1. Introduction and Who Guideline applies to

This guideline is aimed at clinicians in primary and secondary care looking after patients diagnosed with ovarian and / or adnexal mass. This guideline formalises a guidance through diagnosis and management of patients where an ovarian / adnexal mass has been identified while investigating gynae related symptoms or either as incidental finding.

The contributing roles of Ultrasound (US), CT and MRI will be discussed.

The guidelines are evidence based and will be provided in paper and electronic format.

Legal Liability (standard UHL statement):

Guidelines issued and approved by the Trust are considered to represent best practice. Staff may only exceptionally depart from any relevant Trust guidelines providing always that such departure is confined to the specific needs of individual circumstances. In healthcare delivery such departure shall only be undertaken where, in the judgement of the responsible health professional' it is fully appropriate and justifiable – such decision to be fully recorded in the patient's notes.

Background:

Up to 10% of women will have some form of surgery during their lifetime for the presence of an ovarian mass. In premenopausal women almost all ovarian masses and cysts are benign. The overall incidence of a symptomatic ovarian cyst in a premenopausal female being malignant is approximately 1:1000 increasing to 3:1000 at the age of 50.[1] The lifetime risk of developing ovarian cancer is approximately one in 70. A woman with stage I ovarian cancer has a more than 90% five-year survival rate; however, only 20% of cancers are detected this early.[2]

Almost 21.2% of postmenopausal women will be found with an abnormal ovarian morphology, either simple or complex, if routinely investigated. The greater use of ultrasound and other radiological investigations have led to an increasing proportion of ovarian / adnexal masses to come to the attention of gynaecologists. Ovarian cysts may be discovered either as a result of screening, as a result of investigations performed for a suspected pelvic mass or incidentally following investigations carried out for other reasons. [3]

The further investigation and management of these women has implications for morbidity, mortality, resource allocation and tertiary referral patterns and, hence, provides the need for clear guidelines in this area. Preoperative differentiation between the benign and the malignant ovarian mass can be problematic. [3]

Ten percent of suspected ovarian masses in premenopausal women are ultimately found to be non-ovarian in origin. [4]

The underlying management rationale is to minimise patient morbidity by:

- conservative management where possible
- referral to a gynaecological oncologist where appropriate.

Key Points section:

- Transvaginal pelvic ultrasound scan (TVS) is the gold standard and initiates the pathway to investigate ovarian / adnexal mass in women
- Risk of Malignancy prediction is based on IOTA simple rules for premenopausal women and RMI for post-menopausal women
- The Lead clinician is responsible for following the pathway, managing the women and discussing results with her until a cancer diagnosis is made or case referred and further care is taken over by Gynaecological Oncology Multidisciplinary Team (MDT).
- Gynaecological Oncology MDT co-ordinator will communicate by email the recommendation made by the Gynaecological Oncology MDT for all patient's discussed, the Friday morning after the MDT meeting to the Lead Clinician and patient's own GP.

Related UHL documents:

- Imaging referral guidelines in Gynaecology
- Imaging reporting guidelines in Gynaecology
- Gynaecology guideline: Ovarian Masses in Adolescents

2. Guideline Standards and Procedures

1. A transvaginal pelvic ultrasound scan (TVS) should be performed when an ovarian/ adnexal mass is suspected [B] (N.B. where ovaries are not identified on TVS, a TAS should also be performed).CT, MRI, PET-CT scans are not recommended for initial evaluation of pelvic cysts[1,3].

2. Tumour markers should be assessed when a woman has been diagnosed with an ovarian mass in all postmenopausal women and in all premenopausal women with anything other than simple cysts of maximum diameter <50 mm in premenopausal women [B]

3. IOTA Simple Rules are used to classify premenopausal women with adnexal masses: Ultrasound reporting should clearly state presence or absence of B and / or M features in its conclusion for premenopausal women and lead clinician should classify premenopausal patient according to IOTA simple rules into risk groups and manage appropriately. [B, +2] [8,9,10]

4. Ultrasound reporting should clearly state U score (1 or 3) in its conclusion for postmenopausal women and lead clinician should classify premenopausal patient according to their RMI into a risk group and manage appropriately. [1+] [14,15]

5. Asymptomatic patients classified as Low risk for Malignancy (RMI<200 in post-menopausal or only B features for premenopausal women) should remain under or be referred to a general / benign Gynaecologist Consultant clinic for further management as indicated.

