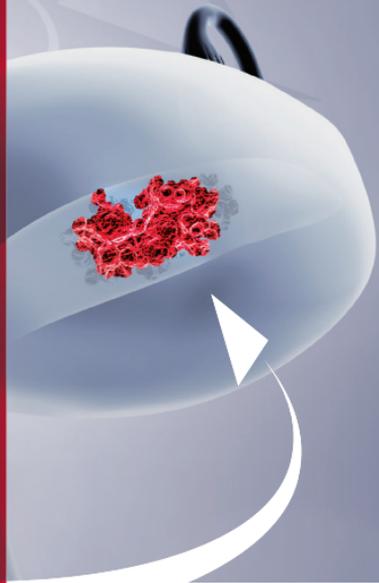


Endometrial Cancer Pocket Guidelines



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POCKET GUIDELINES ENDOMETRIAL CANCER

based on

**ESMO-ESGO-ESTRO Consensus
Conference on Endometrial Cancer**

Colombo, N., Creutzberg C., Amant F., ... Chiva, L. (2016) ESMO-ESGO-ESTRO Consensus Conference on Endometrial Cancer: Diagnosis, Treatment and Follow-up. *International Journal of Gynecological Cancer*, 27(1), 2-30. DOI:10.1097/IGC.0000000000000609.



The first joint European Society for Medical Oncology (ESMO), European Society for Radiotherapy & Oncology (ESTRO) and European Society of Gynaecological Oncology (ESGO) consensus conference on endometrial cancer was held on 11-13 December 2014 in Milan, Italy, and comprised a multidisciplinary panel of 40 leading experts in the management of endometrial cancer. Before the conference, three clinically relevant questions were identified for each subject area/working group, giving a total of 12 clinically relevant questions as follows:

1. Which surveillance should be used for asymptomatic women?
 2. What work-up and management scheme should be undertaken for fertility-preserving therapy in patients with atypical hyperplasia (AH)/endometrial intraepithelial neoplasia (EIN) and grade 1 endometrioid endometrial cancer (EEC)?
 3. Which (molecular) markers can help distinguish (pre)cancerous lesions from benign mimics?
 4. How does the medical condition influence surgical treatment?
 5. What are the indication for and to what extent is lymphadenectomy indicated in the surgical management of endometrial cancer?
 6. How radical should the surgery be in different stages and pathological subtypes of endometrial cancer?
 7. What is the current best definition of risk groups for adjuvant therapy?
 8. What are the best evidence-based adjuvant treatment strategies for patients with low-and intermediate-risk endometrial cancer?
 9. What are the best evidence-based adjuvant treatment strategies for patients with high-risk endometrial cancer?
 10. Does surgery or radiotherapy (RT) have a role in advanced or recurrent endometrial cancer?
 11. What are the most promising targeted agents and which study designs should be used to evaluate their clinical benefit?
 12. What are the most promising targeted agents and which study designs should be used to evaluate their clinical benefit?
- 

Each working group was responsible for reviewing the relevant literature in order to draft preliminary recommendations relating to each of their assigned questions. During the conference, in parallel sessions, the four working groups discussed and reached agreement on recommendations relating to each of their assigned questions. Recommendations from each group were then presented to the entire panel of experts, where they were discussed and modified as required. An adapted version of the “Infectious Diseases Society of America-United States Public Health Service Grading System” was used (table 1) to define the level of evidence and strength of each recommendation proposed by the group¹. Finally, a vote was conducted to determine the level of agreement among the expert panel for each of the recommendations. Panel members were allowed to abstain from voting in cases where they either had insufficient expertise to agree/disagree with the recommendations or if they had a conflict of interest that could be considered as influencing their vote.

Table 1. Levels of evidence and grades of recommendations

Levels of evidence

- I Evidence from at least one large randomized, controlled trial of good methodological quality (low potential for bias) or meta-analyses of well-conducted, randomized trials without heterogeneity
- II Small randomized trials or large randomized trials with a suspicion of bias (lower methodological quality) or meta-analyses of such trials or of trials with demonstrated heterogeneity
- III Prospective cohort studies
- IV Retrospective cohort studies or case-control studies
- V Studies without control group, case reports, experts opinions

Grades of recommendation

- A Strong evidence for efficacy with a substantial clinical benefit, strongly recommended
- B Strong or moderate evidence for efficacy but with a limited clinical benefit, generally recommended
- C Insufficient evidence for efficacy or benefit does not outweigh the risk or the disadvantages (adverse events, costs, ...), optional
- D Moderate evidence against efficacy or for adverse outcome, generally not recommended
- E Strong evidence against efficacy or for adverse outcome, never recommended

¹ Dykewicz CA. Summary of the guidelines for preventing opportunistic infections among hematopoietic stem cell transplant recipients. Clin Infect Dis 2001; 33:139-144.

