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Faster diagnostic pathways

Implementing a timed gynaecology cancer diagnostic pathway

Guidance for local health and care systems

20 March 2023

Contents

Best practice timed diagnostic pathways

Best practice timed pathways support the ongoing improvement effort to shorten diagnosis pathways, reduce variation, improve patient experience of care, and meet the Faster Diagnosis Standard (FDS). The guidance will support cancer alliances and constituent organisations to adopt consistent, system-wide approaches to managing this diagnosis pathway.

This guidance sets out how diagnosis within 28 days can be achieved for the suspected gynaecological cancer pathway. Alongside the pathway itself, resources are highlighted to support implementation of the pathways.

This gynaecology pathway is part of a series, published since April 2018. From previous pathways implemented by cancer alliances, implementation guidance was shared in June 2021, identifying areas that are key to success, such as setting up with clinical and operational engagement, auditing pathways, allocating project management resources, ensuring leadership, analysing data, and sharing successes.

This guidance complements existing resources such as NICE guidelines (including NG12) and should therefore be read alongside such guidance. While the guidance stipulates recommended clinical actions and timings to support pathway design, we recognise that responsibility for clinical decision making remains with local clinical teams with the knowledge and expertise to make appropriate decisions and policies.

The pathway in this document was developed by a multidisciplinary consensus group with clinical leaders from local and specialist services across England, and expert advice from cancer alliances. For any questions about this document please email england.cancerpolicy@nhs.net.

Dame Cally Palmer
National Cancer Director
NHS England

Professor Peter Johnson
National Clinical Director for Cancer
NHS England

John Renninson
Chair of the Gynaecology Task and Finish Group
NHS Cancer Programme

The Faster Diagnosis Standard

We committed in the NHS Long Term Plan to provide a faster diagnosis for patients through the introduction of the Faster Diagnosis Standard (FDS). This standard will ensure patients are told they have cancer, or that cancer is excluded, within a maximum of 28 days from referral. The new standard is intended to:

- reduce the time between referral and diagnosis of cancer
- reduce anxiety for the cohort of patients who will be diagnosed with cancer or receive an 'all clear'
- reduce unwarranted variation in England by understanding how long it is taking patients to receive a diagnosis or 'all clear' for cancer
- represent a significant improvement on the current two-week wait to first appointment target, and a more patient-centred performance standard.

FDS performance data, including a breakdown by suspected cancer pathway, has been published since June 2021, and faster, more streamlined pathways will be a priority.

As the key system-wide organisations for cancer services, cancer alliances will need to work across the local system to ensure that implementation is prioritised by senior stakeholders, clinical leaders, and operational colleagues, and that capacity is prioritised to enable the standard to be delivered.

The FDS has been formally performance managed since October 2021 activity, in line with cancer services recovery, with an initial threshold of 75%. Cancer alliances will need to ensure that they have plans to meet the threshold, which will need to be increased in subsequent years if we are to contribute to achieving the early diagnosis ambitions in the NHS Long Term Plan.

