Evidence-Based Series #4-11

A Quality Initiative of the Program in Evidence-Based Care (PEBC), Cancer Care Ontario (CCO)

Organizational Guideline for Gynecologic Oncology Services in Ontario


Report Date: June 6, 2013

An assessment conducted in November 2016 deferred the review of Evidence-based series (EBS) 4-11, which means that the document remains current until it is assessed again next year. The PEBC has a formal and standardized process to ensure the currency of each document (PEBC Assessment & Review Protocol)

Evidence-Based Series 4-11 is comprised of 3 sections:

Section 1: Guideline Recommendations
Section 2: Evidentiary Base
Section 3: Development Methods, Recommendations Development and External Review Process

For information about the PEBC and the most current version of all reports, please visit the CCO Web site at http://www.cancercare.on.ca/ or contact the PEBC office at:
Phone: 905-527-4322 ext. 42822 Fax: 905-526-6775 E-mail: ccopgi@mcmaster.ca


Organizational Guideline for Gynecologic Oncology Services in Ontario: Guideline Recommendations

Table of Contents

Section 1: Guideline Recommendations ................................................................. 1
Section 2: Evidentiary Base ...............................................................................19
Section 3: EBS Development Methods and External Review Process ..................83
Evidence-Based Series #4-11: Section 1
A Quality Initiative of the Program in Evidence-Based Care (PEBC), Cancer Care Ontario (CCO)

Organizational Guideline for Gynecologic Oncology Services in Ontario: Guideline Recommendations

Table of Contents

A. GUIDELINE OBJECTIVE ......................................................................................... 1
B. RESEARCH QUESTIONS ..................................................................................... 1
C. PATIENT POPULATION ....................................................................................... 2
D. INTENDED USERS .............................................................................................. 2
E. INTRODUCTION ..................................................................................................... 2
F. RECOMMENDATIONS AND KEY EVIDENCE .................................................. 3
  I. GYNECOLOGIC ONCOLOGISTS .................................................................... 3
  II. GYNECOLOGIC ONCOLOGY CENTRES ..................................................... 6
    1. Treatment at gynecologic oncology centres .................................................. 6
    2. Human resources at gynecologic oncology centres ....................................... 7
    3. Physical resources and collaborating services at gynecologic oncology centres .... 8
    4. Annual volumes at gynecologic oncology centres ......................................... 9
  III. AFFILIATED CENTRES.................................................................................. 10
    1. Treatment at affiliated centres ...................................................................... 10
    2. Human resources at affiliated centres ......................................................... 10
    3. Physical resources and collaborating services at affiliated centres .............. 11
    4. Annual volumes at affiliated centres ............................................................ 12
  IV. RELATIONSHIP BETWEEN GYNECOLOGIC ONCOLOGY CENTRES and AFFILIATED CENTRES ................................................................................ 12
  V. MULTIDISCIPLINARY DISCUSSION/EVALUATION ......................................... 14
Evidence-Based Series #4-11: Section 1

A Quality Initiative of the
Program in Evidence-Based Care (PEBC), Cancer Care Ontario (CCO)

Organizational Guideline for Gynecologic Oncology Services in Ontario:
Guideline Recommendations

M. Fung-Kee-Fung, E.B. Kennedy, J. Biagi, T. Colgan, D. D’Souza, L. Elit, A. Hunter, J. Irish,
R. McLeod, B. Rosen and members of the
Gynecologic Oncology Organizational Guideline Expert Panel

Report Date: June 6, 2013

A. GUIDELINE OBJECTIVE
To determine the optimal organization of gynecologic oncology services in Ontario for
patients who have been diagnosed with a gynecologic malignancy in order to ensure high-
quality care and optimal cancer treatment outcomes.

B. RESEARCH QUESTIONS
1. Does treatment by a gynecologic oncologist result in better outcomes than treatment
by a gynecologist (GYN) or general surgeon (GS)?
2. Are there better outcomes for patients with gynecologic cancer treated in designated
centres compared to non-designated centres?
3. Is there a volume-outcome relationship between number of procedures by a
physician/hospital and patient surgical or survival outcomes?

In addition, the Gynecologic Oncology Organizational Guideline Development Group
(the Guideline Development Group) agreed to use the evidentiary base generated by the
research questions above to provide consensus-based guidance regarding implementation of
the optimal system of organization for gynecologic oncology in Ontario. Questions related to
implementation/organization include:

1. How will services be regionally organized? Will specialized gynecologic oncology
centres be designated?
2. If designated centres are recommended:
   • What is the optimal relationship or network of care between designated and non-
designated centres?
   • What are the human and physical resources requirements of a designated
     (specialized) centre?