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PREVENTION AND SCREENING OF ENDOMETRIAL CANCER

1. Which surveillance should be used for asymptomatic women?

A

There is no evidence for endometrial cancer screening in the general population (*LoE II*)

A

Unopposed oestrogen treatment should not be started or should be discontinued in women with a uterus in situ (*LoE III*)

B

Routine surveillance in asymptomatic women with obesity, PCOS, diabetes mellitus, infertility, nulliparity or late menopause is not recommended (*LoE III*)

B

For women with adult granulosa cell tumour, if hysterectomy has not been performed, endometrial sampling is recommended. If this shows no evidence of (pre)malignancy, no further screening for endometrial malignancies is required (*LoE IV*)

B

in patients with epithelial ovarian cancer undergoing fertility-sparing treatment, endometrial sampling is recommended at the time of diagnosis (*LoE IV*)

B

Routine screening for endometrial cancer in asymptomatic tamoxifen users is not recommended (*LoE III*)

B

Surveillance of the endometrium by gynaecological examination, transvaginal ultrasound and aspiration biopsy starting from the age of 35 years (annually until hysterectomy) should be offered to all LS mutation carriers (*LoE IV*)

B

prophylactic surgery (hysterectomy and bilateral salpingo-oophorectomy), preferably using a minimally invasive approach, should be discussed at the age of 40 as an option for LS mutation carriers to prevent endometrial and ovarian cancer. All pros and cons of prophylactic surgery must be discussed (*LoE IV*)

2. What work-up and management scheme should be undertaken for fertility-preserving therapy in patients with AH/EIN and grade 1 ECC?

A Patients with AH/EIN or grade 1 EEC requesting fertility-preserving therapy must be referred to specialized centres (LoE V)

A In these patients, D&C with or without hysteroscopy must be performed (LoE IV)

A AH/EIN or grade 1 EEC must be confirmed/diagnosed by a specialist gynaecopathologist (LoE IV)

B Pelvic MRI should be performed to exclude overt myometrial invasion and adnexal involvement. Expert ultrasound can be considered as an alternative (LoE III)

A Patients must be informed that fertility-sparing treatment is a non-standard treatment and the pros and cons must be discussed. Patients should be willing to accept close follow-up and be informed of the need for future hysterectomy (LoE V)

B For patients undergoing fertility-preserving therapy, MPA (400-600 mg/day) or MA (160-320 mg/day) is the recommended treatment. However, treatment with LNG-IUD with or without GnRH analogues can also be considered (LoE IV)

B In order to assess response, D&C hysteroscopy and imaging at 6 months must be performed. If no response is achieved after 6 months, standard surgical treatment should be performed (LoE IV)

B In case of complete response, conception must be encouraged and referral to a fertility clinic is recommended (LoE IV)

B Maintenance treatment should be considered in responders who wish to delay pregnancy (LoE IV)

B Patients not undergoing hysterectomy should be re-evaluated clinically every 6 months (LoE IV)

B After completion of childbearing, a hysterectomy and salpingo-oophorectomy should be recommended. The preservation of the ovaries can be considered depending on age and genetic risk factors (LoE IV)

3. Which (molecular) markers can help distinguish (pre)cancerous lesions from benign mimics?

- A** In case of uncertainty, low threshold referral to a specialised gynaecopathologist is recommended (*LoE V*)
- B** PTEN and PAX-2 IHC is recommended to distinguish AH/EIN from benign mimics. Other markers that can be used in this context are MLH1 and ARID1a by IHC (*LoE IV*)
- B** IHC is not recommended to distinguish APA from AH/EIN (*LoE V*)
- B** p53 by IHC is recommended to distinguish SEIC from its mimics (*LoE IV*)
- B** A panel of markers must be used in cases where endocervical cancer is suspected. This panel should include at least ER, vimentin, CEA and p16 by IHC and needs to be assessed in the histologic and clinical context. In addition, HPV analysis can be considered (*LoE IV*)
- A** WT-1 by IHC is the recommended marker to determine the origin of serous cancer (*LoE IV*)
- A** Morphology (and not IHC) should be used to distinguish AH/EIN from EEC (*LoE IV*)

