Gynaecological cancer risk stratified follow-up guidelines for TVCA

The following is the proposed document describing a stratified follow-up pathway for Gynaecological cancer patients, taken from the British Gynaecological Cancer Society recommendations (Newton et al, 2020).

Please note: the terms Supported Self-Management Pathway (SSMP) and Patient Initiated Follow up (PIFU) are both used interchangeably throughout this document. Both SSM and PIFU are models of personalised follow up.

1. Introduction and Purpose of this Guideline

This document describes the redesigned stratified follow-up pathway for gynaecological cancer patients (including Endometrial, Cervical, Ovarian and Vulva cancers). It defines the three strata of follow-up support available to this cohort of patients – supported self-management, face-to-face follow-up and end of life care. It outlines which individuals are eligible for entry onto the supported self-management pathway (SSMP) for their aftercare. The document provides guidelines to ensure that:

- All individuals diagnosed with gynaecological cancer receive personalised information and appropriate support to enable them to live actively and well following the end of their cancer treatment.
- A safe, robust, transparent system is utilised to manage their gynaecological cancer surveillance programme and ongoing care.
- Timely, safe and appropriate systems back into specialist services are in place in the event that a concern arises.
- Each individual is provided with verbal and written guidelines about exactly when and who to contact if they have any concerns in the future and this is shared with the GP.

These guidelines also describe the roles and responsibilities of health professionals within primary and secondary care and the patient across the pathway.

This stratified pathway meets the expectations of the National Cancer Survivorship Initiative and NHS Improvement (Cancer) which are included as references.

2. Stratified Follow-Up: Overview of the pathway

The redesigned stratified follow-up pathway for individuals with gynaecological cancer is outlined in Appendix II. The pathway is described from the point of diagnosis, through treatment until living with and beyond the disease or the transition to end of life care.

The pathway has three strata of follow-up:

- **Supported self-management pathway (SSMP**): Patient led follow-up where the individual receives support and interventions to empower them to self-manage their health. They receive surveillance tests (if applicable) but do not have routine clinic appointments.
- **Face-to-face follow-up:** Clinician led follow-up. Clinic appointments are scheduled as required.
- **Supportive/end of life care services**: Clinician led with palliative care input as required.

Once an individual has finished definitive treatment for their gynaecological cancer, they will be reviewed by the clinical team and stratified onto the supported self-management pathway – or the face-to-face follow-up pathway if they are not eligible/unable to self-manage. This will be recorded on a robust database e.g. Somerset/Infoflex/EPR and the GP will be notified of the intended follow-up regime. They will undergo surveillance on the appropriate pathway (if applicable) for a minimum number of years as per the British Gynaecological Cancer Society guidelines.

Patients who are on the SSMP will be under the care of the hospital however, will not have clinical appointments unless requested. Individuals receiving face-to-face follow-up will be reviewed and their needs for ongoing support by secondary care will be reviewed by a named consultant and / or the Multidisciplinary Team (MDT) if required. Individuals may move between pathways as per their individual and clinical needs. For information on the roles and responsibilities of health professionals, teams, and the patient themselves, please refer to Appendix III.

Not all patients with Gynaecological cancers will be eligible to be moved onto self-supported management at the same timepoint. This will depend on their level of risk and treatment to date.

Please find which cohorts are eligible in the tables below:

Table 1 Guidelines for follow-up in endometrial cancer

Endometrial cancer	Clinic-based follow-up	Telephone follow-up ± blood test	PIFU
Low risk (<10% ROR)	If patient declines PIFU (for maximum of 2 years from end of treatment)	If patient declines PIFU (for maximum of 2 years from end of treatment)	Offer from end of treatment (after holistic needs assessment at 3 months)
Intermediate risk	Can be offered if patient declines PIFU for 2 years from end of treatment	Can be offered if patient declines PIFU for 2 years from end of treatment	Offer from end of treatment or after 2 years for all
High-intermediate risk	For 5 years (either telephone follow-up or clinic follow-up)	For 5 years (either telephone follow-up or clinic follow-up)	Offer from 2 years from end of treatment in place of telephone follow-up or clinic follow-up
High risk	For 5 years (either telephone follow-up or clinic follow-up)	For 5 years (either telephone follow-up or clinic follow-up)	Offer from 2 years from end of treatment in place of telephone follow-up or clinic follow-up

PIFU, patient-initiated follow-up; ROR, risk of recurrence.