6. Premenopausal women classified as Intermediate risk for Malignancy and postmenopausal patient with complex, multilocular or bilateral masses on USS should undergo MRI pelvis for further characterisation, and have tumour markers (CA125; plus αFP, βhCG, LDH if <40y and non-simple) organised by the named consultant who will follow up results. [B] [17]

7. Patients classified, as Increased risk for Malignancy should be referred to the Gynaecology-Oncology Multidisciplinary Team [3,8] and a staging CT Chest abdomen and pelvis performed.

8. Asymptomatic, Low risk / benign cysts with a max diameter of < 50-70 mm in premenopausal and < 50mm with normal CA125 in post-menopausal women, can be managed conservatively with repeat TVS and Ca125 in 4 - 6 months and follow up clinic appointment to discuss results (good practice). [B][18]

9. Symptomatic cysts or Low risk / benign cysts > 70mm in premenopausal and > 50mm in post-menopausal women, should be offered surgical management. [C][1,3]

10. Women in whom ascites, omental cake and peritoneal disease have been identified on cross-sectional imaging should be directly referred to Gynaecology-Oncology Multidisciplinary Team (flowchart A or B) as per recommendation Seven.

11. When a referral is made to Gynae On-Call (GAU / SpR / Consultant) for an inpatient in a non-gynae ward, it is responsibility of the on-call medic to make the current responsible clinician aware of this guideline and assess patient in person.

12. All children and teenagers (age <18 years old) diagnosed with a suspicious (intermediate or High risk for malignancy) ovarian / adnexal mass after MRI, should be referred to the Gynae Oncology Consultant – Young adults & Paediatric Gynae Cancer Lead (currently Miss E. L. Moss)

13. Pregnant women diagnosed with an ovarian mass should be assessed with pelvic USS using the simple IOTA rules and reviewed in a General Obstetric Clinic within 2 weeks of diagnosis.

Recommendation One:

A transvaginal pelvic ultrasound scan (TVS) should be performed when an ovarian/ adnexal mass is suspected [B] (N.B. where ovaries are not identified on TVS, a TAS should also be performed) CT, MRI, PET-CT scans are not recommended for initial evaluation of pelvic cysts1,3.

- Request of ultrasound scan should include the minimum required clinical information according to "Imaging referral guidelines in gynaecology", such as: Source of referral, Type of US requested, hormonal and menopausal status, *Tamoxifen*, HRT or contraception method, symptoms of pain or bleeding.

- Pattern recognition of specific ultrasound findings can produce sensitivity and specificity especially when performed by experienced clinicians specialising in women's imaging (2++) [5]

- A transvaginal pelvic ultrasound scan (TVS) should be performed when a woman has been diagnosed with an ovarian mass through a different imaging modality such as Computerised Tomography (CT), CT colonogram etc. This will enable a more accurate assessment of the nature of this mass [6]

- Where ovaries are not identified on TVS, a transabdominal (TAS) should be performed to exclude the presence of large masses above pelvic brim. This may be performed before the TVS at the discretion of the gynaecologist/radiologist/Sonographer.

- Transabdominal USS should not be used in isolation; but is useful to provide supplementary information particularly when the cyst is above the pelvic brim or very large *(new 2017)*[3]

Recommendation Two:

Tumour markers should be assessed when a woman has been diagnosed with an ovarian mass in all postmenopausal women and in all premenopausal women with anything other than simple cysts of maximum diameter <50 mm in premenopausal women [B]

- It is recommended that ovarian masses in postmenopausal women should be assessed using Ca125 ONLY[B] [3,6] This allows the calculation of the Risk of malignancy index. CA125 cannot be used in isolation to determine if a cyst is malignant; due to the non-specific nature of the test a normal value does not exclude ovarian cancer[3].