SURGERY

4. How does the medical condition influence surgical treatment?

A Mandatory work-up must include: Family history; general assessment and inventory of comorbidities; geriatric assessment, if appropriate; clinical examination, including pelvic examination; transvaginal or transrectal ultrasound; and complete pathology assessment (histotype and grade) of an endometrial biopsy or curettage specimen (*LoE V*)

A Extent of surgery should be adapted to the medical condition of the patient (*LoE V*)

A In clinical stage I, grade 1 and 2: At least one of the three following tools should be used to assess myometrial invasion if LND is considered: Expert ultrasound and/or MRI and/or intra-operative pathological examination (*LoE IV*)

C Other imaging methods (thoracic, abdominal and pelvic CT scan, MRI, PET scan or ultrasound) should be considered to assess ovarian, nodal, peritoneal or metastatic disease (*LoE IV*)

B There is no evidence for the clinical usefulness of serum tumour markers, including CA 125 (*LoE IV*)

A Standard surgery is total hysterectomy with bilateral salpingo-oophorectomy without vaginal cuff (*LoE IV*)

B Ovarian preservation can be considered in patients younger than 45 years old with grade 1 EEC with myometrial invasion <50% and no obvious ovarian or other extra-uterine disease (*LoE IV*)

B In cases of ovarian preservation, salpingectomy is recommended (*LoE IV*)

B Ovarian preservation is not recommended for patients with cancer family history involving ovarian cancer risk (e.g. BRCA mutation, LS etc.). Genetic counselling/testing should be offered (*LoE IV*)

A Minimally invasive surgery is recommended in the surgical management of low- and intermediate risk endometrial cancer (*LoE I*)

- 
- C** Minimally invasive surgery can be considered in the management of high-risk endometrial cancer (*LoE IV*)
 - C** Vaginal hysterectomy with salpingoophorectomy can be considered in patients unfit for the recommended surgery and in selected patients with low-risk endometrial cancer (*LoE IV*)
 - C** In medically unfit patients, RT or hormone treatment can be considered (*LoE IV*)

5. What are the indications for and to what extent is lymphadenectomy indicated in the surgical management of endometrial cancer?

A Peritoneal cytology is no longer considered mandatory for staging (LoE IV)

B If a lymphadenectomy is performed, systematic removal of pelvic and para-aortic nodes up to the level of the renal veins should be considered (LoE IV)

D SLND is still experimental, but large series suggest that it is feasible. SLND increases the detection of lymph nodes with small metastases and isolated tumour cells; however, the importance of these findings is unclear (LoE IV)

B Lymphadenectomy is a staging procedure and allows tailoring of adjuvant therapy (LoE III)

A Patients with low-risk endometrioid carcinoma (grade 1 or 2 and superficial myometrial invasion <50%) have a low risk of lymph node involvement, and two RCTs did not show a survival benefit. Therefore, lymphadenectomy is not recommended for these patients (LoE II)

C For patients with intermediate risk (deep myometrial invasion >50% or grade 3 superficial myometrial invasion <50%), data have not shown a survival benefit. Lymphadenectomy can be considered for staging purposes in these patients (LoE II)

B For patients with high risk (grade 3 with deep myometrial invasion >50%), lymphadenectomy should be recommended (LoE IV)

C Lymphadenectomy to complete staging could be considered in previously incompletely operated high-risk patients to tailor adjuvant therapy (LoE V)