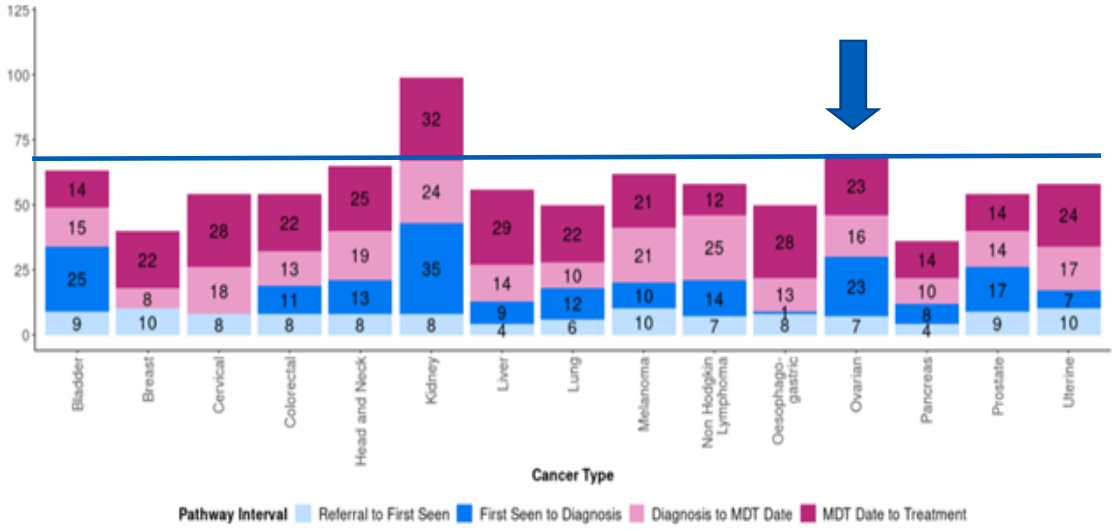
The case for change

- **Gynaecological cancers are the sixth most common cause of cancer in England, affecting more than 19,000 women each year**, and the seventh most common cause of cancer mortality.

- Suspicion of gynaecological cancer is the **fifth most common suspected urgent referral type in England**, representing 9% of all urgent suspected referrals in 2020.
- In 2018, patients with ovarian cancer had some of the **longest intervals between referral and commencement of treatment** among all cancers in England.
  - This varied by cancer alliance with a range of 59 to 88 median days.
- Between 2018 and 2020, **72% of patients diagnosed with gynaecological cancer commenced treatment within 62 days of referral**.
  - This varied by cancer alliance with a range of 60% to 82%.
- For cancer patients in England diagnosed between 2015 and 2019, five-year age standardised net survival was:
  - 44% for ovarian cancer
  - 61% of cervical cancer
  - 69% for vulval cancer
  - 75% for uterus cancer.

A streamlined and more efficient pathway will reduce overall waiting times, avoidable delays and the variation currently seen across the country. Alongside adoption of the best practice timed pathway, cancer alliances must ensure the appropriate resources and capacity are in place to deliver high-quality services to more patients.

Figure 1: Median days from referral to treatment by cancer type, England (2018)



Actions for cancer alliances

In 2023/24, **all systems** are asked to develop plans to:

- Implement and maintain priority pathway changes.
- Increase and prioritise diagnostic and treatment capacity, including ensuring that new diagnostic capacity, particularly via community diagnostic centres (CDCs), is prioritised for urgent suspected cancer.
- Maximise the pace of roll-out of additional diagnostic capacity, delivering the second year of the three-year investment plan for establishing Community Diagnostic Centres (CDCs) and ensuring timely implementation of new CDC locations and upgrades to existing CDCs.
- Deliver a minimum 10% improvement in pathology and imaging networks productivity by 2024/25 through digital diagnostic investments and meeting optimal rates for test throughput.
- Increase GP direct access in line with the national rollout ambition and develop plans for further expansion in 2023/24.

NHS England provide support, funding and guidance to help cancer alliances improve outcomes and reduce variation. The following support is available:

- Funding and programme management to support delivery to achieve the FDS and best practice timed pathway milestones.
- Implementation guidance for achieving pathways.
- Collaboration and networking events to share best practice.

"The patient pathway must consider a combination of ultrasound, biopsy and imaging, and enable onward referral. Each tumour subtype has its own set of investigations and diagnostics which are challenging to schedule in a timely fashion. The initial diagnostics can be undertaken at local units and the more invasive staging investigations may require specialist decision and intervention.

"The key features of this pathway are to implement rapid triaging of patients so they can access the right tests, first time, through use of appropriately staffed one-stop clinics. This will assist the streamlining of transfer of appropriate cases between local unit and specialist centre. This should be integrated with timely booking and reporting of the diagnostic and staging investigations.

"The proposed changes are simple but do require better administration of existing pathways. Their implementation is anticipated to reduce waiting times for critical investigations and decision making and enable prompt starts for treatment for those diagnosed with cancer."

John Renninson
On behalf of the Gynaecology Task and Finish Group, NHS Cancer Programme

Benefits of pathway change

For patients and unpaid carers

- Reduced anxiety and uncertainty of a possible cancer diagnosis, with less time between referral and receiving the outcome of diagnostic tests.
- Improved patient experience from fewer visits to the hospital, particularly to specialist centres if possible, and avoiding emergency admission.