Table 2 Guidelines for follow-up in cervical cancer

Cervical cancer	Clinic-based follow-up	Telephone follow-up ± blood test	PIFU
Low risk (<10% ROR) excluding fertility sparing surgery/LLETZ	For 5 years post-completion of treatment	Not suitable	Offer from 2 years from end of treatment
Intermediate risk	For 5 years post-completion of treatment	Not suitable	Not suitable
High risk	For 5 years post-completion of treatment	Not suitable	Not suitable

LLETZ, large loop excision of transformation zone; PIFU, patient-initiated follow-up; ROR, risk of recurrence.

Table 3 Guidelines for follow-up in ovarian cancer

Ovarian cancer	Clinic-based follow-up	Telephone follow-up ± blood test	PIFU
Low risk (<10% ROR, stage 1A/B fully staged) from end of treatment (surgery ± chemotherapy). Excluding fertility sparing surgery	Can be offered if declines PIFU for 2 years from end of treatment	Can be offered if declines PIFU for 2 years from end of treatment	Offer from end of treatment (after holistic needs assessment at 3 months)
FIGO stages 1C–4	For 3 years from end of treatment	Can be offered for years 4-5 from end of treatment	Not suitable

PIFU, patient-initiated follow-up; ROR, risk of recurrence.

Table 4 Guidelines for follow-up in vulval cancer

Options for follow-up	Vulval cancer
PIFU for 5 years from treatment	Not suitable
Remote/telephone ± bloods	Not suitable
Clinic-based follow-up	Follow-up including clinical inspection for at least 5 years from end of treatment

PIFU, patient initiated follow-up.

2.1 Cancer definition of risk

Endometrial:

Low risk endometrial cancer is defined by the European Society of Medical Oncology- European Society of Gynecological Oncology (ESMO-ESGO)guidelines21 as stage 1 of endometrioid, grade 1–2 histology, with ≤50% myometrial invasion, negative for lymphovascular space invasion, and hence not in need of adjuvant treatment.

Intermediate risk endometrial cancer is defined by the ESMO-ESGO guidelines21 as stage I endometrioid, grade 1–2, ≥50% myometrial invasion, and lymphovascular space invasion negative. These patients are commonly offered vaginal brachytherapy, without external beam radiotherapy, following their hysterectomy.

High-intermediate risk endometrial cancer is defined by the ESMO-ESGO guidelines as patients with grade 1–2 tumors with deep (≥50%) myometrial invasion and unequivocally positive (substantial, not focal) lymphovascular space invasion, and those with grade 3 tumors with <50% myometrial invasion regardless of lymphovascular space invasion status. These patients are treated as high risk for the purpose of these guidelines, due to their higher risk of recurrent disease. High-intermediate risk endometrial cancer represents a heterogeneous group of patients, including both endometrioid and non-endometrioid tumor types, such as serous and clear cell, and ranges from stage IB grade 3 (with or without lymphovascular space invasion and with or without nodal staging) to more advanced International Federation of Gynecology and Obstetrics (FIGO) stages. The risk of recurrence is higher for these patients (>20%) and therefore it is suggested that they should be seen in the clinic for at least the first 2 years, as this is the most frequent time for recurrence. After 2 years patients could be offered PIFU for the remaining 3 years. Again, another alternative is telephone follow-up for the remaining 3 years.

Cervical Cancer

Note Exclusions:
Trachalectomy or Patients who have had a hysterectomy for stage 1A1 are also excluded from PIFU.

In low risk patients (FIGO stage 1B1) who have undergone a radical hysterectomy for treatment of cervical cancer the BGCS recommends follow-up in the clinic setting every 3–4 months in the first 2 years, and then PIFU can be offered.