The general consensus at this time is that multidisciplinary care is the standard for all
cancer types (1), and Cancer Care Ontario supports the use of regularly scheduled
multidisciplinary cancer conferences (MCCs) to prospectively review individual cancer
patients and make recommendations on management (2). The following questions specific to
gynecologic oncology multidisciplinary teams (MDTs) were also asked by the Guideline
Development Group:
1. What are the recommended staff requirements for a gynecologic oncology MDT?

2. What expertise/formal training is required by the members of the MDT?

C. PATIENT POPULATION

The target patient population is women in Ontario who have been diagnosed with gynecologic cancer or have an ovarian mass with Risk of Malignancy Index (RMI) > 200. The scope does not include the following non-invasive cases:

- Cervical intraepithelial neoplasia & carcinoma in situ (≤Stage T1a1);
- Vaginal intraepithelial neoplasia;
- Vulvar intraepithelial neoplasia;
- Ovarian masses with an RMI score of less than 200, as these cases are less likely to be invasive (3);
- Low-risk gestational trophoblastic neoplasia (GTN) that resolves spontaneously.

D. INTENDED USERS

This guideline is intended for use by Ontario policy makers and clinicians involved in the care of gynecologic cancer patients.

E. INTRODUCTION

Rationale for a Guideline

A system-level organizational guideline has been identified by the PEBC Gynecologic Oncology Disease Site Group and the Surgical Oncology Program, through consultation with stakeholders in Ontario, as a key priority. The purpose of the guideline is to provide recommendations for the optimal organization of gynecologic oncology services in Ontario in order to improve access to multidisciplinary care and appropriate treatment, thereby improving outcomes for patients. Designation of this topic as a key priority was based on data suggesting a gap in quality of care in Ontario, including data showing many patients are receiving care in lower volume hospitals and, are therefore, less likely to have access to multidisciplinary care, and that many ovarian and endometrial cancer patients are not receiving adequate surgical staging, which has independently been associated with survival. There are also issues in Ontario with wait times for gynecologic oncology surgery, with only 69% and 67% of surgeries being completed within the wait time target for the first and second quarter of 2012/2013, respectively (4). At the same time, a 16% increase in gynecologic malignancies is projected between 2011 and 2018 (5,6). With an increase in the patient population, there is a need to examine ways to establish a network that will facilitate the flow of these patients through the care continuum. Furthermore, the lower rates of staging in Ontario by both specialists and non-specialists indicate that there is a need for recommendations that will allow a collaborative community of practice to evolve in order to facilitate adherence to guidelines and best practices at a system-wide level (7).

Scope of the Report

The scope of the report is defined by the research questions and includes recommendations for the optimal organizational of gynecologic oncology services in Ontario, including whether patients should receive subspecialty care in designated hospitals, the human and physical resources associated with the delivery of care, and the characteristics of the relationship between designated and non-designated hospitals. The guideline also addresses some aspects of the working of the multidisciplinary team.

Development of the Guidance Document

The recommendations in this document are based on a systematic review of existing guidance documents and primary literature found in electronic databases. Overall, the
evidence base was determined to be of lower quality, based on study design, conflicting findings, and the lack of generalizability of results due to heterogeneity of comparison groups and outcome measures. Thus, the Guideline Development Group, which included expertise in gynecologic oncology, radiation oncology, medical oncology, methodology, and representation from CCO’s Surgical Oncology Program, used an informal consensus-based approach to develop a consensus-based guideline, relying on trends found in the evidence, recommendations from other jurisdictions, and personal opinion based on knowledge of the current situation in the province. The recommendations were reviewed by an Expert Panel (EP) that included the specialties represented on the Guideline Development Group and additional expertise in gynecology, pathology, and nursing as well as a regional vice president. The comments of the EP were incorporated into the draft, which subsequently received EP approval. The document was also disseminated widely to professionals from relevant specialties across Ontario, and to three peer reviewers from outside of the province for their review and feedback, which was incorporated into the guideline draft. A summary of the development process, including the feedback from reviewers is provided in Section 3 of this EBS document.

Overview of Guideline Recommendations

Specific recommendations are outlined in the Recommendations and Key Evidence section below. In summary, the Guideline Development Group’s consensus is a vision for gynecologic cancer care in the province that includes:

- Access to treatment for all invasive cancer at Gynecologic Oncology Centres and affiliated centres, effectively creating networks of care;
- Strong, well-defined accountable partnerships between gynecologic oncology centres and affiliated centres;
- Consistent high-quality treatment provision within and between regional networks, regardless of geographic location;
- Access to multidisciplinary care for all gynecologic oncology patients.

