the only criterion to select QI since it eliminates indicators deemed relevant by consensus.

The main limit of the selection of the indicators is the limited evidence available for the management of cancer of the corpus uteri. Decision on some important clinical questions addressed in the international guidelines is based on consensus rather than on evidence. Checking the internal validity will therefore be required in order to discuss the relevance of indicators which have no impact on the outcome and to add to the evidence for indicators with an a priori low level of evidence. Indeed, when assessing the quality of real-world settings based on such process indicators, the assumption is made that adherence to these QI in real-world settings has an impact on the outcome. Such an assumption should be verified within the cohort of patients in which QI are measured. To our knowledge, very few studies have validated the effect of process indicators on the outcome within the same cohort of patients [26,27]. Results from new clinical trials in the field will be taken into consideration to update the list of QI and data collection after discussion with the expert's panel.

Since February 2013, the online EFFECT module for prospective data collection is available via the online cancer registration application of the BCR [37]. Many Belgian hospitals involved in the management of uterine cancer already agreed to participate. However, participation is on a voluntary basis and will require continuous efforts from all parties involved. Results for the first 6-month period will be available at the beginning of 2014 and will give us a first picture of the main points of variability at the national level. By providing continuous feedback to the participating hospitals, we expect to initiate awareness on the possibility of increasing the Quality of Care for cancer of the corpus uteri.

In this paper, we confirm that the KCE methodology previously used in Belgium for several cancers is reproducible when used by another group for another type of cancer. This methodology may be applicable in other countries as well. Selecting relevant QI for cancer of the corpus uteri was time consuming and we hope that our experience can help others to start similar projects. The list of 41 QI that is proposed in this

paper covers all aspects of the management of uterine cancer. It could be used by other groups, either as such or as a starting point requiring adaptation to the local context.

#### Conflict of interest statement

None of the authors have conflicts of interests to report concerning the manuscript.

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