In patients with **intermediate** (risk of recurrence 10–20%) **or high risk** (risk of recurrence >20%) disease, hospital follow-up - to include taking an appropriate history and clinical examination at each visit—should be undertaken to try and detect recurrent disease. This group of patients usually have FIGO stage ≥1B2 although there are other factors that play a role in the likelihood of recurrence, such as lymph node status and lymphovascular space invasion. Hospital follow-up should be undertaken for 5 years, particularly as these patients may have significant treatment-related toxicity.

Ovarian Cancer

Fertility Sparing Surgery Excluded from PIFU
Patients with fully staged 1A/B ovarian cancer (of any grade) have a low risk of recurrence and therefore could be offered PIFU after they have completed their treatment. All other patient's hospital FU for at least 3 years.

3. Eligibility for Entry onto Supported Self-management Pathway

Individuals who meet the criteria in section 2 may be considered for entry onto a supported self-management pathway.

For individuals participating in clinical trials, follow-up will be determined by the clinical trial protocols. However, it may be possible that the patient can still be on a supported self-management pathway in tandem with clinical trial follow up. All individuals taking part in trials will still access and benefit from the end of treatment outpatient appointment (OPA) - and Health and Wellbeing Events.

Patients will have their suitability for entering the supported self-management pathway considered at the last MDT at which they are presented. They will then have suitability confirmed at their end of treatment appointment. Those who are not eligible will be recorded as not appropriate for SSMP on their MDT proforma within the cancer IT system.

For those entering a supported self-management pathway, the patient should have an outpatient appointment to discuss their follow up plan, offered a Holistic Needs Assessment (HNA) and an End of Treatment Summary should be completed. These are then shared with the patient and their GP.

4. Stratified Follow-Up: The Process

4.1 Diagnosis and treatment:

- Following the completion of definitive treatment and review of histology, the MDT will discuss if the individual is eligible for entry onto the supported self-management pathway with agreement from the Consultant in charge of care (utilising the eligibility criteria outlined in section 2 and 3).

- All individuals newly diagnosed with gynaecological cancer will receive information about the treatment they will receive and how they will be supported during and after the end of treatment.

- This will include a description of both face-to-face and supported self-management follow up options with emphasis placed on the fact that they may move between pathways if their needs change during the follow-up period.

- Patients will be offered a holistic needs assessment around diagnosis and when moving onto the supported self-management pathway. These holistic care plans should be shared with the individual's GP.

4.2 End of treatment and follow-up

- At the end of treatment, all individuals will receive an **'End of Treatment OPA'**. This is an appointment between the patient and the Consultant or the Gynaecological CNS in which the individual will have their holistic needs reviewed and they will receive personalised information regarding their follow-up options. This may be a separate appointment from their routine post-operative review. It is recommended that the patient be provided with verbal and/or written information regarding the following:

    - Possible long-term treatment toxicities/consequences of treatment (tailored to their particular treatment)
    - A personal plan for future surveillance monitoring. This will include an explanation of the process for receiving appointments for these tests and the method of results being communicated to them
    - Red flag symptoms that require re-access to the specialist team. Please see list in Appendix III.
    - A holistic needs assessment and care plan (to be shared with GP)
    - A formal end of treatment summary (to be shared with GP)
    - Contact name and phone number of the Gynaecology specialist team and trust helpline
      (if the trust has a helpline)
    - Nutrition and weight
    - Holistic needs care plan and health promotion
    - Signposting to local health and wellbeing services where available
    - Any local self-help groups and useful phone numbers (e.g. Macmillan Cancer Support, Beating Bowel Cancer)

- The decision regarding which pathway they will enter will be formalised within this End of Treatment OPA and will be included in the Treatment Summary generated by the doctor and sent to the patient. Copies of the Treatment Summary will also be sent to the GP and held within the individual's written or electronic hospital notes.

- At the conclusion of the End of treatment OPA, the patient is transferred onto the supported self-management or face-to-face follow-up pathway. They will also be scheduled/offered opportunity to attend a HWBE and/or support group.

- It is recommended that the GP is sent copies of the same information that is given to the patient. This will provide the GP with the required information to enable them to support the individual in the primary care setting.

