

## **British Gynaecological Cancer Society recommendations for management of women with gynaecological cancer who have received non-standard care during the COVID-19 pandemic**

### **Background**

During the COVID-19 pandemic, there have been significant pressures on clinical services that required adaptation to how care was delivered for women with gynaecological cancer as presented in the BGCS RCOG Framework of Care for patients with gynaecological cancer [[www.bgcs.org.uk/professionals/covid19-resources](http://www.bgcs.org.uk/professionals/covid19-resources)].<sup>1</sup> There have been occasions when it was necessary for treatment to deviate from what would be considered standard of care, due to clinical resource availability, increased risk from COVID-19 infection and prioritisation frameworks.<sup>2-7</sup> In the COVIDSurg study, 17% of 4722 women undergoing surgery for gynaecological cancer across 55 countries had a change in their first line treatment, including delay in treatment or adaptation of surgery.<sup>8</sup> For the majority of patients, the deviation is unlikely to have impacted on their clinical outcomes. However, there will be a cohort of women where this variation has implications for their ongoing care.

The BGCS convened a multi-disciplinary working group to develop recommendations for the onward management and follow-up of women with gynaecological cancer who have been impacted by a change in treatment during

the pandemic. This document discusses 'salvage' measures based on expert opinion that may be useful for clinicians to consider. The recommendations are presented by tumour type and for healthcare systems.

### **Recommendations for Ovarian Cancer**

The COVID-19 pandemic led to significant issues in operating capacity globally, with many centres altering their 'usual' clinical practice according to COVID-19 infection rates and the availability of high dependency units (HDU) for post-operative care. The provision of chemotherapy varied, but most cancer centres in the UK were able to deliver systemic treatment, although some changes were introduced to allow for reduced staff capacity.

#### *Patients with newly diagnosed ovarian cancer*

1. Due to this reduced operating capacity, many centers deferred primary surgery for women with ovarian cancer and some women were not offered surgery either in the primary or interval setting. As a result, some women with ovarian cancer have missed the opportunity to undergo cytoreductive surgery and their prognosis is likely to be worse. This may also have an impact on their management at relapse.
  - Although evidence is not available, it is recommended that women who did not have primary or planned interval surgery and have finished their last cycle of treatment should be offered surgery after six cycles of treatment (or within three months of the last cycle of treatment). If they are currently receiving maintenance treatment,

including PARP inhibitors or bevacizumab, treatment would have to be interrupted in the peri-operative period, but should be restarted within the timeframe specified within the UK Cancer Drug Fund.

- Women who started maintenance treatment after six cycles of chemotherapy and have low volume asymptomatic disease should continue maintenance treatment and be considered for surgery at progression.
  - Women with high volume asymptomatic disease should be considered for surgery or can continue maintenance treatment and be offered surgery at progression.
  - Women with a symptomatic pelvi-abdominal mass should be considered for surgery regardless of the time from chemotherapy.
2. The use of further postoperative chemotherapy after delayed surgery in patients who have already received 6 cycles of neoadjuvant chemotherapy is not routinely recommended, but may be considered depending on the time from last platinum-based chemotherapy, tumour burden at surgery, postoperative residual disease, pathologic response scores and toxicity from previous chemotherapy.
  3. Due to lack of intensive care availability, patients assessed as frail or high risk for peri-operative morbidity may not have been offered surgery during the surges of pandemic. It is recommended that these patients be re-evaluated and fitness to undergo radical surgery re-assessed when the

COVID-19 prevalence changes in that region. As vaccination is established and SARS-CoV-2 infection rates drop, the concomitant risk from surgery will also reduce and this needs to be factored into decision-making. Age alone should not be a deciding factor for surgery.

4. Many centres altered their systemic therapy treatment schedules due to the potential risks for patients in the post-operative and neo-adjuvant chemotherapy (NACT) setting. For example, some women stopped chemotherapy after 4 cycles and others were not offered maintenance treatment with bevacizumab. It is likely that some of these changes will have an impact on overall survival, particularly for women with stage IV or bulky residual disease. It is advised that women who have discontinued chemotherapy after 4 cycles should continue on routine follow-up. Eligible women who have not been offered maintenance bevacizumab or PARP inhibitors should continue with routine surveillance and be considered for PARP inhibitors, where appropriate, at relapse.