- Premenopausal women with simple cysts (all B features, see recommendation 3) of <50mm diameter do not require Ca125. [B] [1]

- Ca125, Lactate dehydrogenase (LDH), αFP and βhCG should be measured in all women under the age of 40 with a complex ovarian mass due to the possibility of germ cell tumors. [C] [3,6]

- **There is currently not enough evidence to support the routine clinical use of other tumour markers [1,3] namely:**

CEA, CA19.9, HE_4, CDX_2, CA72.4, nor αFP, βhCG, LDH in postmenopausal women.

Tumour markers should be requested depending on USS appearance, age and menopausal status [1,3]

Status	Tumour Markers
Premenopausal, simple cyst <50mm	**None**
Premenopausal, simple cyst ≥50mm	**CA125**
Premenopausal, <40y with complex cyst	**CA125, αFP, βhCG, LDH**
Premenopausal, >40y with complex cyst >30mm	**CA125**
Postmenopausal, Cyst >10mm[3]	**CA125**

Recommendation Three:

IOTA Simple Rules are used to classify premenopausal women with adnexal masses: Ultrasound reporting should clearly state presence or absence of B and or M USS features in its conclusion for premenopausal women and lead clinician should classify premenopausal patient according to IOTA simple rules into a risk group and manage appropriately [8,9,10] [B, 2++]

- There are simple ultrasound rules derived from the IOTA Group. The use of specific ultrasound morphological findings without Ca125 has been shown to have high sensitivity, specificity and likelihood ratios. [B] [3]

- The IOTA Group has published the largest study to date investigating the use of ultrasound in differentiating benign and malignant ovarian masses. Using data derived from the IOTA Group, simple ultrasound rules were developed to help classify masses as benign (B-rules) or malignant (M-rules) (see Table). Using these rules the reported sensitivity was 95%, specificity 91%, positive

likelihood ratio of 10.37 and negative likelihood ratio of 0.06. [2++] [7,11]

- A meta-analysis of centre-specific results stratified for menopausal status of two multicentre cohorts comparing SR and RMI-1 (using a cut-off of 200) showed a pooled sensitivity and specificity in premenopausal women of 0.93 [95% CI 0.84-0.97] and 0.83 [95% CI 0.73-0.90] for SR and 0.44 [95% CI 0.28-0.62] and 0.95 [95% CI 0.90-0.97] for RMI-1. An evidence-based approach to the preoperative characterization of any adnexal mass should incorporate the use of IOTA Simple Rules, particularly for women of reproductive age.[12]

IOTA Group ultrasound simple rules to classify masses as benign (B-rules) or malignant (M-rules)			
B- rules	**Presence**	**M-rules**	**Presence**
Unilocular cyst		Irregular solid tumour	
Solid components <7mm		Ascites	
Acoustic shadowing		At least 4 papillary structures	
Smooth multilocular tumour <100 mm		Irregular multilocular tumour >100 mm	
No internal vascularity		Increased internal vascularity	
Total score B		**Total score M**	

- Premenopausal women with only B features present in their USS are considered: Low risk for malignancy

- Premenopausal women with any M features present in their USS and absent any B feature are considered increased risk for malignancy.

- Premenopausal women with any combination of M and B features in their USS are considered: Intermediate Risk for malignancy [13]

Recommendation Four:

Ultrasound reporting should clearly state U score (0, 1 or 3) in its conclusion for postmenopausal women and lead clinician should classify patient according to their RMI into a risk group and manage appropriately. [1+] [14,15]

- A systematic review of diagnostic studies concluded that the RMI was the most effective for women with suspected ovarian malignancy after the menopause. The RCOG and NICE guidelines on ovarian cancer recommends that for women with suspected ovarian malignancy the RMI score should be calculated and used to guide the woman's management. [1+] [6,14]

Calculating RMI RMI = U (0, 1 or 3) x M (3 post-menopausal) x Ca125 in u/ml		
		presence
USS features	**multilocular**	
	Solid areas	
	ascites	
	bilateral	
	metastases	
U score (**0** if 0, **1** if 1, **3** if 2-5 features present)		