4.3 Living Beyond Cancer

Individuals who are eligible and choose the **supported self-management pathway (SSMP):**

- Can contact their Gynaecological CNS with any 'red flag' concerns.
- Will not have routine outpatient appointments.
- Will receive surveillance tests as per the Thames Valley Cancer Gynaecological Cancers guidelines for follow up if appropriate.

At any point during the follow-up pathway, individuals may be contacted and offered access to any relevant clinical trials that may become available.

The individuals **who are not eligible for the supported self-management pathway**:

- Will have a schedule of follow-up surveillance tests, and outpatient appointments that are individualised to their diagnosis/needs.
- Will have their eligibility for entry onto the SSMP revisited during each OPA. If a patient persistently does not attend follow-up appointment, this is an opportunity to discuss SSMP as an alternative means of follow-up for them. However, it is possible that this group of patients may be best suited by continued face to face engagement with the treating team to ensure they are not lost to follow up.

4.3.1 Health and Wellbeing Events

All individuals will be offered information on a Health and Wellbeing programme. Health and Wellbeing Events are education and support sessions that aim to provide individuals with the information and confidence they require to enable them to lead as normal and active life as possible after their cancer treatment. HWBEs also increase awareness of local services, supportive care and opportunities that are available to patients and their families.

The Health and Wellbeing events may be delivered as:

- **1:1 appointments** conducted with individuals at the end of treatment
- **Rolling programmes** (such as the 6-weekly Macmillan HOPE events)
- **Group events** which are scheduled at regular intervals throughout the year and which individuals may have an open invitation to attend if they choose to do so. They give opportunity for interaction between patients and carers, clinicians, clinical nurse specialists, allied health professionals, and complementary therapists. These might also include market stalls of local health promotion services or voluntary agencies
- **Virtual events** which may be run by either the Trust or Thames Valley Cancer Alliance and cover a broad range of topics.

It is recommended that the core content of Health and Wellbeing Events is as follows:

- Expert advice on **health promotion** - to minimise risk of recurrence and support healthy living. Specifically this will include: being physically active, nutrition, healthy weight management, and smoking cessation. To include information/support to effect behavioural change.
- **Support** to ensure that individuals have the confidence and skills to manage their condition themselves as far as possible – i.e. referral to rehabilitation and psychological support services and signposting to local support groups or buddying services.
- Advice on **adjusting to life after treatment** – addressing fears of cancer recurrence.
- Information on **signs and symptoms of recurrence** and **potential consequences of treatment**. All events should clearly convey and reinforce the methods to activate fast-track access back into the system if there are any concerns regarding new symptoms or recurrent disease.
- Information and access to **financial and benefits advice.**
- **Specific issues relevant to the individual's type of cancer.**
- **Vocational rehabilitation.**

The end of treatment appointment with the Consultant/CNS may be tailored to fulfil the function of a Health and Wellbeing Event. However, evidence from National Cancer Survivorship Initiative Health and Wellbeing pilot sites revealed that many patients benefited from group sessions[1].
Specifically the pilots demonstrated that:

- The **informal atmosphere** of group events enhanced the delivery of the Health and Wellbeing messages.
- The **combination of using professionals and volunteers at the Health and Wellbeing group sessions** was effective.
- Participants valued the **group discussions** – this assisted to address issues of isolation and to validate what is 'normal' to experience and feel for a person affected by cancer. This differentiates the clinics from traditional forms of follow-up such as outpatient appointments.

4.3.2 Discharge from the Stratified Follow-up Pathway

Discharge occurs following five years from the point of entry onto either the SSMP or face-to-face pathway (or according to local policy).

- **If their results are normal**, they and their GP will receive a letter of discharge to primary care. This will detail if any ongoing surveillance is required as dictated by local policy.
- **If their results are abnormal**, they will be moved to the face-to-face follow-up pathway for further investigations.

5. Surveillance Investigations

All patients will have their surveillance investigations recorded on the cancer IT database. This database will hold the information required to manage follow up investigations - ordering, checking and results recording.