- Potential for earlier recognition and initiation of pre-optimisation for treatment that could reduce complications and adverse outcomes.

For systems

- Reduced demand in outpatient clinics with increased straight to test provision and use of pathway navigators.
- Allow resources to be targeted at patients with cancer by removing non-cancer patients earlier in the 62-day pathway.
- Improved quality, safety, and effectiveness of care with reduced variation and improvement in outcomes.

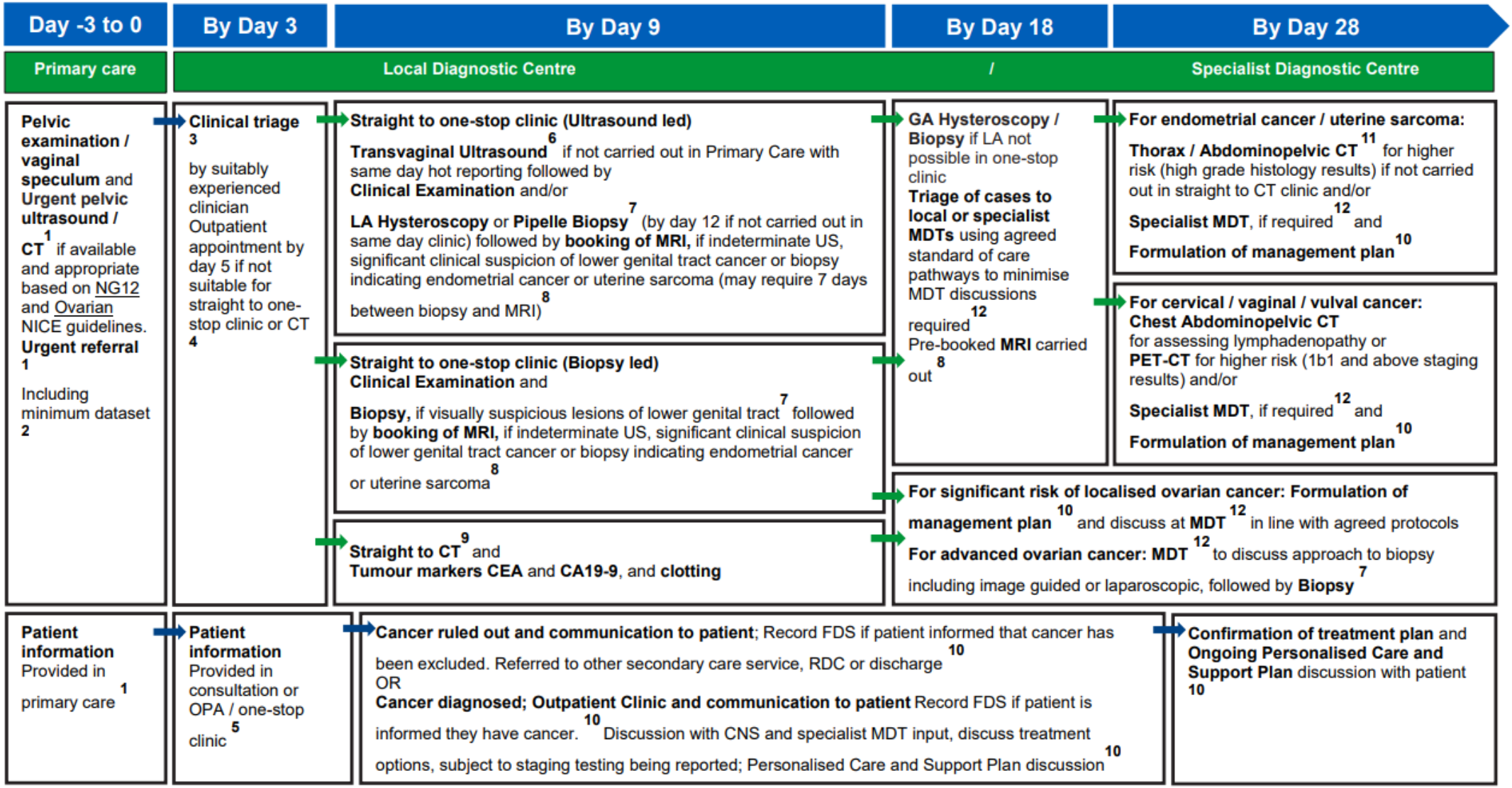
Experience of care

- Patients and carers know they are urgently referred for investigation of suspected cancer and should expect diagnosis within 28 days.
- Ensure that patients and carers' ability to attend appointments is taken into account and additional support is offered, where necessary.
- Patients are communicated with clearly, understand the information provided, and are given additional support, such as access to a clinical nurse specialist (CNS) or navigator, psychological support, buddy system, where necessary.

For Clinicians

- Using a nationally agreed and clinically endorsed pathway to support quality improvement and reconfiguration of gynaecology cancer diagnostic services.
- The use of predetermined diagnostic algorithms and standards of care to streamline clinical decision-making and reduce delays for multidisciplinary team (MDT) discussion.
- Improved ability to meet increasing demand and ensure best use of the highly skilled workforce.

28-day best practice diagnosis pathway



See detailed information on pages 9 to 16

Detailed information

1. **Urgent GP referral pathway** should be used for patients who meet NG12 criteria for suspected cancer pathway referrals. In a scenario where the GP refers the patient for a direct access test and the ultrasound or CT is abnormal and suspicious of cancer, patients should be followed up directly by secondary care, without the need for an additional referral from their GP. The patient would then join the pathway after the first diagnostic test (labelled on this pathway diagram as 'straight to one-stop clinic'. If a patient already meets the NG12 risk threshold for an urgent referral, it should not be delayed for primary care investigations or direct access testing.

   GP examination of the patient before referral is advised unless local protocols have been agreed for direct referral. Referral should not be delayed for examinations or other investigations. **The National Cancer Waiting Times Monitoring Dataset Guidance v11.1** sets out consultant upgrade rules, including from non-GP scenarios such as A&E and acute settings. cancer alliances may set out local arrangements to facilitate patient self-referral access to this pathway.