*Patient with recurrent ovarian cancer*

1. During the COVID-19 pandemic some women with recurrent disease missed the opportunity to undergo secondary surgery and this may have an impact on their survival.<sup>9 10</sup> Women who did not have secondary debulking surgery and have operable disease should be considered for surgery at a further relapse. Secondary surgery after 3 cycles of chemotherapy should not be routinely offered and should be limited to those women who were eligible

for surgery upfront but had the surgery deferred due to the COVID-19 pandemic.

For patients at relapse who did not have surgery at diagnosis, the Arbeitsgemeinschaft Gynaekologische Onkologie (AGO) score which is used to predict operability in patients with a first recurrence of ovarian cancer does not apply and will not be the accurate tool to identify surgical candidates at relapse, i.e. patients with a “negative” AGO score should not be automatically excluded from secondary surgery.<sup>11</sup>

2. Systemic therapy for relapsed ovarian cancer remains platinum-based chemotherapy (at least 4 cycles) followed by a PARP inhibitor for responders.<sup>12</sup> However, during the pandemic some women may have been offered PARP inhibitor treatment without preceding platinum-based chemotherapy. It is recommended that the PARP inhibitor is continued and chemotherapy can then be considered in the event of future progression.
3. Women with low grade ovarian cancer who had surgery deferred should be offered debulking surgery. Where possible these women should be managed as per established guidelines.
4. Some women have been treated on the basis of “positive” peritoneal cytology instead of a biopsy. In some cases, this approach might have led to a misdiagnosis (small risk) and/or a delay in determination of BRCA status. A biopsy to establish the diagnosis remains the gold standard, but in certain

cases it is still acceptable to use a cell block if it is possible to obtain a diagnosis including immunophenotyping. Somatic testing for BRCA variants or HRD testing should be considered either on a biopsy or surgical specimen. It is also possible to perform BRCA/HRD analysis in some cases where there is adequate DNA in the cell block.

## Recommendations for Uterine Cancer

1. Low grade, early-stage endometrial cancer was categorised as a lower priority for surgery during the pandemic, since a delay of more than 4 weeks in treatment initiation was unlikely to impact on survival.<sup>13</sup> When operating theatre capacity was limited, women were commenced on progestogen therapy until surgery was possible. If disease responded to treatment, there would have been no impact on their outcome. However, some women may have been disadvantaged if there was inadequate tumour response or progression, or if there were non-concordant histological findings between the initial low grade endometrial sample and a high grade tumour on the definitive surgical specimen.
  - Women who commenced endocrine therapy due to lack of surgical availability should have definitive surgery within three months of starting hormonal therapy. As soon as surgical capacity allows, there should be clinical review and consideration of re-imaging and surgery when available.

- There should be a robust failsafe system for ensuring those patients who had surgery deferred are tracked.
  - Once surgical treatment is complete, there should be no change to standard ongoing management with any adjuvant therapy based on the final histopathological findings.
2. Many women with endometrial cancer have co-morbidities that also put them at a higher risk of mortality from COVID-19. Surgery may have been contraindicated or deferred, particularly when HDU and ITU availability was very limited and there was less support for optimising patients including bariatric and pre-habilitation services.
- Re-evaluation of disease status should be undertaken including imaging and consider a repeat biopsy.
  - Women who commenced progestogen therapy due to co-morbidities that contra-indicated surgery should be reviewed to assess whether optimisation for surgery is possible or whether definitive radiotherapy is an option.
3. There was a reduction in the number of patients who underwent surgical staging of lymph nodes. Although this may have been a change in practice for some centres, adjuvant treatment is recommended based on whether nodal status is known or unknown.<sup>14</sup> No change to standard management is recommended, although there may have been an increase in use of pelvic radiotherapy if nodal status was unknown.

