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### 1. Introduction and who this guideline applies to:

This guideline aids diagnosis and management of patients where an ovarian / adnexal mass has been identified while investigating gynaecological related symptoms or either as incidental finding in primary and secondary care.

### Related UHL Documents:

- [Imaging referral guidelines in Gynaecology](#)
- [Imaging reporting guidelines in Gynaecology](#)
- [Gynaecology guideline: Ovarian Masses in Children & Adolescents](#)

## **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.<sup>1</sup> 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.<sup>2</sup>

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 are identified. 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.<sup>3</sup>

The further investigation and management of these women has implications for morbidity, mortality, resource allocation and tertiary referral patterns. Preoperative differentiation between the benign and the malignant ovarian mass can be problematic.<sup>3</sup>

Ten percent of suspected ovarian masses in premenopausal women are ultimately found to be non-ovarian in origin.<sup>4</sup>

The underlying management rationale is to minimise patient morbidity by:

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

## **2. Transvaginal pelvic ultrasound**

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) or identified on Computerised Tomography. CT, MRI, PET-CT scans are not recommended for initial evaluation of pelvic cysts<sup>1,3</sup>

- 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<sup>6</sup>
- Where ovaries are not identified on TVS, a transabdominal (TAS) should be performed to exclude the presence of large masses above pelvic brim.
- 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)<sup>3</sup>

## **3. Tumour marker assessment**

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]

- Ovarian masses in postmenopausal women should be assessed using **Ca125 ONLY**[B]<sup>3,6</sup> 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<sup>3</sup>.

- Premenopausal women with simple cysts (all B features, see recommendation 3) of <50mm diameter do not require Ca125. [B]<sup>1</sup>
- Ca125, Lactate dehydrogenase (LDH),  $\alpha$ FP and  $\beta$ hCG 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]<sup>3,6</sup>

**Do not routinely order other tumour markers: CEA, CA19.9, HE4, CDX2, CA72.4, nor  $\alpha$ FP,  $\beta$ hCG, LDH in postmenopausal women.**

**Tumour markers should be requested depending on USS appearance, age and menopausal status<sup>1,3</sup>**

Status	Tumour Markers
Premenopausal, simple cyst <50mm	<b>None</b>
Premenopausal, simple cyst $\geq$ 50mm	<b>CA125</b>
Premenopausal, <40y with complex cyst	<b>CA125, <math>\alpha</math>FP, <math>\beta</math>hCG, LDH</b>
Premenopausal, >40y with complex cyst >30mm	<b>CA125</b>
Postmenopausal, Cyst >10mm <sup>3</sup>	<b>CA125</b>

#### 4. IOTA Simple rules

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<sup>8,9,10</sup>[B, 2++]

<b>IOTA Group ultrasound simple rules to classify masses as benign (B-rules) or malignant (M-rules)</b>			
<b>B- rules</b>	<b>Presence</b>	<b>M-rules</b>	<b>Presence</b>
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	
<b>Total score B</b>		<b>Total score M</b>	

- Premenopausal women with only B features are considered: Low risk for malignancy
- Premenopausal women with any combination of M and B features are considered: Intermediate Risk for malignancy
- Premenopausal women with any M features present in their USS and no B features are considered increased risk for malignancy<sup>13</sup>.

## 5. RMI score

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+] <sup>14,15</sup>

- 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+] <sup>6,14</sup>

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

- ☐ Postmenopausal women with an RMI < 25 carry a < 3% risk of malignancy
- ☐ Postmenopausal women with an RMI > 50 and < 250 carry a 20% risk of malignancy <sup>3</sup>
- ☐ Postmenopausal women with an RMI > 250 carry a >75% risk of malignancy <sup>3,16</sup>

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.**

### 5.1 Asymptomatic low risk for malignancy:

Asymptomatic patients classified as Low risk for Malignancy (RMI<200 in post-menopausal or only B features for premenopausal women with CA125 <200u/ml) should remain under or be referred to a general / benign Gynaecologist Consultant clinic for further management as indicated.

- 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] <sup>3</sup>

### 5.2 Intermediate risk for Malignancy and postmenopausal patient with complex, multilocular or bilateral masses.

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] <sup>17</sup>

- 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 further managed as per Low risk group by remaining under or being referred to a general gynaecologist.<sup>16</sup>
- 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)<sup>18</sup>

### 5.3 Increased risk for Malignancy

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

- Patient's named consultant should complete Gynaecology-Oncology Multidisciplinary Team referral pro forma (appendix B) and email it to Gynaecology-Oncology MDT coordinator at [CancerCentreGynaecology@uhl-tr.nhs.uk](mailto:CancerCentreGynaecology@uhl-tr.nhs.uk).
- Cases referred up to Tuesday 3pm 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 back to patient's named consultant (copy to GP) on Friday a.m. by Gynaecology-Oncology Multidisciplinary Team coordinator for further action.