   Information to be provided by Primary Care to the patient includes information about FDS and urgent suspected cancer pathway and expected timelines, including that the patient should be available within the next nine days initially for appointments and tests, which is likely to include straight to test.

   As part of recovery of services and effective referral management, cancer alliances are encouraged to use this guidance and other policies to support work locally, with commissioners, to provide educational opportunities for GPs on cancer symptoms, urgent referral processes and the locally agreed minimum dataset, including in hard to reach and outlier GPs.

2. **A minimum dataset to accompany the referral** and facilitate straight to clinic and immediate diagnostics, to be agreed locally, should include:
   - description of referral reason in line with NG12 guidelines
   - patient demographics
   - estimated glomerular filtration rate (eGFR)
   - full blood count
   - urea and electrolytes

- renal function including creatinine
- anticoagulant status
- WHO performance status
- co-morbidities, including:
  - diabetes status
  - dementia
  - mental health conditions, such as claustrophobia
- body mass index
- prescribed medication (when auto-populated in practice IT system)
- allergies
- family history of cancer
- presence of metal implants or pacemakers
- need for interpreter
- mental capacity to consent.

For patients with suspected ovarian cancer, minimum dataset should also include tumour marker CA125 with confirmation of suspicious features of ovarian cancer on ultrasound (when carried out to IOTA/Royal College of Obstetricians and Gynaecologists [RCOG] standards); and in patients aged below 40, also include alpha-fetoprotein (AFP), Beta-hCG, and lactate dehydrogenase (LDH), if available – the referral should still be made while awaiting results.

For patients with suspected vulval cancer, minimum dataset should include information on high-risk HPV status or chronic vulval inflammatory condition, eg lichen sclerosis.

3. **Clinical triage can be undertaken** by a suitably experienced clinician. This includes a CNS, who has the training and authority to triage to one-stop clinics or order imaging investigations, such as CT, to allow the patient to go straight to imaging.