4. Adjuvant treatment may have been omitted when it was unlikely to impact on overall survival, and, in particular, vaginal brachytherapy was not available in some centres. Patients may also have decided not to have adjuvant therapy due to their concerns about having additional treatment during the pandemic. Therefore there will be a cohort of women who are at higher risk of relapse, particularly of loco-regional recurrence, if vaginal vault brachytherapy or EBRT was omitted.<sup>15 16</sup> Whereas low grade, low risk endometrial cancer most frequently recurs in the vaginal vault within the first 2 years, loco-regional recurrence can occur later with a higher risk of lymph node disease in intermediate and high-intermediate risk tumours.<sup>17 18</sup>

- Patients at increased risk of local recurrence should be considered for regular clinical review with the aim of detecting a salvageable asymptomatic recurrence, rather than having patient-initiated or virtual follow-up since they were not treated on a standard pathway.
- Surveillance imaging at 6 months and 18 months post-surgery should be considered for women with high-intermediate and high-risk disease who have not had EBRT, nodal staging and for those who have not had standard adjuvant therapy.

5. In England, in order to reduce the use of chemotherapy, immunotherapy with nivolumab was approved by the Cancer Drug Fund for first line or



subsequent treatment of recurrent or advanced endometrial tumours with mismatch repair deficiency. It is recommended that the immunotherapy is continued and chemotherapy can then be considered in the event of future progression.

### **Recommendations for Cervical Cancer**

Radiotherapy treatment for cervical cancer involves the combination of external beam radiotherapy (EBRT) with concurrent chemotherapy, followed by intrauterine brachytherapy. Lack of resources, including anaesthetic support or staffing redeployment, may have necessitated changes to the intrauterine brachytherapy treatment pathway, with some centres using an altered fractionation or referring to another treatment centre. Delays during treatment may have occurred due to lack of brachytherapy availability or due to patients having SARS-CoV-2 infection. It may have been necessary to use additional EBRT in place of brachytherapy. There would be no impact to patient outcome if the change in fractionation still delivered treatment doses that meet the GEC-ESTRO guidelines.<sup>19 20</sup> A significant delay that prolonged the total treatment time can reduce local control, while omitting brachytherapy significantly reduces cure rate.<sup>21-23</sup>

- No change to standard ongoing surveillance is required if the total tumour dose was within GEC-ESTRO guidelines.

- Where there was a long gap with a total treatment time greater than 56 days or when lower tumour doses were delivered, increased surveillance with MRI imaging over the following 2 years would be recommended.
- It is recommended that patients in whom brachytherapy was omitted or who had incomplete treatment should be evaluated by an examination under anaesthetic and biopsy with consideration of completion surgery.

## **Vulval cancer**

### *Initial treatment*

Apart from tailoring treatment to the more advanced presentation of vulval carcinoma during the COVID-19 pandemic, most gynaecological cancer centres in the United Kingdom maintained standard management of this disease. Surgery for vulval cancer was prioritised and most centres proceeded in accordance with BGCS guidelines <sup>24</sup>. However, some hospitals may have encountered difficulty in accessing nuclear medicine resources for Technetium-99m sentinel lymph node procedures for cancers presenting as small (<4 cm) tumours without clinical lymphadenopathy. Other centres may have proceeded with radical vulval surgery, but omitted staging systematic inguinofemoral lymphadenectomy for larger tumours in order to reduce surgical morbidity and covid-related perioperative risks. As a consequence, there may be some women with vulval cancer managed during the pandemic who did not undergo standard surgical lymph node staging.

Groin node recurrence risk is greatest in the first two years after diagnosis, particularly during the first 12 months. Therefore, the morbidity and risks

associated with delayed surgical groin node staging of clinically normal lymph nodes, performed some months after primary vulval surgery, may outweigh the benefit of the diminishing probability of early diagnosis of nodal involvement. One study suggested that three-monthly ultrasound of the groins for two years following negative sentinel node dissection was cost-effective in the detection of lymph node metastasis following sentinel lymph node assessment.<sup>25</sup>

- Patients whose surgery excluded surgical lymph node staging may therefore be monitored with at least three-monthly clinical and ultrasound review until 12-24 months following surgery, aimed at early detection of nodal metastases.

### *Surveillance*

Due to lack of clinical capacity and risks to patients of in-person appointments during peak periods of the pandemic, some patients may have missed follow up appointments or had them replaced with telephone or video consultations.