## 6. Asymptomatic, Low risk / benign cysts management

Asymptomatic, Low risk / benign cysts with a max diameter of 50-70 mm in premenopausal and >10mm and <50mm with normal CA125 in post-menopausal women, can be managed conservatively with repeat TVS and Ca125 in 4 - 6 months and 12 months [B]<sup>18</sup>

### Pre-menopausal women

- < 50 mm simple cyst (all B features) in premenopausal women requires no monitoring or follow-up.<sup>16,18</sup>
- 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 annually<sup>1</sup>. If cyst changes then tumour markers (CA125; plus αFP, βhCG, LDH if <40y if cyst is non-simple) should be repeated and responsible clinician should reassess risk category and follow pathway again.
- If woman becomes symptomatic, responsible clinician should reassess risk category and consider the need for intervention.

### Post-menopausal women

- < 10 mm simple cyst (U score 0) in postmenopausal women requires no monitoring or follow-up and can be discharged.<sup>3,16,18</sup>
- 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 period of one year. If there are no changes, patient should be reassured and surveillance discontinued. Further routine scans are not warranted unless new symptoms develop.
- If cyst changes in nature or CA125 increases, responsible clinician should reassess risk category and follow pathway again.

## **7. Symptomatic cysts or Low risk / benign cysts > 70mm in premenopausal and > 50mm in post-menopausal women**

Symptomatic cysts or Low risk / benign cysts > 70mm in premenopausal and > 50mm in post-menopausal women, unresponsive pelvic abscess or suspected torsion should be offered timely surgical management to reduce morbidity[C]<sup>1,3</sup>

- 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 the most likely diagnosis based on inflammatory markers, clinical findings and imaging (Pelvic Inflammatory Disease, Tubo-Ovarian Abscess) appropriate antibiotic treatment should be commenced<sup>19</sup> and PID management guideline followed. Tumour markers are unreliable in the presence of infection.
- Where patients fail to respond adequately to antibiotics, surgical intervention (drainage or excision of pelvic abscess) must not be withheld even if malignancy cannot be excluded.
- Where torsion is suspected clinically – urgent surgical intervention is indicated to preserve ovarian function.<sup>20</sup> Delay in intervention in cases of unresponsive Pelvic abscess and suspected torsion leads to increased morbidity and loss of ovarian function leading to potential litigation. There is no place for delayed intervention due to unnecessary MDT referral in the absence of frank features of malignancy (omental cake, ascites, extraovarian disease).

## **8. Ascites, omental cake and peritoneal disease**

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 section 5.3

## **9. Gynae On-Call Referral**

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 sections 2 and 5.3 appropriately.
- If it is TVS that triggered the referral follow guideline flowchart A or B

## **10. Children and teenagers (age <18 years old) diagnosed with a suspicious (Intermediate or High risk for malignancy)**

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

- 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<sup>15</sup>



## 11. Pregnant women diagnosed with an ovarian mass

Pregnant women diagnosed with an ovarian mass in the first trimester should be assessed with pelvic USS using the simple IOTA rules and reviewed by the gynaecology consultant on call. Women identified in the second or third trimesters should be seen and assessed in a General Obstetric Clinic within 2 weeks of diagnosis. Follow up USS should be arranged post-natally where needed.

- Simple cysts in the first trimester are most likely to be corpora lutea and theca-lutein cysts and will usually resolve by 14-16 weeks gestation.
- Cysts that persist beyond 16 weeks gestation are more likely to be non-functional such as dermoid cysts or endometriomata.
- Pregnant women with low risk cysts >5cm 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 16 – 20 weeks of pregnancy<sup>22</sup>. Laparoscopic approach is preferred with open entry over the use of a Veress needle. A midline incision is recommended if open surgery is needed. Pre-operative USS will ensure the cyst has not resolved spontaneously negating the need for surgery.
- Ca125,  $\alpha$ FP and  $\beta$ -hCG should not be routinely used as their levels are usually raised in pregnancy so are of limited diagnostic value during pregnancy<sup>22</sup>. USS imaging has greater sensitivity over blood markers in pregnancy.
- Pregnant women with intermediate and high risk ovarian masses on imaging should be referred to the Gynae Onc MDT. The incidence of ovarian malignancy in pregnancy is between 4-8 in 100,000 pregnancies<sup>22</sup>. MRI can be used safely in all trimesters but is only indicated in cases of diagnostic uncertainty.
- Cysts that have not been managed surgically during pregnancy or delivery should be reassessed with TV USS +/- tumour markers depending on cyst appearance, by 6 weeks post-delivery. There is a risk of torsion as the uterus involutes. This should be organised prior discharge from Maternity. Where the cyst has not resolved, follow up should be arranged on GAU if the woman is symptomatic or outpatients if asymptomatic.