More resources may be needed in order to meet the recommendations outlined in this guidance document, as we are recommending that some cases be shifted to subspecialty care and more comprehensive pathology reviews. We hope that these recommendations will result in improvements in practice for individuals who are already practicing in higher volume teaching centres, including better adherence to existing guidance, and greater collaboration among specialties, resulting in improved access to treatment and better outcomes for gynecologic oncology patients in Ontario throughout the patient journey from diagnosis to treatment, recovery, and palliative care.

F. RECOMMENDATIONS AND KEY EVIDENCE

I. GYNECOLOGIC ONCOLOGISTS

<table>
<thead>
<tr>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definitive surgical treatment of the following invasive cancers should be performed by gynecologic oncologists:</td>
</tr>
<tr>
<td>• cervical cancer (Stage ≥T1A2);</td>
</tr>
<tr>
<td>• endometrial cancer (grade 2 or 3), including high-risk histology i.e., uterine clear cell or papillary serous carcinoma, malignant mixed Mullerian tumour;</td>
</tr>
<tr>
<td>• ovarian cancer, including germ cell, epithelial cell and stromal cancers, and all suspicious ovarian masses with a Risk of Malignancy Index score greater than 200 (3);</td>
</tr>
<tr>
<td>• vulvar cancer;</td>
</tr>
<tr>
<td>• vaginal cancer.</td>
</tr>
</tbody>
</table>
Recommendation

Patients who have intermediate to high GTN and low-risk GTN in need of chemotherapy need to be assessed and treated by gynecologic oncologists.

Recommendation

Definitive surgical treatment of grade 1 endometrial cancer may be performed by a GYN or gynecologic oncologist.

Recommendation

Definitive surgical treatment of gynecologic malignancies is not within the domain of general surgery.

Qualifying statements

- As evidence has shown that adherence to recommended clinical practice guidelines can be sub-optimal for gynecologic oncologists at teaching centres, it will be important to implement initiatives that improve adherence to accepted clinical practice guidelines and to identify and fill gaps in guidance for the Ontario context (7).
- The correlation between preoperative biopsy for endometrial adenocarcinoma and the final tumour grade determined by the hysterectomy specimen has been found to range from 15% to 30% in several studies (8-10). A large population-based study from Ontario, using data from 1996-2000, found that the discordance between pre- and postoperative diagnosis of grade 1 tumours was 27% (11). These data suggest that the capacity of the preoperative biopsy to identify lower risk patients is limited. The Guideline Development Group recognizes this limitation and provides further recommendations below, including multidisciplinary care and optimization of the quality of initial pathology reporting in order to ensure that as many patients as possible receive surgery from the appropriate recommended specialty.

Key Evidence

Evidence for an advantage with treatment by a gynecologic oncologist was mixed. In a systematic review that included ovarian cancer patients, 7 of 15 studies that compared treatment by a gynecologic oncologist to a GYN found a survival advantage with treatment by a gynecologic oncologist; however, the significant effects were found only for selected subgroups according to particular FIGO stages, with the positive effect more pronounced in patients with a poorer prognosis (12). They also found that survival was worse for patients treated by GYN, compared to GS in 7 of 11 studies that assessed this comparison, with the differences limited to specific FIGO stages in three studies. Surgery by gynecologic oncologist resulted in a significant advantage compared to surgery by GYN according to various measures of optimal debulking in 6 of 11 studies of patients with advanced disease. Surgery by GYN versus GS resulted in a significant advantage when the outcome was degree of cytoreduction in five of nine studies. All studies evaluating physical specialty and completeness of surgical staging found a significant association in favour of gynecologic oncologist compared to GYN or others.

Our systematic review found a significant association between survival for ovarian cancer and physician specialty in one of four studies that met the inclusion criteria; however, this study compared gynecologic oncologist/GYN care to GS care. Two studies assessed the relationship between physician specialty and surgical outcomes. A study that used Ontario data from 1996 to 1998 found no difference in survival for patients by surgical discipline (gynecologic oncologist vs. GYN), after controlling for prognostic factors associated with stage...
of disease; however, a significant gynecologic oncologist advantage was found for risk of repeat surgery (13), compared to the categories GYN, GS and other physician type. The second study found that subspecialist gynecologists were significantly more likely to adequately stage patients (14).