- Postmenopausal women with an RMI < 25 bear a < 3% risk of malignancy
  Postmenopausal women with an RMI > 50 and < 250 bear a 20% risk of malignancy [3]
  Postmenopausal women with an RMI > 250 bear a >75% risk of malignancy [3,16]

- A systematic review of diagnostic studies concluded that the RMI I was the most effective for women with suspected ovarian malignancy. The pooled sensitivity and specificity in the prediction of ovarian malignancies was 78% (95% CI 71–85%) and 87% (95% CI 83–91%) respectively for an RMI score of 200 (Evidence level 1++). **Therefore RMI of 200 will be used to discriminate low to increased risk of malignancy in adnexal masses.**

Recommendation Five:

Asymptomatic patients classified as **Low risk for Malignancy** (RMI<200 in post-menopausal or only B features for premenopausal women) should remain under or be referred to a general / benign Gynaecologist Consultant clinic for further management as indicated.

- Patients should be clinically assessed and managed appropriately. See recommendation 9.

- The use of specific ultrasound morphological findings known as simple ultrasound rules derived from the IOTA Group, without Ca125, has been shown to have high sensitivity, specificity and likelihood ratios for premenopausal women. [B] [3]

Recommendation Six:

Premenopausal women classified as Intermediate risk for Malignancy and postmenopausal patient with complex, multilocular or bilateral masses on USS should undergo MRI pelvis for further characterisation, and have tumour markers (CA125; plus αFP, βhCG, LDH if <40y and non-simple) organised by the named consultant who will follow up results. [B] [17]

- The patient's named consultant will discuss with patient her intermediate risk status and explain need for a further imaging modality. (Good practice)

- Cases classified as benign on MRI abdomen and pelvis will be furthered managed as per Low risk group by remaining under or being referred to a general gynaecologist. [16]

- Cases classified as malignant or unclassified with suspicious features on MRI will be managed as per Increased Risk group by referral to Gynaecology-Oncology Multidisciplinary Team as follows (statement 3 Quality standard NICE) [18]

Recommendation Seven:

Patients classified, as **Increased risk for Malignancy** should be referred to the Gynaecology-Oncology Multidisciplinary Team [3,8] and a staging CT Chest abdomen and pelvis performed.

- Lead clinician's team member should complete Gynaecology-Oncology Multidisciplinary Team referral pro forma (appendix B) and email it to Gynaecology-Oncology Multidisciplinary Team coordinator.

- Cases referred up to Wednesday 12:00 will be discussed in weekly Gynaecology-Oncology Multidisciplinary Team that takes place every Thursday, lunchtime, in Seminar Room at Osborne Building ground floor (LRI). Lead clinician and team members are welcome to attend Gynaecology-Oncology Multidisciplinary Team and highlight potential management issues.

- MDT recommendations are communicated officially, by email and / or fax, back to Lead Clinician (copy to GP) on Friday a.m. by Gynaecology-Oncology Multidisciplinary Team coordinator for further action.

Recommendation Eight

Asymptomatic, Low risk / benign cysts with a max diameter of 50- 70 mm in premenopausal and < 50mm with normal CA125 in post-menopausal women, can be managed conservatively with repeat TVS and Ca125 in 4 - 6 months and follow up clinic appointment to discuss results (good practice). [B][18]

Pre-menopausal women

- < 50 mm simple cyst (all B features) in premenopausal women requires no monitoring or follow-up and can be discharged. [16,18]

- If cyst 50 – 70 mm a further TVS should be arranged after 4 months and if cyst remains unchanged, a repeat USS should be performed annually1. If cyst changes then tumour markers (CA125; plus αFP, βhCG, LDH if <40y if cyst is non-simple) should be repeated and General Gynaecologist should reassess risk category and follow pathway again.

- If woman becomes symptomatic, General Gynaecologist should reassess risk category and follow pathway again.

Post-menopausal women

- < 10 mm simple cyst (U score 0) in postmenopausal women requires no monitoring or follow-up and can be discharged. [3],[16,18]

- If cyst 10 – 50 mm, (U score 0) a further TVS should be arranged at 4 - 6 monthly intervals with CA125 at the same interval for a maximum period of one year. If there are no changes, patient should be reassured and discharged back to the GP. Further routine scans are not warranted unless new symptoms develop.