   Patients can be triaged into one of the three straight-to-clinic services, or if complex, may require a face-to-face outpatient appointment (as detailed in point 4 below). For simpler cases, it may be possible to agree local criteria and for a non-clinical member of staff to triage these patients; for example this may be appropriate for patients presenting with post-menopausal bleeding who will be

triaged to the one-stop clinic (ultrasound led) and may require ultrasound and/or hysteroscopy and biopsy, or where suspicion of ovarian cancer for women over 50 with elevated CA125 and palpable mass and/or ascites or with previous ultrasound with risk of malignancy index greater than 200, who will be triaged straight to CT.

Telephone or video consultation should only be used to determine suitability for straight to one-stop clinic and pre-assessment, if a face-to-face appointment is not suitable, as physical clinical assessment should inform the referral. Preparation for any tests can be communicated to patients.

Suitability for treatment and any requirements for pre-habilitation (eg diabetes, weight reviews, insertion of inferior vena cava (IVF) filters) should be considered at this stage in the pathway. Patients should be triaged using IOTA models or risk of malignancy algorithms to low, high or indeterminate risk, referring also to ESGO/RCOG guidance.

4. **An outpatient appointment (OPA)** should be provided for this cohort of patients (those medically unfit for straight to one-stop or that require a face-to-face appointment). The recommended first line investigation should be performed and reported within six days of OPA so that this cohort can progress on the pathway in the same timeframes. If a suspicious lesion is identified, patients should have access to a CNS with expertise in gynaecology cancer for support (from this stage onwards).

   Patients who attend OPA should have same day tests to reduce repeat visits and improve patient experience. If this is not possible, tests should be on the next day (ie within 24 hours). Consider ring-fencing urgent cancer slots in advance and releasing them if no longer required. The clinical triage consultation or first OPA is also an opportunity to collect minimum dataset items from the patient, if not provided in the primary care referral, and to collect tumour markers CA19-9 and CEA.

5. **Patients and care-givers should be asked** what information they require about the pathway, provided with standard leaflets about investigations when sending confirmation of appointment, confirmation of next step(s) and any patient needs required to prepare for the day (for example, can they eat and drink before), and whether they have any disabilities or language barriers.

Preferences for amount of information and when it is provided will vary, and therefore it will help to provide caseworker/navigator telephone contact details to provide support throughout the pathway and outside of clinic times, provide signposting to charities and support services, provide information about care-givers attending appointments, and offer follow-up if patients do not receive confirmation of appointment in expected timescale.

Where possible, continuity of caseworker/navigator should be provided to enable familiar contact and to build trust. Patients should also be informed that it is likely they will receive a procedure and/or diagnostic test on the same day at the first face to face appointment.

6. **Transvaginal ultrasound** ideally carried out by a specialist practitioner in gynaecology ultrasound, based on IOTA/RCOG standards, whether in clinic or externally provided, measuring endometrial thickness and appearance of the junctional zone to determine management, and to a locally agreed minimum reporting dataset and algorithm. If ultrasound is suboptimal or incomplete then the next step should be rapid referral for an expert ultrasound scan, to be carried out by day 12.

7. **Hysteroscopy** should be carried out in the event of a focal lesion or polyp, or patients on tamoxifen, or recurrent bleeding with negative biopsy. **Outpatient hysteroscopy** environment needs to be considered and delivered to a high standard, including equipped and staffed recovery facilities.

   Patients may not tolerate outpatient hysteroscopy, so may need to allow for time to book a general anaesthetic (GA) hysteroscopy or endometrial biopsy. In these circumstances, the patient should be added to admissions list, and co-ordination with pre-operative assessment units and anaesthetists should be commenced, with the GA hysteroscopy/biopsy needing to be completed by day 15. Consider ring-fencing slots in advance and releasing them if same day hysteroscopy is carried out. Pain control/management/recovery facilities should be in place to support more effective outpatient hysteroscopy, and reduce failure rate.

   Pipelle biopsy should be carried out if ultrasound indicates endometrial thickness of 4mm or more, or suspicious appearance of the junctional zone, which should be carried out according to British Gynaecological Cancer Society (BGCS) Guidelines. All patients with significant suspicion of endometrial or

ovarian cancers should be informed that genomic tests may be performed on their tissue samples.