Three studies assessed survival difference for endometrial cancer patients with treatment by gynecologic oncologist versus GYN/other (15-17). One found no significant difference for gynecologic oncologist versus GYN in a population with stage IA-IIA disease (17), while another other found a significant advantage for gynecologic oncologist versus other for all stages combined (15). A study that used Ontario data from 1996 to 2000 found that there was no difference in 5-year survival for gynecologic oncologist versus other after controlling for stage and other prognostic variables (16). Three of three studies found that surgery by a gynecologic oncologist involves a more comprehensive assessment of tumour invasion and more accurate determination of stage, compared to surgery by a GYN in both early-stage endometrial cancer and for all stages combined (15,17,18).

No studies were found that looked at outcomes by physician specialty for cervical cancer, vulvar cancer, vaginal cancer or GTN.

**Justification**

The limited and inconsistent nature of the evidence led the Guideline Development Group to develop the consensus-based recommendation that all invasive ovarian cancer patients receive treatment by a gynecologic oncologist. The Guideline Development Group concluded that the evidence for a link between gynecologic oncologist care and overall survival was not strong, perhaps due to data-quality issues. However, a systematic review did find a strong association between gynecologic oncologist care and completeness of surgical staging (12). Furthermore, a study conducted in Ontario found that repeat surgery, which is associated with increased risk or morbidity, was significantly more likely to occur with treatment by GYNs, GSs or other physicians than by gynecologic oncologists, after controlling for stage and other prognostic factors (13). A second study found that physician specialty (“specialized gynecologists” vs. GYNs) was significantly associated with adequate staging (14). As completeness of staging is important for long-term survival in early ovarian cancer, the Guideline Development Group concluded that these patients should have access to gynecologic oncologist care in Ontario. Optimal debulking is a critical prognostic factor in advanced ovarian cancer. More than half the studies in a systematic review found that optimal debulking was more likely with subspecialty care, providing further rationale for the Guideline Development Group’s recommendation that all invasive ovarian cancer patients receive treatment by gynecologic oncologists.

In Ontario, there is no guideline for surgery for endometrial cancer, and patterns of practice vary across the province. It is the consensus opinion of the Guideline Development Group that all endometrial cancer patients whose biopsy is read as grade >1 preoperatively should be treated by gynecologic oncologists because of the finding that subspecialists provide more-comprehensive staging procedures including appropriate lymph node and upper abdominal assessment (15,17,18). Staging has been found to be a predictor of mortality because, although not of direct survival benefit, it serves as a proxy indicator for overall quality of management (19).

It is the consensus of the Guideline Development Group that endometrial cancer patients whose biopsy is read as grade 1 preoperatively may have surgery performed by gynecologic oncologists or GYNs, because the risk of lymph node metastases in patients with confirmed grade 1 adenocarcinoma is approximately 2.8% (20). Therefore, in the Guideline Development Group’s opinion, the potential value of treatment by a gynecologic oncologist (i.e., comprehensive surgical staging) does not outweigh the considerable increase in human
resources and operating room time that would be required for all patients with endometrial cancer to have surgery performed by a gynecologic oncologist.

The consensus of the Guideline Development Group is that surgical treatment of vulvar cancer should be performed by gynecologic oncologists, due to the relative rarity of this carcinoma (approx. 150 cases per year in Ontario), and the need for meticulous attention to optimizing margins and balancing the risk of local recurrence with the morbidity associated with inguinal lymph node dissection (21). The recommendation that all invasive cervical cancer be treated by a gynecologic oncologist is based on knowledge of the technically demanding nature of the radical hysterectomy procedure and its relatively infrequent performance by most gynecologists.

The consensus of the Guideline Development Group is that treatment of moderate- and high-risk GTN should be performed by gynecologic oncologists or gynecologic oncologists in collaboration with Medical Oncology, due to the relative rarity of this carcinoma, and the need for meticulous attention to timely aggressive treatment in order to obtain cure and to minimize adverse events. The recommendation that all moderate- and high-risk GTN and low-risk GTN that require chemotherapy be treated by a gynecologic oncologist or a gynecologic oncologist in collaboration with a Medical Oncologist is based on the rarity of this tumour, potential high curability if dealt with aggressively, and toxicity of multi-agent chemotherapy.

II. GYNECOLOGIC ONCOLOGY CENTRES
1. Treatment at gynecologic oncology centres

<table>
<thead>
<tr>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gynecologic oncologist care should be delivered within designated gynecologic oncology centres.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>In addition to surgical care, gynecologic oncology centres will be equipped to provide radiation therapy and systemic therapy for all invasive gynecologic oncology disease sites, and act as the hub for management of all invasive cases.</td>
</tr>
</tbody>
</table>

**Qualifying statement**
- As evidence has shown that adherence to recommended clinical practice guidelines can be sub-optimal for gynecologic oncologists at designated centres, it will be important to implement initiatives that improve adherence to accepted clinical practice guidelines and to identify and fill gaps in guidance for the Ontario context.