6. How radical should the surgery be in different stages and pathological subtypes of endometrial cancer?

- B** Radical hysterectomy is not recommended for the management of stage II endometrial cancer (*LoE IV*)
- B** Modified (type B) or type A radical hysterectomy should be considered only if required for obtaining free margins (*LoE IV*)
- B** Lymphadenectomy is recommended for clinical or intra-operative stage II endometrial cancer (*LoE IV*)
- A** Complete macroscopic cytoreduction and comprehensive staging is recommended in advanced endometrial cancer (*LoE IV*)
- B** Multimodality management should be considered for the treatment of advanced endometrial cancer when surgery may significantly impair vaginal function (*LoE IV*)
- B** In non-EEC (apparent stage I), lymphadenectomy is recommended (*LoE IV*)
- C** Staging omentectomy is not mandatory in clear-cell or undifferentiated endometrial carcinoma and carcinosarcoma (*LoE IV*)
- C** Staging omentectomy should be considered in serous carcinoma (*LoE IV*)

ADJUVANT TREATMENT

7. What is the current best definition of risk groups for adjuvant therapy?

A definition of risk groups to identify patients at risk of recurrence who may benefit from adjuvant therapy has been devised by the consensus panel and is shown in table 2.

Table 2. New risk groups to guide adjuvant therapy use

Risk group	Description	LoE
Low	Stage I endometrioid, grade 1-2, <50% myometrial invasion, LVSI negative	I
Intermediate	Stage I endometrioid, grade 1-2, ≥50% myometrial invasion, LVSI negative	I
High-intermediate	Stage I endometrioid, grade 3, <50% myometrial invasion, regardless of LVSI status	I
	Stage I endometrioid, grade 1-2, LVSI unequivocally positive, regardless of depth of invasion	II
High	Stage I endometrioid, grade 3, ≥50% myometrial invasion, regardless of LVSI status	I
	Stage II	I
	Stage III endometrioid, no residual disease	I
	Non-endometrioid (serous or clear-cell or undifferentiated carcinoma, or carcinosarcoma)	I
Advanced	Stage III residual disease and stage IVA	I
Metastatic	Stage IVB	I

FIGO 2009 staging used; molecular factors were considered but not included; tumour size was considered but not included; nodal status may be considered for treatment recommendations

8. What are the best evidence-based adjuvant treatment strategies for patients with low- and intermediate-risk endometrial cancer?

A

In patients with low-risk endometrial cancer (stage I endometrioid, grade 1–2, <50% myometrial invasion, LVSI negative), no adjuvant treatment is recommended (*LoE I*)

B

In patients with intermediate-risk endometrial cancer (stage I endometrioid, grade 1–2, ≥50% myometrial invasion, LVSI negative), adjuvant brachytherapy is recommended to decrease vaginal recurrence (*LoE I*)

C

In patients with intermediate-risk endometrial cancer (stage I endometrioid, grade 1–2, ≥50% myometrial invasion, LVSI negative), no adjuvant treatment is an option, especially for patients aged <60 years (*LoE II*)

B

In patients with high-intermediate risk endometrial cancer (stage I endometrioid, grade 3, <50% myometrial invasion, regardless of LVSI status; or stage I endometrioid, grade 1–2, LVSI unequivocally positive, regardless of depth of invasion):

1. Surgical nodal staging performed, node negative:

a. Adjuvant brachytherapy is recommended to decrease vaginal recurrence (*LoE III*)

C

b. No adjuvant therapy is an option (*LoE III*)

2. No surgical nodal staging:

B

a. Adjuvant EBRT recommended for LVSI unequivocally positive to decrease pelvic recurrence (*LoE III*)

B

b. Adjuvant brachytherapy alone is recommended for grade 3 and LVSI negative to decrease vaginal recurrence (*LoE III*)

C

3. Systemic therapy is of uncertain benefit; clinical studies are encouraged (*LoE III*)

9. What are the best evidence-based adjuvant treatment strategies for patients with high-risk endometrial cancer?

In patients with high-risk endometrial cancer (stage I endometrioid, grade 3, $\geq 50\%$ myometrial invasion, regardless of LVSI status):

1. Surgical nodal staging performed, node negative:
 - B** a. Adjuvant EBRT with limited fields should be considered to decrease locoregional recurrence (*LoE I*)
 - B** b. Adjuvant brachytherapy may be considered as an alternative to decrease vaginal recurrence (*LoE III*)
 - C** c. Adjuvant systemic therapy is under investigation (*LoE II*)
2. No surgical nodal staging:
 - B** a. Adjuvant EBRT is generally recommended for pelvic control and relapse-free survival (*LoE III*)
 - C** b. Sequential adjuvant chemotherapy may be considered to improve PFS and cancer-specific survival (CSS) (*LoE II*)
 - B** c. There is more evidence to support giving chemotherapy and EBRT in combination rather than either treatment modality alone (*LoE II*)

