

BGCS framework for care of patients with gynaecological cancer during the COVID-19 Pandemic

Background

The BGCS suggest the following as a framework for Gynaecological Cancer Centres and Gynaecological Cancer Units in the UK to aid management decisions. This guidance adheres to principles laid out in the NHS document, 01559, 'Clinical guide for the management of cancer patients during the coronavirus pandemic', March 2020.

This framework is intended to aid decision-making by Gynaecological Cancer Centre clinicians and Cancer Unit clinicians and NHS Trusts, in the event that the facility for cancer services is compromised due to a combination of factors, including staff sickness, lack of theatre availability and supply chain shortages among others. This guidance encompasses inpatient and outpatient activity, diagnostics and management and is across all modalities of anticancer treatment. In putting together this framework, the working group gave high weighting to procedures and treatments with the most robust evidence of benefit, the potential for cure or progression beyond operability where survival was expected to be > 12 months, symptom relief for patients with symptoms not amenable to alternative measures and cancer types where cancer cure or survival > 12 months would be compromised by delay in treatment.

The situation with the COVID-19 pandemic is evolving and will impact differently across the UK, depending on local resource availability and scale of the pandemic affected population. Therefore, this framework is only intended as an aid to support MDTs making challenging clinical decisions and to provide examples to fit the national cancer prioritisation categories as outlined in the NHS document 01559. Decisions may vary dependent on local circumstances, resources and as the pandemic evolves.

General Principles

In the event of disruption to cancer services, clinicians may need to prioritise treatment for those most in need. It is important that all decisions taken, are done so with multidisciplinary team (MDT) input and clearly communicated with patients. Deviations from what would normally be considered standard of care may be appropriate in the context of what is safely deliverable during a pandemic. These variations should be recorded in the MDT decision-making and reasons clearly documented. Patients with a diagnosis of cancer must remain tracked within MDT's, even if a decision is made to defer treatment. MDT's may need to consider alternate ways of meeting, such as virtual meetings.

Regular communications within the MDT team, working closely with NHS management, timely communication with patients and carers and regular reviews of this progressing situation will underpin the safe delivery of cancer care for women with gynaecological cancer. MDT's are encouraged to work collaboratively, both regionally and nationally to discuss decisions that are very challenging.

Patients and their families should be fully involved in discussions around whether the risks of beginning or continuing their cancer treatment could outweigh the benefits, given that many patients, especially those receiving systemic, are more at risk of becoming seriously unwell if they contract the coronavirus infection.

In particular, where patients are considered 'at high risk' (e.g. due to a combination of age, performance status, co-morbidities, cancer load, and frailty) an individualised decision must be made, with full patient involvement to understand the potential pros and cons of anticancer treatment versus delaying definitive treatment during the current pandemic situation and documented by the MDT. The need for perioperative intensive care support should be incorporated into any decision-making processes, due to the high risk of such a support not being available due to emergency care requirements.

The increased mortality and morbidity risks from a potential COVID-19 infection caused by embarking on cancer surgery or anticancer treatments during the pandemic, and the options of deferring surgery or non-surgical treatments, should be included in the informed consent process and clearly documented. Modelling by Williams et al suggests that mortality from chemotherapy is doubled in presence of COVID 19 infection, in the > 50 age group(<https://www.medrxiv.org/content/10.1101/2020.03.18.20038067v1.full.pdf>) Treatment escalation plans and resuscitation plans in different scenarios should be discussed with patients and clearly documented.

Where conservative methods of treatment have been demonstrated to show efficacy – e.g. Levonorgestrol intrauterine system (LNG-IUS/ Mirena) for early stage uterine cancer in patients with comorbidities/elderly/unfit for treatment, these should be actively considered and discussed with patients.

Greater utilisation of non-surgical options including radical radiotherapy or neo-adjuvant chemotherapy may allow a delay in major resection surgery until there is greater availability of services, such as ITU support. Where decisions about adjuvant treatment need to be made, prioritisation of what is deliverable safely locally may need to take precedence over a small additional survival benefit.

Utilisation of procedures, such as sentinel lymph node assessment, where this has previously been audited in the Trust, may enable selected patients to be spared full lymphadenectomies. The BGCS has previously issued a consensus statement. <https://www.bgcs.org.uk/sentinel-consensus-document-for-endometrial-and-cervical-cancer-bgcs/>

Enhanced recovery pathways should be employed to facilitate early patient discharge and minimise the risk to patients and the impact on the healthcare service.