**Key Evidence**
Six studies that assessed outcomes with centralization or regionalization of gynecological cancer met the inclusion criteria for the systematic review.

The effect of centralization of gynecologic oncology services after the implementation of the 1999 UK National Health Service *Improving Outcomes in Gynecologic Cancer (IOG)* (22) recommendations was assessed in the East Anglia region of the UK. Mortality was reduced significantly for patients with gynecologic cancer in the post-centralization study period compared to pre-centralization (HR: 0.71, 95%CI 0.64-0.79%, p<0.001). Overall, the improvements were attributed to “access to specialized surgery” and “management within a multidisciplinary team” (23); however, as there were known deficiencies in quality of care in the UK prior to the implementation of this guidance in 1999, it is not clear whether or not a comparable improvement could be expected if similar guidelines were implemented in this jurisdiction. Another study looked at outcomes before and after implementation of the IOG
recommendations and found no differences; however, this study included areas where the guidance had not been fully implemented (24). The only study that controlled for clustering of outcomes among facilities found there was no evidence of improved ovarian cancer patient survival with hospital teaching status, although a difference had been found before controlling for clustering (25).

In a study of vulvar cancer in West Midlands, UK (26), 15 different surgical procedures were described before centralization. After centralization, only four types of surgery were performed, and 84% of patients that required lymph node dissection had this procedure, although heterogeneity of surgical technique remained evident. Implementation of centralization that included specialized gynecologic pathology assessment also coincided with improved histology reporting and achievement of adequate excision margins. Although only 52% of case notes had enough information to evaluate 5-year disease-specific survival, survival improved from 51.3% pre-centralization to 73.8% post-centralization (p=0.055). Munstedt found that in the population of patients for whom lymphadenectomy is recommended and feasible, it was more likely to be performed in central hospitals; however, even in these centres, adherence to appropriate guidelines was found to be lacking (27). The treatment of ovarian cancer was slowly centralized over a decade in Denmark (28). A significant reduction in mortality for stage IIIC-IV ovarian cancer patients was found for patients treated in tertiary centres compared to others.

**Justification**

As the evidence for treatment at designated centres was mixed and may have limited applicability to the Ontario context, the recommendation for treatment of most invasive gynecologic cancers by gynecologic oncologists at designated gynecologic oncology centres is the opinion of the Guideline Development Group, based on the consensus that gynecologic oncology centres will be best equipped to provide the resources that are needed to support the work of gynecologic oncologists, including proximity to other members of the multidisciplinary team, and more specialized pathology expertise, capacity to support multidisciplinary cancer conferences, facilitation of accrual to clinical trials, and the necessary human and physical resources outlined in the recommendations below.

### 2. Human resources at gynecologic oncology centres

**Recommendations**

The multidisciplinary team at a gynecologic oncology centre should include:

- A minimum of two full-time gynecologic oncologists.
- A minimum of two radiation oncologists.
- A minimum of one specialist in Medical Oncology, with an interest in gynecologic malignancies.
- An adequate number of pathologists with a specialty or special interest in gynecologic pathology.
- Access to molecular scientists for Microsatellite Instability testing, genotyping for placental molar disease and human papillomavirus testing.
- Specialists in Radiology, including one with expertise in gynecologic diagnostic imaging and interventional radiology.
- Access to specialized oncology nursing, and advanced practice nursing.

The following medical specialists should be on site:

- Psycho-social-sexual counselling and support.
- Palliative care physician or specialist, which may include assessment at the
gynecologic oncology centre, with seamless linkage to and coordination with providers in the patient’s home community.

- Specialists in general or colorectal surgery, anaesthesia, urology, plastic surgery, or other areas as needed.
- Access to dietitians.

Access to the following medical specialists should be available as required:
- Geneticist/genetic oncology clinic where patients with hereditary predisposition to cancer can receive counselling and appropriate testing when indicated.
- Access to an expert in reproductive medicine.

**Key evidence and justification**

The detailed requirements for human resources are the opinion of the guideline development group, based on the resources that the group determined would be necessary to support the treatment of patients with invasive gynecologic cancer in gynecologic oncology centres.

3. Physical resources and collaborating services at gynecologic oncology centres

**Recommendations**

The following physical resources and collaborating services should be available at gynecologic oncology centres:

- **Surgery services** should be appropriately equipped and resourced to provide:
  - Minimally invasive surgery (laparoscopic/robotic).
  - An intensive care unit (ICU).
  - Dedicated surgical beds for gynecologic oncology patients, with nursing expertise.
  - A fully developed nutrition service, including total parenteral nutrition.
  - Access to specialized stoma care.