- If cyst changes or CA125 increases General Gynaecologist should reassess risk category and follow pathway again.

Recommendation Nine

Symptomatic cysts or Low risk / benign cysts > 70mm in premenopausal and > 50mm in post-menopausal women, should be offered surgical management. [C][1,3]

- Patient needs to be clinically assessed and consider risk (co-morbidities, previous surgery, fertility) versus benefit of surgery (risk of torsion, rupture, emergency admission and surgery).
- If patient doesn't wish to proceed with surgical management or surgical risks exceed benefit, then patient should be followed up as per recommendation eight.
- Where infection / sepsis is suspected (Pelvic Inflammatory Disease, Tubo-Ovarian Abscess) appropriate antibiotic treatment should be commenced. [19]
- Where torsion is suspected – urgent surgical intervention is indicated to preserve ovarian function. [20]

Recommendation Ten:

Women in whom ascites, omental cake and peritoneal disease have been identified on cross-sectional imaging should be directly referred to Gynaecology-Oncology Multidisciplinary Team (flowchart A or B) as per recommendation Seven.

Recommendation Eleven:

When a referral is made to Gynae On-Call (GAU / SpR / Consultant) for an inpatient in a non-gynae ward, it is responsibility of the on-call medic to make the current responsible clinician aware of this guideline and assess patient in person.

- If it is a CT report that triggered the referral follow recommendation One and Ten appropriately.
- If it is TVS that triggered the referral follow guideline flowchart A or B

Recommendation Twelve:

All children and teenagers (age <18 years old) diagnosed with a suspicious (**Intermediate or High risk** for malignancy) ovarian / adnexal mass after MRI, should be referred to the Gynae Oncology Consultant – Young adults & Paediatric Gynae Cancer Lead (currently Miss E. L. Moss)

- See separate guideline for Ovarian Mass in Adolescents
- Once cancer is diagnosed, all these cases should be referred to East Midlands Children's and Young Persons' Integrated Cancer Service and Pediatric Cancer MDT [15]

Recommendation Thirteen:

Pregnant women diagnosed with an ovarian mass should be assessed with pelvic USS using the simple IOTA rules and reviewed in a General Obstetric Clinic within 2 weeks of diagnosis.

- Pregnant women with low risk cysts should be informed for the potential risk of torsion and offered surgical treatment, discussing pros and cons of surgery versus conservative management. Ideal timing to perform this type of surgery is 14 – 20 weeks of pregnancy.
- Ca125, αFP and β-hCG should not be checked as their levels are of no diagnostic value during pregnancy.
- Pregnant women with intermediate and high risk ovarian masses should be referred to the Gynae Onc MDT.
- Cysts that have not been managed surgically during pregnancy should be reassessed with TV USS +/- tumour markers depending on cyst appearance, by 6 weeks post-natal. The patient should be seen in a *"Consultant Direct"* appointment in the Gynaecological Assessment Unit which should be organized prior discharge from the Obstetric unit.

3. Education and Training

None

4. Monitoring Compliance

What will be measured to monitor compliance	How will compliance be monitored	Monitoring Lead	Frequency	Reporting arrangements

