Risk Stratifying Adult Patients with Suspected or Diagnosed Cancer during the COVID-19 Pandemic (exc National Screening) for Gynaecological Cancer

Purpose of this document:	To provide clear processes for all Provider Trusts to implement with regard to the clinical management of Adult Patients with suspected or diagnosed gynaecological cancer through the COVID-19 pandemic, in order that patients are treated consistently and equitably across the Region. Please refer to this document in conjunction with GM Cancer COVID-19 Cancer Management SOP V1 (for instruction on processes relating to management of patients in Somerset).
Exclusions:	This paper relates to Adult Patients only. Children, Teenage and Young Adult Cancers should be managed in accordance with normal protocol. Excludes National Screening Programme
Version Control:	
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1. Introduction

This document sets out the process to be implemented in relation to the cessation and risk stratification of Adult Patients with suspected or diagnosed cancer in the event that diagnostic and treatment resources are limited as a result of the COVID-19 pandemic, or where clinical risk exceeds normal treatment or diagnostic pathways.

Given the rapid changes, this document is expected to be updated, in line with any changes to National Guidance.

2. Key Message

ANY PATIENTS WHO MAY REQUIRE CANCER DIAGNOSTICS, EVEN IF THIS IS POST PANDEMIC, **MUST** BE RETAINED BY THE TRUST **AND** REMAIN ON A PTL, **AND** ON A DEDICATED COVID WAITING LIST.

ONLY PATIENTS WHO DO NOT NEED ANY SECONDARY CARE APPOINTMENTS OR DIAGNOSTICS ON A SUSPECTED CANCER PATHWAY CAN BE DISCHARGED.

3. PTL Management

Clinical Leads should risk stratify PTLs in accordance with the following criteria and categorise into the appropriate group:

Action	Criteria
Step Down	As per normal PTL management on receipt of all necessary diagnostic results and a non-cancer decision. No change to current practice.
Safe Discharge	Following review (telephone/ virtual/ face to face) and no suspicions of cancer/no further diagnostics required, then safe discharge is appropriate and should be recorded by MDT tracker as COVID SAFE DISCHARGE. This is essentially the same as STEP DOWN during the COVID pandemic.

Suspend	Diagnostics for suspected gynaecological cancers need to be suspended if: • COVID positive women (until well and not self-isolating) • Women who are shielding/ self-isolating (until no longer doing so) • Women at high risk of COVID complications (age>70yrs, significant comorbidities such as respiratory disease, diabetes, immunosuppression), • Women wish it due to COVID • NHS capacity issues due to COVID 19. All cancer cases must still be discussed at SMDT for treatment planning and prioritisation in line with NHS guidance. Gold standard cancer treatments may need to be suspended due to COVID if • Priority Level 3 • Alternative treatments offered due to the COVID crisis (e.g. Mirena IUS for endometrial atypia/stage 1a G1 endometrial cancer) • Complex surgery in women at high risk of COVID complications (age>70yrs, significant comorbidities such as respiratory disease, diabetes, immunosuppression) • Lack of NHS capacity due to COVID • Palliative Treatments All diagnostics or treatments that are suspended due to COVID must be recorded by MDT trackers as SUSPEND COVID with a documented review date. The patients & GP must be notified that the treatment has been suspended due to COVID.
Active Management	During the COVID pandemic, cancer diagnostics and treatments will continued to be offered: i) Outpatients/diagnostics identified as appropriate ii) Management according to current process with clear clinical engagement Active management will continue for women who are not on the SUSPEND COVID pathway (as above) so long as there is local Unit capacity for outpatient and GA diagnostics If no capacity, the SUSPEND COVID pathway is followed. Telephone/virtual triage can be used in Suspected cancer

	referrals so long as there is rapid access to diagnostics. Pipelle Endometrial biopsy rather than outpatient hysteroscopy is suitable for most women with postmenopausal bleeding ((Please refer to the RCOG, BSGE and BGCS guidance) Those that require treatments will be prioritised in line with NHS guidance and NHS capacity.