- **Radiation Therapy services** should be appropriately equipped and resourced to provide:
  - On-site services, including capacity for the administration of brachytherapy.

- **Systemic Therapy services** should be appropriately equipped and resourced to provide:
  - Chemotherapy and biologic agents, and oncology pharmacy support for inpatient and outpatient services.
  - Chemotherapy and biologic agents should be administered by nurses (RNs) who have completed the de Souza Institute Chemotherapy and Biotherapy Provincial Standardized course.
  - Intraperitoneal chemotherapy.

- **Pathology services** should be appropriately equipped and resourced to provide:
  - Intraoperative frozen-section analysis.
  - Immunohistochemistry (IHC) and molecular testing.
  - Cytopathology/cytology services.

- **Radiology services** should be appropriately equipped and resourced to provide:
  - A full range of diagnostic imaging, including ultrasound (all modalities, including Doppler), computerized tomography, magnetic resonance imaging, angiography and interventional radiology.
  - Nuclear medicine capabilities to assess sentinel lymph nodes.

- **Access to a Community Care Access Centre.**
Key evidence and justification

The detailed requirements for physical and collaborating services are the opinion of the guideline development group, based on the resources that the group determined would be necessary to support the treatment of patients with invasive gynecologic cancer in gynecologic oncology centres.

4. Annual volumes at gynecologic oncology centres

**Recommendation**

A minimum annual volume of 150 new surgical cases is recommended for each gynecologic oncology centre.

**Recommendation**

A minimum annual volume of 100 new gynecologic oncology radiation therapy cases is recommended for each gynecologic oncology centre.

Qualifying statements

- Volumes for systemic therapy were addressed in PEBC guideline #12-10, which concluded: “After numerous discussions, the Group determined that [systemic therapy] service volumes should depend on local conditions. A centre should have a sufficient patient volume to maintain competency and safety” (29).
- If brachytherapy is offered, a minimum of 10 cervical cases should be treated annually, according to PEBC guideline #21-2 (30).

Key evidence

There were no studies specifically designed to test the optimal patient volumes to ensure safe and effective patient care. Furthermore, there is no agreed upon set of criteria for defining safe and effective care. Seventeen studies assessed the relationship between physician and/or hospital volumes and surgical or survival outcomes for one or more disease sites. Higher physician volumes were related to improved survival and surgical outcomes in two (31,32) and four studies (14,21,33,34), respectively. Higher hospital volumes were related to improved survival and surgical outcomes in three (35-37) and five studies (14,31,37-39), respectively. The definition of high volume, when reported, ranged between >4 (33) and at least 100 (40) for physician volumes, and >7 (33) and at least 200 (40) for hospital volumes.

Justification

Although a trend towards improved outcomes with higher volumes was found in some studies, the definitions of “high volume” and “low volume” were highly variable in the literature; therefore, the recommendation for annual volumes of new surgical cases at
gynecologic oncology centres is the opinion of the guideline development group, based on a consensus regarding a reasonable workload for gynecologic oncologists in Ontario, supported by CCO program data (2009-2010). This volume is considered a sufficient caseload to justify the resource investment necessary for a gynecologic oncology centre, and to maintain the skills of the multidisciplinary team.

The recommendation for radiation therapy volumes is the consensus of the Guideline Development Group, based on minimum numbers needed to ensure competency and quality of care (41).

III. AFFILIATED CENTRES

1. Treatment at affiliated centres

**Recommendation**

Treatment centres that develop a formal affiliation with GOCs may provide any or all of the following services:

- surgery for endometrial cancer patients that are determined preoperatively to be lower risk (i.e., grade 1);
- radiation therapy for all gynecologic oncology disease sites;
- systemic therapy for all gynecologic oncology disease sites.

**Recommendation**

Appropriate pathology review must be available for all new patients, and access to multidisciplinary team management, including a multidisciplinary cancer conference (MCC) review or documented collaborative discussion between at least two disciplines, or a multidisciplinary clinic appointment at a gynecologic oncology centre must be provided.

**Key evidence and justification**

As there was no evidence found in the literature search to support the establishment of treatment at affiliated centres, these recommendations are the consensus of the Guideline Development Group, which agreed that, provided a strong linkage was established and maintained with a gynecologic oncology centre, radiation and systemic therapy could be delivered at affiliated centres, in order to allow patients to receive ongoing treatments closer to home.