## 3. Education and Training

None

## 2. Monitoring Compliance

<u>What will be measured to monitor compliance</u>	<u>How will compliance be monitored</u>	<u>Monitoring Lead</u>	<u>Frequency</u>	<u>Reporting arrangements</u>
<ul style="list-style-type: none"><li>• All women &lt; 40 years old have LDH, <math>\beta</math>hCG and <math>\alpha</math>FP checked prior referral to MDT. (100%)</li></ul>	Audit	Consultant lead	TBC	TBC
<ul style="list-style-type: none"><li>• All women with an ovarian / adnexal mass have CA125 checked prior referral to MDT. (100%)</li></ul>	Audit	Consultant lead	TBC	TBC
<ul style="list-style-type: none"><li>• All postmenopausal women with an RMI&gt;200 should be referred to Gynae Onc MDT (100%)</li></ul>	Audit	Consultant lead	TBC	TBC

<ul style="list-style-type: none"> <li>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%)</li> </ul>	Audit	Consultant lead		
<ul style="list-style-type: none"> <li>No premenopausal women with only B features on USS should be referred to Gynae Onc MDT (0%)</li> </ul>	Audit	Consultant lead		
<ul style="list-style-type: none"> <li>No postmenopausal women with an RMI &lt;50 should be referred to Gynae Onc MDT (0%)</li> </ul>	Audit	Consultant lead		

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## 6. Key Words

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

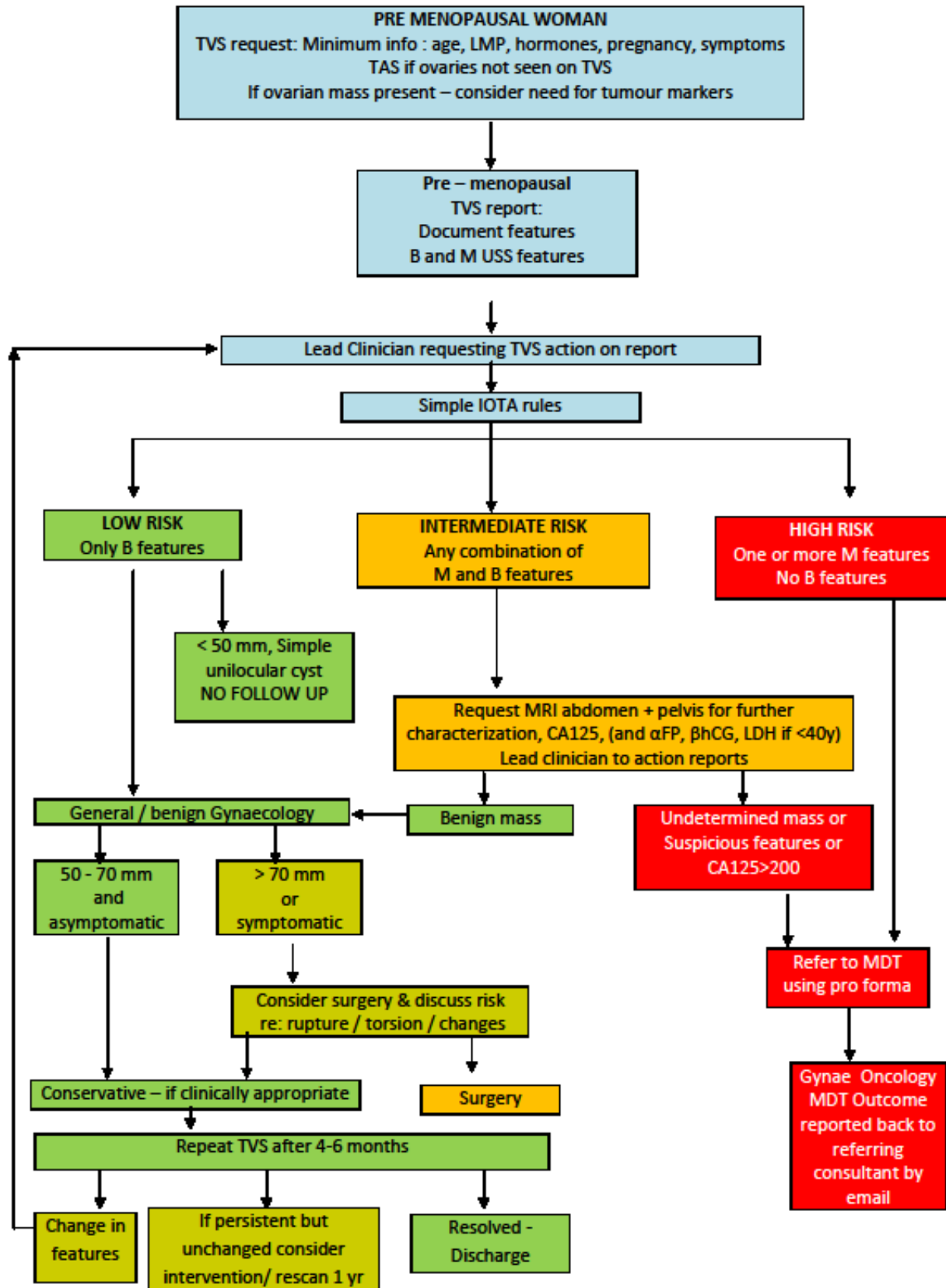
The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs.

As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.

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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.
June 2024	4	Miss Olivia Barney - Consultant Gynaecology Guidelines and Governance Groups	Updated Symptomatic cysts or Low risk / benign cysts > 70mm in premenopausal and > 50mm in post-menopausal women Section 11 Pregnant women diagnosed with ovarian mass section updated Re-formatted and minor word changes throughout

## Flow chart A: Pre-menopausal management



## Flow chart B: Post-menopausal management