4. Management of Long Term Follow Up/CNS lists/Recently treated patients (patients NOT on a live PTL)

Clinical Leads to review FU clinic waiting lists/recent treatment lists and categorise into groups to safely discharge/suspend with review date/actively manage.

Action	Criteria
Safe Discharge	Applies if following review, no further input from secondary care required. Currently no stratified follow up pathways are agreed for Gynaecological cancers although there is evidence that this is safe for early low grade endometrial cancers. Safe discharge of, low grade endometrial cancers (Stage 1A G1/2) can have SAFE DISCHARGE COVID if • Clinicians are satisfied there are processes in place to support women and provide easy contact/access to clinic review. • A dedicated CNS key worker • Women are happy to participate. • Women are provided with an End of Treatment summary which includes clear information on red flag symptoms, details of key worker and expectation to be seen quickly in clinic if clinical concerns.

Suspend	Currently no cancer follow ups have been suspended. This may be reviewed as the COVID pandemic evolves. If follow up is suspended due to COVID, Local Units must ensure clear • SOP/guidance is in place • Usual follow up resumes once the pandemic is over. • Women notified they are on the SUSPEND COVID follow up.
Active Management	• Manage according to current process with clear clinical engagement. • Due to the COVID pandemic, reviews may be remotely (telephone/virtual). • All cancers should be followed up at the usual intervals. • Clinical assessment is needed if concerns about progression/recurrence • Follow up tests such as ca125, ultrasound scans or CT scans may be arranged in primary care to reduce hospital attendance, local units will need to address the feasibility/ appropriateness of this.

5. Management of New GP referrals (excludes National Screening Programmes)

Each tumour group should ensure processes are in place for the daily triage of referrals and follow the following tumour specific guidance:

PLEASE NOTE:
Referrals cannot be rejected without discussion with primary care. Patients may be discharged after telephone appointments **if cancer is no longer suspected and there is no longer need for any cancer diagnostics**. Telephone appointments can now be counted as 'first seen appointment' as per national guidance.

1. Cancer Services / Booking Centre: distribute referrals as per tumour group decision.
2. Cancer Services / Booking Centre: Register patients on PAS as per normal process
3. Clinical leads: review emails daily in accordance with criteria of safely discharge after review if cancer no longer suspected and no further cancer investigations needed/suspend with review date/actively manage and respond to generic email.

Action	Criteria
Safe Discharge	Same as Safe Discharge in PTL Management section

(following review and no further input from secondary care required)	
Suspend	The usual cancer treatment will be suspended if • Alternative to Gold standard treatment agreed at SMDT • Mirena IUS/ oral progestogen for early low grade endometrial cancer or atypia. • Defer completion surgery for stage 1a1 cervical cancer diagnosed on Lletz. • Defer complex surgery and offer alternative chemotherapy/ radiotherapy for some cancers (agreed at SMDT)
Active Management	Manage according to current process with clear clinical engagement Same as Active Management in PTL Management section.

MDT/sMDT Guidance:

- Maintain weekly MDT: remotely if needed
- Aim to minimise number of staff present at MDT e.g. 1 surgeon, 1 oncologist, 1 pathologist, 1 radiologist and one Gynae Clinical Nurse Specialist

6. Annotation - delays/treatment plan changes on Cancer Tracking system

If general delays (identified through referral management and tracking) are observed, the recording of formal clinical prioritisation (following PTL clinical review and prioritising), and the recording of treatment types offered that would not normally be considered outside of the COVID-19 pandemic (From MDT / treatment planning) must be formally documented for each patient (see SOP).

7. Clinical Prioritisation

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. Cockroft-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 comorbidities. 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.
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.
SACT	**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.

8. Alternative treatment given / recommended

Clinical Leads should use the following criteria when making decisions that result in changes to a patient's treatment from that which would have been offered prior to the COVID-19 pandemic:

Discussed and agreed at SMDT and agreed by patient.

9. Research