5. Supporting References (maximum of 3)

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6. Key Words

Adnexal mass, ovarian cyst, pelvic USS, IOTA, RMI

7. Audit:

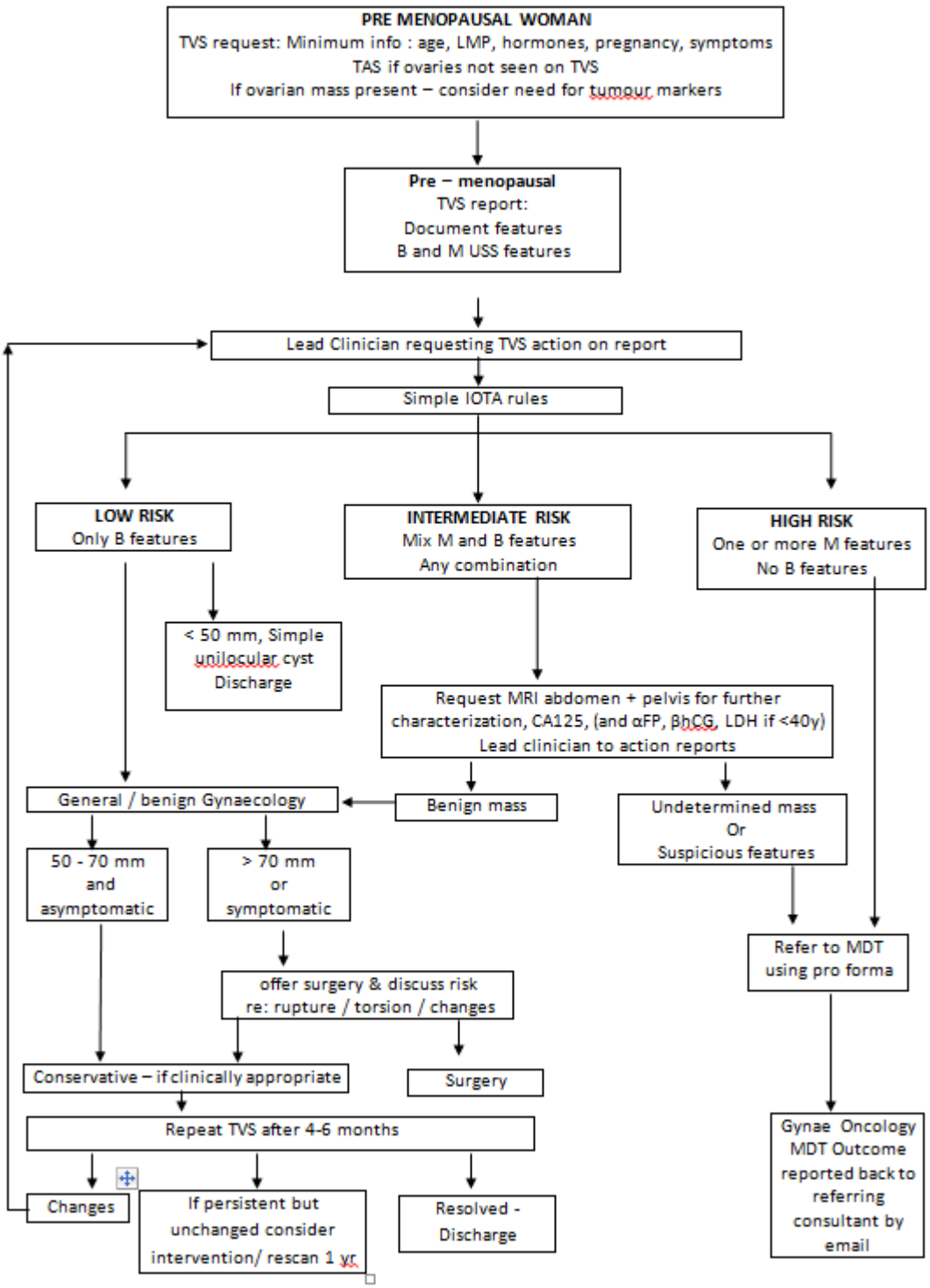
Auditable indicators
• All women < 40 years old have LDH, βhCG and αFP checked prior referral to MDT. (100%) • All women with an ovarian / adnexal mass have Ca125 checked prior referral to MDT. (100%) • All postmenopausal women with an RMI>200 should be referred to Gynae Onc MDT (100%) • All premenopausal women with at least one M feature on USS scan and in the absence of B features should be referred to Gynae Onc MDT (100%) • No premenopausal women with only B features on USS should be referred to Gynae Onc MDT (0%) • No postmenopausal women with an RMI <50 should be referred to Gynae Onc MDT (0%)