Image guided biopsy procedures should be carried out within five days of request. **Histopathology reports for tissue sampling** should usually be available in seven days. This may be longer if ancillary tests are required to establish a diagnosis or if the pathway for a sample reaching the reporting laboratory is delayed. All histopathology should have a designated point of receipt, sign-off and management responsibility to ensure that reporting is not lost between different clinicians.

Draining of ascites for symptom control in ovarian cancer, should be carried out, where technically possible, at the same time as the biopsy, and within seven days of the request. It is recognised that biopsy may need to be delayed until draining of ascites can be carried out, where possible this should be done on the same day.

8. **Booking of MRI** to be carried out at the one-stop clinic when further investigation is required for cervical, vaginal, vulval, endometrial cancers, or uterine sarcoma. The patient should be supported to discuss next steps and prepare for MRI appointment. General cancer dedicated ring-fenced MRI slots should be available. MRI should be carried out to O-RADS minimal standards, to avoid the requirement for repeat procedures.

   For patients with persistent abdominal symptoms, raised CA125 and normal pelvic scan, consider use of the local ‘non-specific symptoms rapid diagnostic centre pathway, which would include where there is no other obvious cause for the symptoms and finding such as endometriosis, heart and liver failure or known inflammatory bowel conditions. These patients have a significant incidence of malignancy in other sites.

9. **Straight to CT** should be considered for women over 50 with elevated CA125 and palpable mass and/or ascites or with previous ultrasound with risk of malignancy index greater than 200.

   Where CA125 is elevated and has abdominal symptoms, but with normal pelvic ultrasound scan and no other obvious cause for elevated CA125 or abdominal symptoms on primary care ultrasound, consider redirecting to non-specific rapid diagnostic centre (RDC) pathway after the CT. They may still have gynaecology/peritoneal malignancy, or other urgent condition that would be

more appropriate in a non-site specific RDC pathway, rather than being discharged to primary care.

This could also be considered in presentations of clinically apparent ascites, raised CA125 and pelvic mass in primary care if no local capacity within required timeframes.

10. **Patients should be informed** about cancer being ruled out, or diagnosed at the earliest face-to-face opportunity, unless the patient has expressed an alternative method of communication in order to speed up communication. In this timed pathway, this can be done at a one-stop clinic, a follow-up testing or results outpatient appointment, or at a treatment planning outpatient clinic.

    When cancer is ruled out, the patient may still require further routine testing in secondary care before an alternative non-cancer diagnosis can be identified. Best practice would be to refer the patient to an alternative routine in a secondary care service within the same provider if one is identified, rather than being discharged back to primary care.

    Running parallel general gynaecology clinics alongside ultrasound led clinics using 'hot slots', can allow patients to undergo an ultrasound scan and be followed up by the gynaecology clinic on the same day.

11. **When gynaecology cancer is ruled out, or highly unlikely and other cancers are not ruled out** it may be appropriate, following a CT, to refer the patient on to an alternative tumour site specific pathway, or a RDC pathway, where non-specific or vague symptoms can be considered.

    When cancer is diagnosed and a discussion with the patient has been held, the patient will be followed up through the relevant pathway for cervical, vaginal, vulval, endometrial or ovarian cancer. They will be added to a waiting list for surgery, if appropriate, or seen at a cancer centre for consent and pre-operative assessment on the same day, and fast access ring-fenced anaesthetic review appointments to avoid unnecessary travel and improve patient experience.

    For continuity of care, it is best practice for the CNS from triage and diagnostics to be available in the clinic. For endometrial cancer, the patient could be consented for Lynch Syndrome testing as per NICE endometrial guidance (DG42); and for ovarian / peritoneal cancer, consented for t.BRCA/HRD/g.BRCA/PALB2, if included in local policy, advising patients that

testing may not be required if histology does not show ovarian / peritoneal cancer. This will support timely opportunity for access to PARP inhibitors.

Cancer waiting time rules (including 'clock start' and 'clock stop') are set out in the National Cancer Waiting Times Monitoring Dataset Guidance v11.1. **Formulation of management plan** should consider next steps.