Subject to local arrangements, Cancer Units and Cancer Centres will need to make joint decisions on location of cancer surgery so that cancer surgery capacity can be utilised between sites. For instance, patients with uterine cancer who do not need lymph node assessment may after careful discussion and agreement across cancer centres and units be performed at cancer units in order to allow capacity to be best utilised.

Outpatient activity

Hospital face-to-face visits should be minimised and alternatives for routine follow-up such as virtual clinics (telephone or videoconference) or patient-initiated follow-up should be considered. Pre-assessment visits, including pre-Systemic Anticancer Therapies can be performed virtually. This could be delivered by specialist nurses in addition to medical staff, where appropriate. BGCS guidance on Patient initiated follow up is available [here](#) and can be modified based on availability of local resource and clinical decision-making.

Two-week wait referrals for suspected cancer

NHS Guidance has been issued <https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/03/cancer-alliance-information-on-managing-cancer-referrals-19-march-2020.pdf>

Two-week wait (2WW) referrals may need to be triaged at trusts, with the consent of the referring primary care professional, to prioritise patients who need to be seen urgently and investigated within the 2WW pathway. These deviations from standard 2WW pathways should be documented and reasons provided. Safety-netting mechanisms should be in place for patients whose referrals are downgraded. Consideration of initial virtual clinic appointments (telephone/video) or straight to test strategies can be made in order to minimise patients needing to physically attend hospital and may provide additional information to aid triage decisions. Ideally, virtual appointments should be performed so that friends/family can also attend, either remotely (e.g. mini videoconference or teleconference), or be with the patient, if this is feasible and in keeping with patient choice.

However, the appointment 'breaking bad news' may be best done at a face to face appointment and with access to CNS support. This will enable signposting to services and transparent communications.

Post-menopausal bleeding

Triage for those with post-menopausal bleeding by USS and virtual appointment with results and management plan may need to be considered. Many patients are **unlikely to have access to an examination by their GP**, so those with a low risk profile, normal cervical screening history and an endometrial thickness <4 mm could be managed by patient-initiated follow up over a 3-6 month period. Patients that report continuing bleeding during the follow-up period can be invited for clinical examination. A record of all of those on patient-initiated follow-up should be maintained and clinical review considered, if required, once outside of the pandemic period.

Performing the most definitive investigation at first face-to-face visit (e.g. outpatient hysteroscopy/ pipelle), allocating the most experienced hysteroscopists to these clinics will minimise need for further investigation under GA, since this is may not be available for a considerable period. Insertion of a LNG-IUS, in those with suspicious findings, at initial hysteroscopy prior to histology being available, may limit face-to-face contact and may mitigate delay of definitive treatment where surgical treatment is constrained due to service pressures.

Ovarian cysts

Use of MRI or IOTA ultrasound (simple rules or AdNEX) to delineate likelihood of malignancy in women with raised RMI, but clinically low risk of malignancy (e.g. premenopausal women with likely endometriosis) may be utilised to triage patients for surgery. Patients with masses identified by careful triage as likely benign, after MDT discussion for difficult cases, can have surgery deferred by 3 - 6 months. Those with RMI < 200 could be considered for virtual clinic appointments and follow up during the pandemic period.

Prioritisation of procedures

SURGERY

Categorisation of patients

Priority level 1a Emergency: operation needed within 24 hours to save life, e.g.: surgery for complications such as anastomotic leak; bowel perforation; peritonitis; burst abdomen.

Torsion or rupture of suspected malignant pelvic masses. Heavy bleeding from molar pregnancy requiring initial or repeat surgical evacuation or hysterectomy

Priority Level 1b Urgent: operation needed with 72 hours, e.g.: surgery for acute mechanical intestinal obstruction/impending perforation in a gynaecological cancer patient with an obvious single transition point in the imaging and where lines of life prolonging treatment exist. Life-threatening bleeding from cervical or uterine cancer, where there is reasonable expectation of surgery being curative and conservative measures have failed or are unavailable. Urgent radiotherapy may be more appropriate in some cases.

Priority Level 2: Elective surgery with expectations to cure, to be performed within 4 weeks to save life/progression of disease beyond operability. Further prioritisation within this category should be based on urgency of symptoms, complications (such as local compressive symptoms), biological priority (expected growth rate) of individual cancers.