In patients with high-risk, stage II endometrial cancer:

1. Simple hysterectomy, surgical nodal staging performed, node negative:
 - B** a. Grade 1–2, LVSI negative: Recommend vaginal brachytherapy to improve local control (*LoE III*)
 - B** b. Grade 3 or LVSI unequivocally positive:
 - C** i. Recommend limited field EBRT (*LoE III*)
 - C** ii. Consider brachytherapy boost (*LoE IV*)
 - C** iii. Chemotherapy is under investigation (*LoE III*)
2. Simple hysterectomy, no surgical nodal staging:
 - B** a. EBRT is recommended (*LoE III*)
 - C** b. Consider brachytherapy boost (*LoE IV*)
 - B** c. Grade 3 or LVSI unequivocally positive: Sequential adjuvant chemotherapy should be considered (*LoE III*)

In patients with high-risk, stage III endometrial cancer and no residual disease:

1. EBRT is recommended to:

- B a. Decrease pelvic recurrence (*LoE I*)
- B b. Improve PFS (*LoE I*)
- B c. Improve survival (*LoE IV*)

B 2. Chemotherapy is recommended to improve PFS and CSS (*LoE II*)

3. There is more evidence to give chemotherapy and EBRT in combination than either alone in stage III disease:

- B a. IIIA: Chemotherapy AND EBRT to be considered (*LoE II*)
- B b. IIIB: Chemotherapy AND EBRT to be considered (*LoE II*)
- B c. IIIC1: Chemotherapy AND EBRT to be considered (*LoE II*)
- B d. IIIC2: Chemotherapy AND extended field EBRT to be considered (*LoE II*)

In patients with high-risk, non-endometrioid cancers:

1. Serous and clear cell after comprehensive staging:

- B a. Consider chemotherapy; clinical trials are encouraged (*LoE III*)
- C b. Stage IA, LVSI negative: Consider vaginal brachytherapy only without chemotherapy (*LoE IV*)
- C c. Stage \geq IB: EBRT may be considered in addition to chemotherapy, especially for node-positive disease (*LoE III*)

2. Carcinosarcoma and undifferentiated tumours:

- B a. Chemotherapy is recommended (*LoE II*)
- C b. Consider EBRT; clinical trials are encouraged (*LoE III*)

ADVANCED AND RECURRENT ENDOMETRIAL CANCER

10. Does surgery or RT have a role in advanced or recurrent endometrial cancer?

C

For patients with advanced or recurrent disease, surgery is recommended only if optimal cytoreduction (no residual disease) can be achieved. In selected cases, palliative surgery is recommended to alleviate specific symptoms (*LoE IV*)

C

Exenteration can be considered in selected patients with locally advanced tumours, and for isolated central local relapse after radiation, if clear margins are expected (*LoE IV*)

C

Complete resection of distant oligometastases and pelvic or retroperitoneal lymph node relapse can be considered if technically possible according to localisation of disease (*LoE V*)

B

Histological type should not influence the decision whether or not to proceed with surgery (*LoE IV*)

A

RT with curative intent is indicated in patients with isolated vaginal relapse after surgery (*LoE III*)

C

For vaginal or pelvic nodal recurrence, chemotherapy with RT could be considered in patients with high-risk features for systemic relapse (*LoE IV*)

C

Use of systemic therapy or surgery before RT for vaginal or pelvic node recurrence could be considered in certain patients (*LoE V*)

C

Re-irradiation could be considered in highly selected patients using specialised techniques (*LoE V*)

A

RT is indicated for palliation of symptoms related to local recurrence or systemic disease (*LoE IV*)

B

RT may be indicated for primary tumours that are unresectable, or where surgery cannot be performed or is contraindicated for medical reasons (*LoE IV*)