Outpatient clinic should include the CNS assigned to the patient earlier in the pathway, from clinical triage (day 0 to 3) or when a likely cancer diagnosis was discussed (day 1 to 18). **Personalised care and support planning** should be based upon the patient and clinician(s) completing a holistic needs assessment (HNA), usually soon after diagnosis.

The HNA ensures conversations focus on what matters to the patient, considering wider health, wellbeing, practical issues and support in addition to clinical needs and fitness. This enables shared decision-making regarding treatment and care options.

Early consideration of the patient's fitness for radical therapy should be addressed as soon as possible in the pathway to minimise delays in expediting treatment. Local protocols and initiatives should be developed in collaboration with perioperative medicine, elderly care and specialist dietitians. Anaesthetic assessments for patients with comorbidities should also be undertaken.

12. **Thorax/abdominopelvic CT** should be carried out to locally agreed standards by a member of the gynaecology/gynae-oncology radiology MDT, covering minimum reporting dataset for malignancy scans. General cancer dedicated ring-fenced CT slots should be available.

13. **The local diagnostic MDT** should be used for patients where there is still uncertainty or unconfirmed suspicion. **The core roles at the specialist MDT** are lead clinician, radiologist and pathologist, to review investigation results with a CNS and pathway navigator. An oncologist with an interest in gynaecological cancer and a radiologist with an established gynaecological interest should be present at the specialist MDT.

    The capacity required to deliver these core roles should be reflected in job plans. Other specialist MDT advice may need to be sought for rare and unusual tumours that cross-over with other specialities. National guidance on how to maximise effectiveness of MDT meetings is also available. **Locally agreed, clear criteria for referral to specialist MDT** can also support with efficient

pathway management. A multidisciplinary clinic with surgeon, oncologist, pre-op staff, including anaesthetist and allied health professionals (AHPs) such as therapeutic radiographer and specialist dietitian should be considered. This aims to improve patient experience, improve communication, and prevent delays in starting treatment.

Additional information

Audit tool

Can be used to undertake a baseline audit of services being delivered and whether sufficient capacity is in place to routinely deliver, identify areas for improvement, select measurements for improvement, and conduct re-audits as part of continuous improvement.

Day	Pathway step	Service change?	Capacity in place?
-3 to 0	GP referral and locally agreed minimum dataset		
	Patient information resources, co-developed with patients		
By day 3	Clinically led triage and local protocols to reduce delays		
By day 9	Straight to one-stop clinic provision for all eligible patients		
	CT/MRI dedicated all tumour cancer slots from clinical triage, and/or follow-up from one-stop clinic investigations		
	Histopathology results taken during procedures should generally be reported within 5 working days		

By day 18	PET-CT scan, if required, should be carried out to nationally agreed service specifications and reported within seven working days of request		
	MDT for review and planning of potential treatment options, with alternative treatment options pre-agreed based on potential outcome of further tests		
By day 28	Treatment options discussed at multi-disciplinary outpatient clinic		

Cancer alliance workspace

Cancer alliances access this workspace for national guidance, resources, and to share learning. Please use this space to upload materials you have developed locally and that you think would be useful for colleagues implementing this pathway across the country.

Acknowledgements

This guidance was developed by the NHS Cancer Programme and builds on experience and expertise provided by the Gynaecology Task and Finish Group membership, including clinical representatives: John Renninson, Richard Clayton, Nadia Ali-Ross, Tim Duncan, Partha Sengupta, Hilary Maxwell, Gerry van Schalkwyk, Nishat Bharwani, Faye Cuthbert, Hannah Tharmalingam, Tom Bourne, Sudha Sundar, Marcia Hall, Axel Walther; Operational representatives: Alison Armstrong, Ali Jones, Stephen Scott; and Patient / Charity representatives: Karen Hobbs, Athena Lamnisos, Kathryn Gilmore, and the NHS Cancer Programme: Cally Palmer, Peter Johnson, David Fitzgerald, Dan Cariad, Matthew Keeling, Sehrish Hussain, Peter Hawkins, Ayesha Dave, Tarana Akther, Maite Bikenge

NHS England
Skipton House
80 London Road
London
SE1 6LH

Contact: enquiries@england.nhs.uk

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