For gynaecological cancers, this may include:

Suspected germ cell tumours, intrauterine brachytherapy for cervical cancer, pelvic confined masses suspicious of ovarian cancer, early stage cervical cancer, high grade/high risk uterine cancer and resection of primary vulval tumour in selected patients.

Priority Level 3: can be delayed by 10-12 weeks with no predicted negative outcome:

In some patients, delaying surgery to a point where there is greater availability of intensive care support may be advisable and of limited impact on the survival outcome from malignancy. Patients in this category include early stage, low grade uterine cancer patients managed conservatively with LNG-IUS and oral progestogens. Patients with low volume cervical cancer completely excised at loop excision.

Advice specific to Ovarian Cancer

Patients with Ovarian Cancer pose a particular challenge. Whilst treatment for advanced ovarian cancer is aimed to delay progression and prolong remission, many patients will achieve long and durable remissions (median survival 4-5 years). However, at first presentation, surgery to achieve complete removal of all visible cancer often requires prolonged surgical time and possible multi-visceral resection potentially necessitating ITU support and prolongation of postoperative stay; ITU capacity may be unavailable and surgical time limited due to prioritisation of other services.

In situations where primary surgery is not feasible, the BGCS proposes:

- 1) Neo-adjuvant chemotherapy either with single agent carboplatin or carboplatin and paclitaxel. Consideration should be given to the routine use of filgrastim to reduce the incidence of neutropenia in patients receiving combination therapy. Where possible, this should be considered Priority 2. Neoadjuvant bevacizumab should be used with caution as it has not been shown to improve survival and may be associated with a greater risk of bowel perforation in extensive disease involving the

bowel. In much of the UK, GFR measurements to calculate carboplatin dose are based on radionucleotide excretion. Cockcroft-Gault or Wright methods of calculating GFR should be considered in lieu of radionucleotide methods at this time. Image guided biopsy facilities may be constrained due to pressure on radiology and it may be necessary to rely on cytology to confirm diagnosis of malignancy prior to treatment.

- 2) Patients scheduled for Interval Debulking surgery (IDS) can be assessed after 3 cycles with CT scan (+/- diffusion weighted MRI) or consideration of laparoscopy and proceed to IDS, if there is a potential for macroscopic cytoreduction. Patients may also be counselled to continue with chemotherapy and the decision for surgery reviewed after 6 cycles of chemotherapy depending on resource availability.
- 3) There is no information about the outcome of patients receiving initial surgery following the completion of chemotherapy. Decisions about this should be made on an individual basis depending on the volume of residual disease, symptoms and co-morbidities.
- 4) In the absence of overall survival benefit from secondary debulking benefit in recurrent ovarian cancer, these patients should be managed with chemotherapy unless surgery would relieve symptoms. These patients would be classed as priority level 3.

Chemotherapy and radiotherapy

In the event of limited chemotherapy capacity clinicians will be advised to follow local guidelines and those based on NHS England recommendations. This will require a detailed discussion with the patient, which should take into account the benefit of chemotherapy and the risk of COVID-19 infection whilst on chemotherapy. Where possible alternative and less resource-intensive regimens (such as single agent carboplatin or PARP inhibitors) should be considered where appropriate or the use of prophylactic growth factors with combination therapies may be warranted.

As general principles, patients receiving curative radiotherapy for locally advanced disease should be prioritized over patients receiving adjuvant therapy. Patients where adjuvant therapy is likely to reduce local recurrence, but not likely to prolong survival, can be carefully counselled and RT withheld.

CHEMOTHERAPY

Considerations for Chemotherapy for patients with gynaecological cancer during Covid-19 pandemic

Ovarian cancer - Women with high grade serous and endometrioid ovarian cancer can be expected to respond well to first line platinum-based chemotherapy and this should be considered high priority due to significant survival gain and symptomatic benefit. Maintenance bevacizumab is significantly resource intensive, lacking data on survival advantage and should be considered low priority. Where possible chemotherapy for platinum sensitive relapse should be considered for symptomatic patients and delayed if possible for patients without symptoms or with small volume disease unlikely to lead to significant pathophysiological complications in the next three months. Chemotherapy for platinum resistant disease would be low priority, particularly in the absence of symptoms; alternative strategies to manage symptoms should be considered. For any patients already on treatment consider stopping earlier than planned (there are no data to suggest 5 cycles of first-line therapy are inferior to 6 or more). If patients are eligible for PARP inhibitors following good response to chemotherapy starting oral therapy early after cycle 4 may be considered. Chemotherapy for non-serous, non-endometrioid ovarian cancers and low-grade cancers offers limited benefit and adjuvant chemotherapy in these patients is of lower priority. Endocrine therapies may be considered where appropriate and chemotherapy in the recurrent setting deferred where possible clinically.