- Due to the field change effect of pre-disposing condition, in-person follow up with vulvoscopy/visual inspection should be re-instated as soon as possible <sup>24 26</sup>.
- Patients should be encouraged to self-manage and between appointments report new lesions or, in those with lichen sclerosis, new symptoms or lesions that do not start to respond to daily Dermovate within 2 weeks.

Patients with a previous vulval cancer should be seen urgently in these situations.

### **Recommendations for Follow Up**

Due to the need to reduce in-person hospital attendances, alternative follow up models were introduced with increased use of remote consultations and patient-initiated follow up (PIFU).<sup>26</sup> This was a necessary change during the pandemic and a positive consequence has been more widespread experience of these models of care. However, the need for rapid change in practice may have meant there was a loss of risk stratification and some women may not have been included in the decision to have ongoing PIFU. Patients have reported feeling abandoned by the sudden change in follow up protocol, and many have had a long period without face-to-face review.

There is a particular risk that during this period there has been reduced detection of additional needs for vulnerable patients or safeguarding issues, and there may have been increased numbers of patients who have been lost to follow-up.

- Ongoing development of PIFU and remote consultation models should be supported.
- Centres should ensure women are appropriately selected and counselled for their ongoing follow up plan.

### **Recommendations on Diagnostic Pathways and the Duty of Candour**

The panel noted that COVID-19 pandemic has led to increased numbers of women presenting with advanced gynaecological cancer and often as an emergency. This may have been due to a lack of medical access because of resource pressures, or due to a delay in presentation because of patient concerns about accessing medical care during the pandemic, particularly impacting on frailer patients. Whilst acknowledging their presentation may have been delayed, these women should be managed according to established national and international guidelines.

When there has been a delay or variation in treatment, there is a duty of candour to discuss with patients how their care varied from the normal pathway and potential implications for their ongoing care.<sup>27</sup>

### **Recommendations on COVID-19 Vaccination**

Vaccination for COVID-19 significantly reduces the risks of infection and should be encouraged for all women planned for and undergoing cancer treatment.<sup>28-30</sup>

The BGCS has received reassurance from the Joint Committee on Vaccination and Immunisation (JCVI) that clinicians may expedite the second dose of vaccine to 4 weeks after the first vaccine for patients undergoing treatment for cancer.<sup>31</sup>

### **Supportive care and Patient perspectives**

The challenges delivering care during the COVID-19 pandemic has profoundly impacted on holistic and psychological support for patients and their families. At a time of high uncertainty and anxiety for women with gynaecological cancer, the

necessary reduction in direct patient contact will have affected their relationship with the clinical team. Many women had their care managed by a different team, or even in a different centre, and there may have been challenging palliative care decisions. This will impact on our ongoing rapport and communication with patients and it is essential to prioritise reinstatement of supportive care services.

### *Clinical Nurse Specialists*

Clinical nurse specialists (CNS) and advanced nurse practitioners are core members of the multi-disciplinary team who manage multiple concerns for gynaecology oncology patients, including a range of both physical and psychological concerns.<sup>32</sup> The CNS workforce is a highly skilled one with a deep understanding of their patient's needs. Significant and rapid changes came at a time when many nurses were redeployed to support the general nursing demands of the pandemic, leaving women without appropriate essential support. Whilst the pandemic has created many challenges, equally it has provided opportunities. The CNSs are ideally positioned to support the new digital healthcare technology programme and supporting patients face to face in the community. The CNS will be pivotal in delivering effective remote assessment, helping patients navigate new technology, and advocating for patients.<sup>33</sup>

- Centres should recognise the need for additional clinical nurse specialist and holistic support resources for patients and carers in the recovery period.