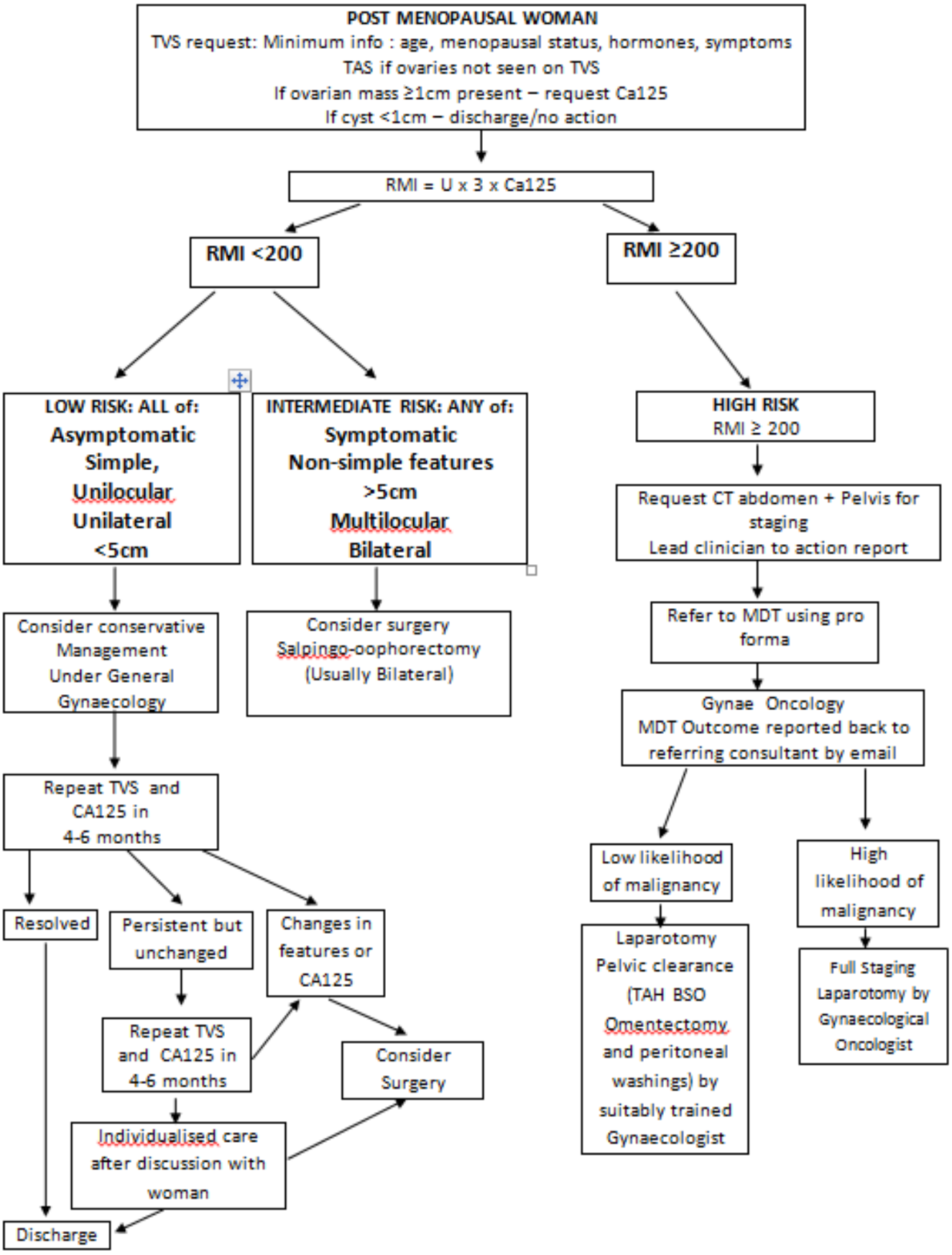
The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs.
As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.

DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT			
Author / Lead Officer:	Eva Myriokefalitaki (Miss Olivia Barney, Dr Yvette Griffin)	**Job Title:** Gynae Oncology Sub Speciality Fellow Trainee	
Reviewed by:	Olivia Barney, Neelam Potdar, Nicola Hartley and Yvette Griffin		
Approved by:	Gynaecology Guidelines and Governance Groups	**Date Approved:**	

REVIEW RECORD			
Date	**Issue Number**	**Reviewed By**	**Description Of Changes (If Any)**
14.11.17	2	Miss O Barney	RMI cut off revised as per RCOG Guidance for post-menopausal women July 2016. Management of Post-menopausal cysts has altered slightly.
07.10.20	3	Olivia Barney, Neelam Potdar, Nicola Hartley and Yvette Griffin	Guideline reformatted. Hyperlinks added to related documents. Otherwise no changes.