5.1 Surveillance requests will be recorded on the cancer IT database at data entry following diagnosis. All patients will have three years of tests on the anniversary of diagnosis or date of surgery (unless the consultant indicates otherwise)

5.2 A safe and robust system of checking surveillance tests will be developed and implemented. It is recommended that the electronic database generates a monthly list of individuals who require surveillance tests. The test requests will then be made and appointment information sent to the patients. The results are checked by a CNS/Clinician and the patient and GP notified that they are normal. These results will be recorded onto the cancer IT database. Any missing results will be followed up to ensure all patients receive their surveillance test results. Any abnormalities (e.g. signs of reoccurrence or incidental findings) should be acted upon.

5.3 Patients will be informed of their surveillance test schedule from their end of treatment summary letter and their personal surveillance schedule. Patients will be informed to contact the specialist team if they do not receive a request for surveillance by the end of the month that it is due. It is recommended that the trust have a system in place to outline which team members will have the responsibility to resolve issues regarding missed surveillance appointments.

5.4 Other surveillance such as for those at high genetic risk will be recorded and managed on an individual basis.

6. Clinical Governance

Over the duration of the follow-up pathway, the clinical governance responsibility for patients on the face-to-face and supported self-management pathways lies with the named clinician working in conjunction with the MDT (CNS and radiology).

7. Re-accessing Specialist Services as required

All patients and their GPs will be aware of how to access the specialist team if concerns arise. Safe robust systems will be in place to facilitate this.

7.1 Patients and their GPs will have written contact numbers and guidelines regarding concerning symptoms requiring input from the specialist team. Access will be via the Gynaecological CNS during the first five years and thereafter via a GP referral.

7.2 If a patient is on the SSMP and is required to have further investigations following their routine surveillance tests, they will be recalled as per local trust policy. Patients will be informed of this possibility at their end of treatment clinical appointment. Patients on the personalised stratified follow-up pathway will be seen in clinic for a review within two weeks and further investigations ordered as required. It is recommended that trusts identify a clinic for these patients to attend to ensure rapid access when required.

8. Evaluation

8.1 It is recommended that user feedback is conducted by a postal questionnaire (or electronic if patient preference) which is sent to all patients three months following the End of Treatment OPA. The aim of the questionnaire is to establish if patients' needs have been met.

8.2 Baseline measures/process mapping: Establishing baseline measures prior to implementation is critical to enable measurement of improvements at a later date.
Recommended data for collection includes:

- **New cancer diagnosis : Follow up ratios** for Gynaecological patients
- Number of **Surgical** outpatient clinics per week
- Number of **Oncology** outpatient clinics per week
- Number of **cancer patients** seen at each outpatient clinic
- Average number of new **cancer patient** slots per clinic
- Average number of follow-up **cancer patient** slots per clinic
- Number of telephone clinics to follow up cancer patients. Average number of cancer patients reviewed at each telephone clinic.
- Number of virtual clinics to follow up cancer patients. Average number of cancer patients reviewed at each virtual clinic.
- Readmission rates for cancer patients

8.3 On-going measures: Establishing the data collection and measures to be utilised to demonstrate effectiveness also needs to be agreed prior to implementation. Data on all or some of the following would be useful:

- Reduction in outpatient attendances

- Improved patient experience - Patient Reported Experience Measures (PREMS)
- Patient Reported Outcome Measures (PROMS)
- No. of calls to helpline or clinical nurse specialist from patients post treatment
- Cancer waiting times
- Number/ % of Patients with a care plan
- Number/% of Patients who receive a Treatment Summary at end of treatment
- Number of patients enrolled to a supported self-management pathway
- Patients' narratives/stories
- Number/% of patients accessing Health and Wellbeing services/events
- Number/% of missed investigations/appointments
- Measurement of recurrence (however this is multifactorial and may not be dependent on the type of follow up pathway a patient is on)

8.4 It is recommended that measurement of the health related quality of life and wellbeing of gynaecological cancer patients is assessed approximately one year post entry onto the stratified model of follow-up. PROMS tools to consider:

- **EORTC QLQ-C30**
  Description: A questionnaire which assesses the quality of life of cancer patients. It comprises 30 questions which focuses upon functional (physical, cognitive, emotional, and social); specific symptom (fatigue, pain, and nausea and vomiting); global health and quality of life domains. A tumour specific module is also available as required.
  Permissions/Licencing: Permission required. There is no fee for academic use. Permissions obtained via the EORTC website.
  Website: http://groups.eortc.be/qol/eortc-qlq-c30

- **FACT-G:** A general quality of life instrument intended for use with a variety of chronic illness conditions. It assesses the functional status of patients with specific cancer diagnosis. The sub-scales included within the questionnaire are as follows: physical, social/family, emotional, and functional wellbeing. Originally validated in a general cancer population, it has condition-specific subscales to complement it, including one for gynaecological cancer (**FACT-C).**
  Permissions/Licencing: Permission for use is obtained by completing a user agreement on the FACIT website. There is no fee for use of the tool.
  Website: http://www.facit.org/

- **EQ-5D-5L:** A standardised instrument for use as a measure of health-related quality of life and of health outcome. The measure has five dimensions: mobility, self-care, usual activity, pain/discomfort, and anxiety/depression. The instrument comprises two parts: respondents rate their health on the dimensions/levels as well as record an overall assessment of their health on a visual analogue scale.

  Permissions/Licencing: Requires written consent of the EuroQol Executive Office. Registration form able to be completed electronically via the EuroQol website
  Website: https://euroqol.org/

9. Guideline Monitoring

It is recommended that auditing occur three months following the implementation of these guidelines at trust level – and on an annual basis provided there are no significant adjustments required.

10. References

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Appendix I: Definitions

Cancer IT System: The local cancer database (Somerset or Infoflex).

Follow Up Clinician: Consultant/Registrar/ANP or CNS

Eligibility Criteria: An agreed description of the safety and appropriateness of entry onto the supported self-management pathway for individuals with gynaecological cancer.

End of Treatment OPA: The final outpatient appointment with a member of the consultant team and/or the Gynaecological CNS after the individual's treatment is completed.

Face-to-Face Pathway: The follow-up pathway in which individuals with cancer continue to have face-to-face, phone, or email contact with the specialist team as part of continuing follow-up.