### *Patient perspectives*

COVID-19 has significantly affected cancer patients and family members. It should be recognised that women may feel that their care has changed even when these changes may not be perceived as important by healthcare professionals. The European Society of Gynecological Oncology (ESGO)-European Network of Gynecological Cancer Advocacy Groups (ENGAGE) conducted a survey in 16 countries obtaining 1251 patient responses. Women were found to be more fearful of cancer progression (70.9%) than developing COVID-19. Many patients, however, had high level anxiety that the disruption and uncertainty resulting from the COVID-19 pandemic would lead to changes to their planned cancer treatment with 32.6% reporting that their treatment or follow-up had been modified.<sup>34</sup>

Studies have reported patients have high levels of anxiety, concerns about the impact on their cancer care and a perception of medical abandonment during the pandemic..<sup>35-38</sup> A qualitative analysis of 800 online forum posts and charity staff interviews with UK gynaecology cancer charities shows that patients are extremely anxious about the impact of these changes to their current and future cancer care and have used the Cancer charities as their first port of call in the pandemic to avoid burdening health care staff [personal communication S. Sundar, June 2021]. Signposting patients to support services from cancer charities can alleviate some of the burden on clinical nurse specialists.

It will be important for health care professionals to acknowledge and address these concerns as services recover so they may provide reassurance and appropriate care to their patients. Health care professionals working

collaboratively with cancer charities can help restore trust in services for those impacted.

### **Implications for Gynaecology Oncology Services**

As hospitals start to recover from the acute pressures of the pandemic, there will be a significant backlog of patients awaiting investigations and surgery.<sup>39</sup>

There is likely to be a surge of referrals for patients who have deferred presentation, and a higher proportion with advanced disease. Due to clinical pressures, there may have been delay or even cessation of screening and surveillance programmes, while prophylactic surgery was deferred. Centres should aim to reinstate these preventative services as soon as possible.

It should be recognised that the alteration in clinical pathways and working practices may have impacted on team dynamics, with a risk of increased stress, anxiety and sickness. Workforce planning and holistic support to staff should be prioritised during the recovery period. It is likely that training will have been impacted with many trainees redeployed to alternative roles, and it will be important to optimise ongoing training opportunities.

### **Gynaecological Cancer Research**

At the beginning of the COVID-19 pandemic, the majority of UK sites paused active trial recruitment. Research staff and clinical teams were redeployed to COVID-19 wards and intensive care units which severely limited the ability to deliver trial work although some studies continued where clinical care was dependent on the trial treatment. There was significant national variability in trial



activity. There were amendments to many trials to allow for remote monitoring and consent. The quality of remote assessments and the short- and long-term impact of these on trial data are unknown.

After the pandemic, there will be residual clinical pressures impacting on the delivery of systemic anti-cancer therapies (SACT), while significant pressure on the availability of imaging and research biopsies may have a negative impact on the results of trials. The UK NCRI Gynaecology Oncology group has identified key national and international trials for local teams to prioritise in their trial recovery plan. These include ovarian (ICON9; FIRST; DICE; PROMPT), endometrial (ATTEND; LEAP; COPELIA; DETECT), cervix (INTERLACE; COMICE; NOVEL), surgical/ prevention (PROTECTOR; FORECEE; ROCKETS; ROCKETS- GEN), rare tumours (PEACOCK; ATARI; RANGO) and imaging (MROC) categories.

There was excellent recruitment within the UK into COVID-19 studies including COVID-SURG Gynaecological cancer international study and UKCOGS (UK COVID-19 Gynaecological cancer study) to record changes in treatment as a result of the pandemic and assess outcomes. Currently COVID-19 studies remain prioritised with trials staff and resources continuing to be diverted away from cancer research. The ongoing prioritisation of COVID-19 and the financial blow to charities is likely to impair new trial development and delivery. There remains a national strategic plan and commitment to recognize the importance of clinical trials in patient care. The immediate research priorities include resource sparing trials

including chemotherapy sparing regimens; de-escalation radiotherapy schedules, and registration, data-collection and bio-bank studies.

## **Conclusions**

COVID -19 has resulted in unprecedented disruption to cancer care and has required rapid and flexible adaptation to our delivery of care for women with gynaecological cancer. Almost no evidence exists on how best we can restore outcomes for women adversely impacted and whose care deviated from standard care. We hope that our consensus document based on expert opinion will help guide women and clinicians on best options for 'salvage' and follow-up. Careful data collection into outcomes in those impacted will provide insight into how these salvage measures work in practice and provide valuable learning for future surges. As services recover, it will be important to assess the impact on individual patient pathways, and to ensure patients concerns about their ongoing care are addressed.

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