The recommendation for primary surgery for lower risk endometrial cancer patients is based on the rationale outlined above under Recommendation 1. Gynecologic Oncologists. In the opinion of the Guideline Development Group, appropriate pathology review and access to multidisciplinary consultation are essential for low-grade endometrial patients prior to surgery in order to ensure the best possible accuracy when assigning preoperative grade.

2. Human resources at affiliated centres

**Recommendations**

It is recommended that affiliated centres have:

- If surgery is offered:
  - a minimum of one gynecologist with a commitment to gynecologic oncology and skills to perform minimally invasive surgery. Centres should strive to have all gynecologic oncology surgeries performed by a small number of gynecologists who discuss grade 1 endometrial cancer patients with a gynecologic oncologist at a gynecologic oncology centre prior to surgery.
- a pathologist with an interest in gynecologic pathology who is networked to gynecologic oncology centre.

- If radiation is offered, a minimum of one radiation oncologist is required.

- If systemic therapy is offered, a medical oncologist [Level 1-3 Regional Systemic Treatment Program (RSTP)], or family physician or nurse (Level 4 RSTP), networked to a gynecologic oncologist or medical oncologists at a gynecologic oncology centre.

**Key evidence**

The detailed requirements for human resources are the opinion of the guideline development group, based on the resources that the group determined would be necessary to support the treatment of patients with invasive gynecologic cancer in centres that are affiliated with gynecologic oncology centres.

The recommendation for systemic therapy at RSTPs is an endorsed recommendation from previous PEBC guideline #12-10 (29).

### 3. Physical resources and collaborating services at affiliated centres

**Recommendations**

It is recommended that physical and collaborating resources at affiliated centres are appropriately equipped and resourced to provide:

- Resources to assess the risk of malignancy of a suspicious adnexal mass, including ultrasound (15) and standardized ultrasound reports (42).

- If surgery is offered:
  - minimally invasive surgery (laparoscopic/robotic).
  - a quality-assurance process to ensure that assignment of the pathologic grade for endometrial cancer patients is reviewed prior to surgery. This may include options such as a quality-assurance program at the affiliated centre, a discussion among pathologists at the affiliated centre, or a review by a gynecologic pathologist at a GOC.

- basic histopathology and IHC testing. Pathology services should be networked to a GOC for non-routine technical testing, as necessary.

- If systemic therapy is offered:
  - chemotherapy and biologic agents, and oncology pharmacy support for inpatient and outpatient services.

Centres offering systemic therapy must be designated RSTPs. Where intra-peritoneal therapy is offered, centres must be Level 1-3 RSTPs (29).

**Key Evidence and justification**

The detailed requirements for physical and collaborating services, including options for pathology review, are the opinion of the guideline development group, based on the resources that the group determined would be necessary to support the treatment of patients with invasive gynecologic cancer in centres that are affiliated with gynecologic oncology centres.

With respect to pathology review, there is widespread agreement on the benefits of pathology review for the planning of initial management of endometrial cancer patients. Pathology reviews have been performed by body system subspecialists in pathology (e.g., gynecologic pathologists), but in the guideline development group’s experience, such subspecialty opinions are not always available in a timely fashion, particularly at anticipated affiliated hospitals; therefore, additional options have been recommended. The issue of which types of specimens may need a secondary review is under further study in a
forthcoming PEBC guideline, which will inform acceptable pathology review procedures for gynecologic pathology.

The recommendation for systemic therapy at RSTPs is an endorsed recommendation from previous PEBC guideline #12-10 (29).

4. Annual volumes at affiliated centres

<table>
<thead>
<tr>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>There is insufficient evidence to specify a target volume for annual number of new surgical, radiation or systemic therapy cases at affiliated centres.</td>
</tr>
</tbody>
</table>

Qualifying statements

- Volumes for systemic therapy were addressed in PEBC guideline #12-10, which concluded: “After numerous discussions, the Group determined that [systemic therapy] service volumes should depend on local conditions. A centre should have a sufficient patient volume to maintain competency and safety” (29).
- If brachytherapy is offered, a minimum of 10 cervical cases should be treated annually, according to PEBC guideline #21-2 (30).

Key evidence

While the guideline development group recognized that a relationship between higher surgical volumes and improvement in outcomes was identified in the systematic review, the inconsistency of the relationship and the variability in defined cut-offs led the guideline development group to conclude that it would not be appropriate to arbitrarily recommend minimum annual volumes at this time for affiliated centres.

As stated above in the section on annual volumes in gynecologic oncology centres, there is no minimum volume specified for systemic therapy, based on PEBC guideline #12-10.