Uterine cancer - For women with advanced, high-grade, endometrial cancer, adjuvant chemotherapy may increase the chance of cure and should be considered if resources allow or deferred in some cases for up to three months. In lower risk endometrial cancers, the benefit of adjuvant chemotherapy is less significant and may be deferred or omitted. In women with stage IV disease, chemotherapy may be offered, where possible, dependent on the availability of resources and the use of prophylactic filgrastim or single agent chemotherapy may be warranted. Endocrine treatment may be an appropriate alternative. In relapsed disease treatment should be considered based on the individual's symptoms and risk factors. Again, endocrine therapy or treatment delay should be considered where appropriate.

For cervical and vulval cancers - Chemoradiotherapy for locally advanced cervical, vaginal and vulval cancers is a high priority and should be delivered wherever possible as local resources allow. Palliative chemotherapy in metastatic cervix cancer should be considered where resources allow but treatment second line and beyond is of limited benefit and low priority. First line chemotherapy for metastatic vulval cancer should be considered based on the individual's symptoms and risk factors but treatment second line and beyond is of limited benefit and low priority. Chemotherapy for germ cell tumours should be offered to all new patients as high priority.

NHSE recommendations for chemotherapy are summarised below.

Priority level 1

- Curative therapy with a high (>50%) chance of success

- Adjuvant (or neo) therapy which adds at least 50% chance of cure versus surgery or radiotherapy alone or treatment given at relapse

For Gynaecological cancers, this includes chemotherapy for germ cell tumours and Gestational trophoblastic tumours. Concurrent chemoradiation for cervical cancer.

Priority level 2

- Curative therapy with an intermediate (15 - 50%) chance of success
- Adjuvant (or neo) therapy which adds 15 - 50% chance of cure versus surgery or radiotherapy alone or treatment given at relapse

For Gynaecological cancers, this may include chemotherapy for patients with high grade serous or endometrioid ovarian cancer, particularly where the patient is known to have a BRCA mutation, low volume disease or good performance status.

Priority level 3

- Curative therapy with a low chance (10 - 15%) of success
- Adjuvant (or neo) therapy which adds 10 - 15% chance of cure versus surgery or radiotherapy alone or treatment given at relapse
- Non-curative therapy with a high (>50%) chance of >1 year of life extension

For Gynaecological cancers, this may include chemotherapy for some patients with high grade serous or endometrioid ovarian cancer, newly diagnosed or first platinum-sensitive relapse. Women with advanced, high-grade, endometrial cancer.

Priority level 4

- Curative therapy with a low (0 - 15%) chance of success
- Adjuvant (or neo) therapy which adds < 10% chance of cure versus surgery or radiotherapy alone or treatment given at relapse
- Non-curative therapy with an intermediate (15 - 50%) chance of > 1 year life extension

For example, chemotherapy for cervical and endometrial cancer in first recurrence with good performance status, or advanced previously untreated disease. Some patients with platinum sensitive relapsed ovarian cancer.

Priority level 5

- Non-curative therapy with a high (>50%) chance of palliation / temporary tumour control but < 1 yr life extension

For example, chemotherapy for platinum resistant ovarian cancer, recurrent endometrial cancer.

Priority level 6

- Non-curative therapy with an intermediate (15-50%) chance of palliation / temporary tumour control and < 1 yr life extension

For example, chemotherapy for metastatic or recurrent cervical cancer or endometrial cancer in second recurrence.

Considerations for Radiotherapy during Covid-19 pandemic

There may be reduced radiotherapy availability requiring prioritisation of patients depending on local resource and demands. With the possibility that all cancer surgery is suspended then definitive radiotherapy will be required to treat some early stage cancers. Changes to current practice may be required to reduce departmental workload.