11. What are the optimal systemic therapies for advanced/recurrent disease?

- C** Hormone therapy is indicated in advanced or recurrent EEC (*LoE II*)
- B** Hormone therapy is more likely to be effective in grade 1 or 2 endometrioid tumours (*LoE IV*)
- B** Hormone receptor status should be determined before hormone therapy is initiated, as it is more likely to be effective in patients with positive PgR and ER status (*LoE III*)
- C** Biopsy of recurrent disease could be considered as there may be differences in hormone receptor status in the primary and metastatic tumour (*LoE III*)
- A** Hormone therapy is the preferred front-line systemic therapy for patients with hormone receptorpositive tumours—grade 1 or 2 and without rapidly progressive disease (*LoE V*)
- A** Progestogens (e.g. MPA 200 mg or MA 160 mg) are generally recommended (*LoE III*)
- C** Other hormonal agents to consider after progestins include tamoxifen, fulvestrant and aromatase inhibitors (*LoE III*)
- A** The standard of care is six cycles of 3- weekly carboplatin and paclitaxel. This is based on the preliminary communication of a randomised trial showing similar efficacy and less toxicity compared with cisplatin/ doxorubicin/paclitaxel (*LoE I*)
- C** There is no standard of care for second-line chemotherapy (*LoE V*)

12. What are the most promising targeted agents and which study designs should be used to evaluate their clinical benefit?

B

PI3K/PTEN/AKT/mTOR pathway, PTEN, RAS-MAPK, angiogenesis (especially FGFR2 and VEGF/VEGFR), ER/PgR and HRD/MSI are altered in endometrial cancer and their relevance should be studied in clinical trials with targeted agents (*LoE III*)

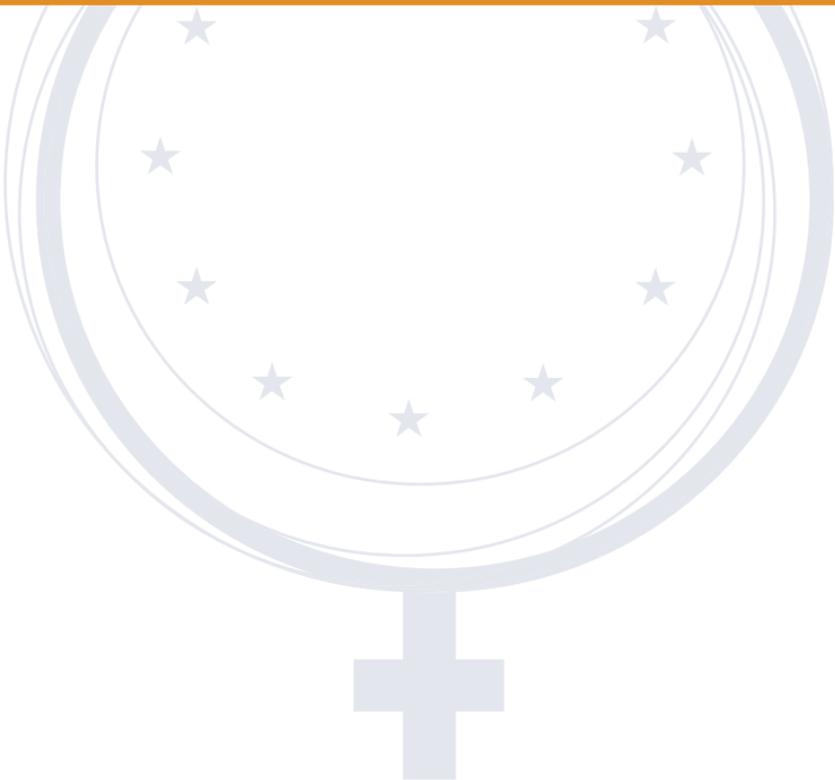
A

Drugs targeting PI3K/mTOR pathway signalling and angiogenesis have shown modest activity but no agent has been approved for clinical use, and further biomarker- driven studies are warranted (*LoE III*)

A

Clinical trial designs for new, targeted therapy:

1. Basket studies with multiple cohorts related to histological subtypes and/or molecular alterations are considered a priority
2. Biomarker-driven clinical trials with biopsy at entry and sequential biopsies in trials with molecular end points are recommended
3. PFS or PFS at a defined time-point are the preferred primary end points for early phase trials
4. OS is the preferred primary end point in phase III trials, unless crossover is planned or expected (*LoE V*)



These Guidelines were developed by the ESMO, ESGO and the ESTRO, and are published jointly in the *Annals of Oncology*, the *International Journal of Gynecological Cancer and Radiotherapy & Oncology*. The three societies nominated participants who attended the consensus conference.

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