IV. RELATIONSHIP BETWEEN GYNECOLOGIC ONCOLOGY CENTRES and AFFILIATED CENTRES

<table>
<thead>
<tr>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>A formal partnership with processes to ensure accountability must be in place between affiliated centres and gynecologic oncology centres (Figure 1). As stated above under affiliated centres, appropriate pathology review must be available for all new patients, and access to multidisciplinary team management, including a multidisciplinary cancer conference (MCC) review or documented collaborative discussion between at least two disciplines, or a multidisciplinary clinic appointment at a gynecologic oncology centre must be provided.</td>
</tr>
</tbody>
</table>

Key evidence

This recommendation is the consensus of the Guideline Development Group.
Figure 1. Model for service provision for gynecologic oncology patients in Ontario, depicting networks of care comprising partnerships between gynecologic oncology centres and affiliated centres.
V. MULTIDISCIPLINARY DISCUSSION/EVALUATION

**Recommendation**

All patients with newly diagnosed gynecologic malignancy should have access to a GOC, MCC or be the subject of a collaborative discussion, which would include assessment at a multidisciplinary clinic, or a documented discussion with clinicians from at least two disciplines.

The primary purpose of the MCC is to ensure that all appropriate diagnostic tests, treatment options, and treatment recommendations are generated for each cancer patient discussed prospectively in a multidisciplinary forum (2).

Required participants at an MCC include:
- Gynecologic Oncologist
- Radiation Oncologist
- Medical Oncologist
- Pathologist
- Radiologist
- Clinical nurse specialist

Optional members include:
- Gynecologists performing endometrial cancer surgery

**Recommendation**

Patients who are not discussed in an MCC, but rather are the subject of a collaborative discussion, should also undergo appropriate pathology review. This statement applies in particular to low-grade endometrial cancer patients, as accurate determination of grade will impact their location of treatment and extent of surgery.

**Recommendation**

Members of the MDT must meet the specialist training required to practice in the province. Non-oncology specialists should have an interest in oncology, and non-gynecology specialists should have an interest in gynecology. GYO s must be certified in gynecologic oncology by the Royal College of Physicians and Surgeons or an equivalent.

**Key evidence and justification**

The general consensus at this time is that the model of the MDT is the standard of care for all cancer types (1). Several audits in England show that multidisciplinary care, among other factors, is associated with better survival in ovarian, cervical and endometrial cancer (43). A previous review by the PEBC supported the use of regularly scheduled MCCs to prospectively review individual cancer patients and make recommendations on management (2). The Guideline Development Group for this project endorses the 2006 PEBC MCC standards, including MCCs for gynecologic cancers (2).

While it is recommended that all patients have access to an MCC, it is recognized by the Guideline Development Group that MCCs do not have the capacity to discuss every new gynecologic cancer patient prospectively. In the UK, where it is recommended that every cancer patient be discussed, the process has been very time consuming, and insufficient time available to discuss every patient has been identified by others as a problem (44,45). In recognition of this, the Guideline Development Group has provided other options such as the collaborative discussion.
Recommendations for the minimum skill set and experience for MDT members that treat gynecologic malignancies was the consensus of the Guideline Development Group, based on currently accepted definitions for these specialities in Ontario.

**Funding**
The PEBC is a provincial initiative of Cancer Care Ontario supported by the Ontario Ministry of Health and Long-Term Care. All work produced by the PEBC is editorially independent from the Ontario Ministry of Health and Long-Term Care.

**Updating**
All PEBC documents are maintained and updated as described in the PEBC Document Assessment and Review Protocol.

**Copyright**
This report is copyrighted by Cancer Care Ontario; the report and the illustrations herein may not be reproduced without the express written permission of Cancer Care Ontario. Cancer Care Ontario reserves the right at any time, and at its sole discretion, to change or revoke this authorization.

**Disclaimer**
Care has been taken in the preparation of the information contained in this report. Nonetheless, any person seeking to apply or consult the report is expected to use independent medical judgment in the context of individual clinical circumstances or seek out the supervision of a qualified clinician. Cancer Care Ontario makes no representation or guarantees of any kind whatsoever regarding the report content or use or application and disclaims any responsibility for its application or use in any way.

**Contact Information**
For information about the PEBC and the most current version of all reports, please visit the CCO website at [http://www.cancercare.on.ca/](http://www.cancercare.on.ca/) or contact the PEBC office at:

Phone: 905-527-4322 ext. 42822  Fax: 905-526-6775  E-mail: ccopgi@mcmaster.ca
REFERENCES


5. Ontario Cancer Registry: Cancer Care Ontario, iPort. Date of Publication: Feb 2013.


22. UK NHS. Improving Outcomes in Gynaecological Cancers; The Manual. London (UK);1999 July.