General measures to consider include:

- Using the most clinically appropriate hypo-fractionated schedule.
- Simplified techniques for planning and treatment verification may be used with appropriate adjustment of target volumes
- Chemotherapy access for chemo-radiotherapy treatments should be prioritised as outlined in NHS England Chemotherapy Priority Category 1.
- Anaesthetic availability may be the determining factor for capacity for some radiotherapy such as intrauterine brachytherapy
- The number of intrauterine insertions should be minimised, delivering multiple fractions per insertion if possible. Simplification of technique may be necessary depending on imaging and planning availability
- Consider omission of adjuvant radiotherapy when there is no or limited survival advantage such as adjuvant brachytherapy for intermediate risk endometrial cancer.

NHS Priority Levels for Radiotherapy

Extending the total treatment time of radiotherapy can have a deleterious impact on tumour control. The Royal College of Radiologists defines tumours where survival is impacted by any delays in treatment as category one and those where short delays have less effect as category two.

Priority level 1: Patients with RCR category 1 tumours currently being treated with (chemo)-RT and Brachytherapy for Category 1 tumours on EBRT

For gynaecological cancer, this includes radical radiotherapy for cervical, vaginal and vulval cancers, and intrauterine brachytherapy for cervical cancer

Priority level 2: Urgent palliative radiotherapy to save loss of function/ life

Examples include urgent palliative radiotherapy in patients with malignant spinal cord compression who have useful salvageable neurological function and palliative radiotherapy to stop bleeding.

Priority level 3: Radical radiotherapy for Category 2 tumours where radiotherapy is the first definitive treatment OR Post-operative radiotherapy where there is known residual disease following surgery in tumours with aggressive biology

This includes adjuvant radiotherapy for residual disease, positive resection margins or nodal involvement in cervical, vaginal, vulval and endometrial cancers. Definitive radiotherapy for uterine tumours may be necessary for selected cases.

Priority level 4: Palliative radiotherapy for symptom control

This includes palliative radiotherapy for metastatic disease and pelvic masses

Priority level 5: Adjuvant radiotherapy

This includes post-operative radiotherapy for fully resected high-risk endometrial cancer.

Support for women

Women undergoing investigation and treatment for gynaecological malignancies usually have the support of a clinical nurse specialist (CNS). The CNS is crucial to support women at this time, provide information, answer questions and support complex decision making. They help to navigate complex pathways. They are a key patient advocate liaising with clinical teams about patient choice and preferences. However, as hospitals will be facing unprecedented demand on nursing care, the CNS's will inevitably be re-deployed to support inpatient clinical care on wards.

This is going to be a frightening and worrying time for women who are currently undergoing treatment, those who relapse and those newly diagnosed. A key member of the team may not be available and departments should consider how support will be offered to women. The charitable sector has made a significant contribution to the care of women with gynaecological cancers and it is anticipated their role at this time will be crucial. The BGCS will be working closely with gynaecological cancer charities to enable women to best supported in this difficult time.

The BGCS recommends that:

- Where more than one CNS is available that ward work is alternated to allow one CNS to work as a CNS
- Cancer units could consider cross cover of CNS's through generic working of CNS's across tumour sites
- Trusts consider who will take CNS telephone calls i.e. administrative staff, cancer care co-ordinators and have mechanisms in place for a clinical member of the team to review and respond to these. Alternatives such as using email by CNS staff may allow remote working where possible.
- Have safety netting in place so that patients can be contacted by a CNS when normal service resumes
- Departments/Trusts consider signposting patients to other sources of support i.e. the charitable sector. Suggestions would be to contact clinical teams with clinical concerns/queries, contact charitable sector with emotional concerns when the CNS is not available.
- Innovative ways of working to access charitable sector support, with patient consent and trust permissions to discuss concerns may need to be considered.

Self care

These are challenging times for all those working to provide services for women with suspected or confirmed gynaecological cancer. Many will experience anxiety for themselves, their loved ones and patients at the same time as providing much needed care. A strategy to seek help and a readiness to signpost colleagues when vulnerable, to support services, will be important to ensure our wellbeing during and after this pandemic.

Detailed guidance on the use of PPE is available on

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/874316/Infection_prevention_and_control_guidance_for_pandemic_coronavirus.pdf

Data on safety at interventional procedures is still emerging (e.g. aerosolisation risk at Laparoscopy) and will need to be regularly reviewed and practice changed to keep health care providers safe.