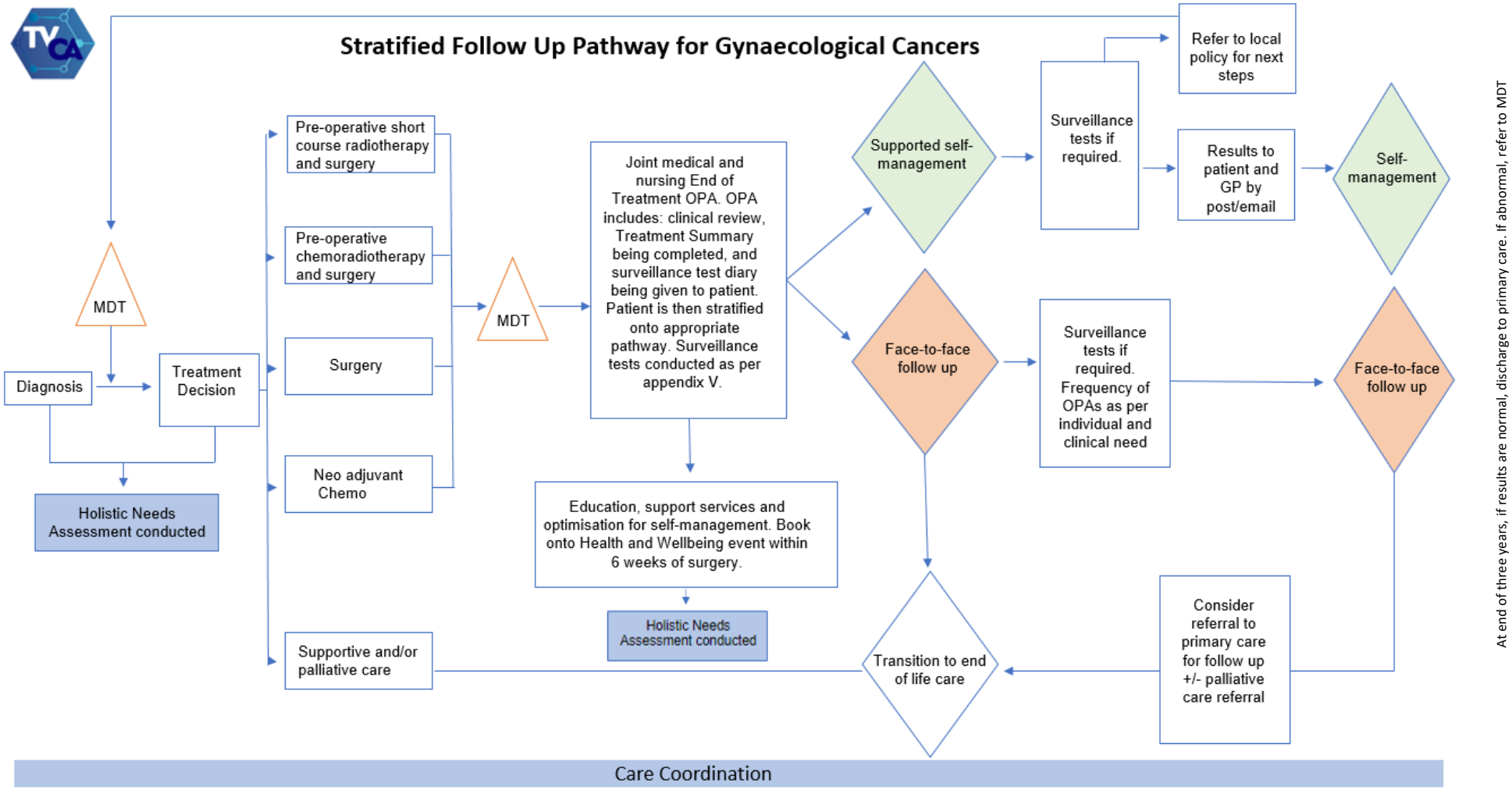
Stratified Follow-up: A model of follow-up in which the clinical team and the person living with cancer make a decision about the best form of aftercare based on the individual's clinical and personalised needs. Individuals enter either a face-to-face pathway or a supported self management pathway.

Patient Initiated Follow-up: a model of follow-up which gives patients and their carers the flexibility to arrange their follow-up appointments as and when they need them. PIFU can be used with patients with long or short-term conditions and following treatment or surgery. Adopting this approach makes it easier and more convenient for patients to receive care and support when they need it, whilst avoiding unnecessary trips to hospitals and clinics, saving them time, money, and stress.

Supported self-management pathway (SSMP): The follow-up pathway in which patients are empowered with the knowledge and skills to self-manage their condition. They are given information about the symptoms to look out for and who to contact if they notice any of these alert symptoms, future scheduled tests, and how to contact the specialist Gynaecological team if they have any concerns. They do not receive any further OPA unless further investigations or support is required.

Treatment Summary: The NCSI Treatment Summary template is completed by the medical team at the end of primary treatment. It includes information on possible treatment toxicities and /or consequences of treatment, signs and symptoms that require referral back to a specialist team, an ongoing management plan, and a summary of information given to the individual about their cancer and future progress and any required GP actions to support the patient. Copies are sent to the GP and provided to the patient when they are discharged.
The treatment summary can be automatically generated on the two main cancer information systems: Somerset and InfoFlex.

Appendix II: Stratified Follow-Up Pathway for Gynaecological Cancer Patients



Appendix III: Alert Symptoms

Symptoms checklist

It is recommended that this is given to all patients as a means of highlighting symptoms that should trigger obtaining advice from the Gynaecological CNS. Much of this can be assessed over the phone, with the patient being asked a detailed history, regarding onset duration, exacerbating and reliving factors and any action already taken. Then given advice +/- signposted to their GP.

However some of these symptoms combined with telephone triage may necessitate an outpatient appointment.

Red flag signs/symptoms

- Vaginal bleeding
- Worsening or persistent abdominal pain
- Weightloss
- Bladder/bowel symptoms