DISTRIBUTION RECORD:			
Date	**Name**	**Dept**	**Received**
January 2018	All Gynaecologists and Gynaecology Nurses	Gynaecology	
November 2020	All Gynaecologists and Gynaecology Nurses	Gynaecology	


PRE MENOPAUSAL WOMAN
TVS request: Minimum info : age, LMP, hormones, pregnancy, symptoms
TAS if ovaries not seen on TVS
If ovarian mass present – consider need for tumour markers
Pre – menopausal
TVS report:
Document features
B and M USS features
Lead Clinician requesting TVS action on report
Simple IOTA rules
LOW RISK
Only B features
INTERMEDIATE RISK
Mix M and B features
Any combination
HIGH RISK
One or more M features
No B features
< 50 mm, Simple unilocular cyst
Discharge
Request MRI abdomen + pelvis for further characterization, CA125, (and αFP, βhCG, LDH if <40y)
Lead clinician to action reports
General / benign Gynaecology
Benign mass
Undetermined mass
Or
Suspicious features
50 - 70 mm
and
asymptomatic
> 70 mm
or
symptomatic
Refer to MDT using pro forma
offer surgery & discuss risk
re: rupture / torsion / changes
Conservative – if clinically appropriate
Surgery
Repeat TVS after 4-6 months
Changes
If persistent but unchanged consider intervention/ rescan 1 yr
Resolved - Discharge
Gynae Oncology MDT Outcome reported back to referring consultant by email



Title: Ovarian or Adnexal Mass UHL Gynaecology Guideline
Author: Eva Myriokefalitaki Gynae Onc SST
Contact: Hayley Archer – Clinical Risk and Quality Standards Midwife
Approved by: Gynaecology Governance Group
Trust Ref No: C53/2015
Written: November 2015
Last Review: October 2020
Next Review: October 2023

Appendix A: Referral pro forma to Gynae Oncology MDT

Dear Colleague,
Thank you for referring your patient to the Gynae Oncology MDT. In order to facilitate our review and more appropriate recommendation regarding management of this case, please provide us with the following relevant information and e-mail the form to the Gynae Onc MDT Co-ordinator. (CancerCentreGynaecology@uhl-tr.nhs.uk)
Kind regards
Gynae Onc MDT

Patient Name, Surname	
S-number **DoB:** **Consultant:** **Outpatient / ward admitted**	
Co-Morbidities **Previous Surgeries** **Previous Cancer diagnosis** **Current medication** **BMI** **WHO status**	
Presenting complain /Symptoms **Available imaging** **Tumour markers** **Available / pending cyto/histopathology** **Reason for referral / question**	

Appendix B: Classifications of quality of evidence.

Classification Code	Quality of Evidence	Definition
A	**High**	High-quality diagnostic studies in which a new test is independently and blindly compared with a reference standard in an appropriate spectrum of patients. Systematic review and meta-analyses of such high-quality studies
B	**Moderate**	Studies with a blind and independent comparison of the new test with the reference standard in a set of non-consecutive patients of confined to a narrow spectrum of patients Studies in which the reference standard was not applied to all patients Systematic reviews of such studies
C	**Low**	Studies in which the reference standard was not objective Studies in which the comparison of the new test with the reference standard was not blind or independent Studies in which positive and negative test results were verified using different reference standards Expert opinion

Appendix C: Classification of evidence levels

1++	High-quality meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a very low risk of bias
1+	Well-conducted meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a low risk of bias
1-	Meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a high risk of bias
2++	High-quality systematic reviews of case–control or cohort studies or high-quality case–control or cohort studies with a very low risk of confounding bias or chance and a high probability that the relationship is causal
2+	Well-conducted case–control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal
2-	Case–control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal
3 4	Non-analytical studies, e.g. case reports, case series Expert opinion