Guidelines & Protocols in OBGY

A Ready Reckoner

1st Trimester Revisited

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Volume 1

Team NOGS 20-21

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Dear Members,

It gives me immense pleasure to release the first volume our **'READY RECKONER - The Guidelines and Protocols in Ob-Gy'**.

In this era of evidence based medicine, it is expected that all treatment modalities be guidelines based. To have a quick access to the standard guidelines and have them well sorted out, we will be releasing this ready reckoner on various essential topics every month.

This **first of its kind and unique attempt** is our small effort to simplify protocols.

With great pleasure we announce the release of its first volume : **'First Trimester Revisited'**. I am sure, this release will be valuable in your daily clinical practice and help in quick amending.

I will fail in my duty if, I don't acknowledge the tremendous efforts and contributions from the Coordinator, Dr. Jayshree Upadhay and Clinical Secretary, Dr. Sumeet Baheti. They have toiled very hard to compile these guidelines for your benefit .

Happy reading ...

Wishing you all Safe and Ethical Clinical Practice ...

Academically yours,

Dr. Vaidehi Marathe

President NOGS - 2020-21

The Team

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FOGSI ICOG Good Clinical Practice Guideline

Basic essential care recommended for all pregnant women

- All pregnant women must be counselled for regular Antenatal visits
- Minimum one visit in first trimester, monthly visits till 30 weeks, every 2 weekly till 36 weeks and weekly visits till delivery.
- Blood investigations for Hb, Blood grouping and Rh Typing, VDRL, Blood sugar - R, and Routine Urine examination with albumin & sugar should be done.
- A repeat Hb and Urine Sugar to be done in third trimester
- Immunization with 2 doses of TT / Td
- Iron, Folic Acid and Calcium Supplements
- At least one Ultrasound for congenital anomalies should be done before 20 weeks of pregnancy
- Delivery by a doctor or a trained birth attendant
- Education on nutrition, diet and hygiene
- Education in breast feeding and birth spacing and contraception methods

Additional care and investigations to be preferably offered if available for routine ante-natal care of normal healthy woman

Besides the basic essential ANC the following should be preferably offered if easily available.

- Preconception counselling and care
- Counselling for HIV, HbsAg and HCV testing
- Counselling and screening for Thalassaemia, Down's syndrome
- Repeat blood for Hb, Blood sugar screening and Urine Evaluation in each trimester
- Ultrasound evaluation once in each trimester
- Institutional delivery recommended
- Additional screening for infections, growth retardation, thyroid dysfunctions

Women centered care and informed decision making

- Pregnant women should have written/pictorial information about antenatal care with stress on diet, anaemia prevention and regular checkups
- Pregnant women should be offered evidence-based information and support to enable them to make informed decisions regarding their care.
- Pregnant women should be informed about the purpose of any screening test before it is performed.
- Antenatal care should be readily and easily accessible to all women and should be sensitive to the needs of individual women and the local community.

Antenatal Appointments

- for routine antenatal care for healthy pregnant women with uncomplicated pregnancies
- **First Appointment** – ideally should be in early pregnancy (prior to 12 weeks)

    - Give information, with an opportunity to discuss issues and ask questions; offer verbal information supported by written information (on topics such as diet and lifestyle considerations, pregnancy care services available, maternity benefits and sufficient information to enable informed decision making about screening tests)
    - Identify women who may need additional care and plan pattern of care for the pregnancy
    - Check blood group and RhD status
    - Offer screening for anaemia, hepatitis B virus, HIV, rubella susceptibility and syphilis
    - Offer screening for asymptomatic bacteriuria

- Offer early ultrasound scan for gestational age assessment as far as possible. Ultrasound scans to determine gestational age using:
  - Crown-rump measurement if performed at 10 to 13 weeks
  - Biparietal diameter or head circumference at or beyond 14 weeks
- Offer screening for Down's syndrome if available
  - Nuchal translucency at 11 to 14 weeks
  - Serum screening
- Weight and BP Record

Remember

First Trimester

- Dating Scan
- Nuchal Transluscency Scan at 11-14 wks
- Double Marker

16 - 20 weeks –

- The next appointment should be scheduled at 16 weeks to review, discuss and document the results of all screening tests undertaken; reassess planned pattern of care for the pregnancy and identify women who need additional care
- Investigate a haemoglobin level of less than 10 g/dl and start iron supplementation
- Measure blood pressure and test urine for proteinuria
- Offer ultrasound screening for structural anomalies (20 weeks)
- For a woman whose placenta is found to extend across the internal cervical os at this time, another scan in third trimester should be offered and the results of this scan reviewed at next appointment

24 - 28 weeks

- Give information with an opportunity to discuss issues and ask questions
- Measure blood pressure and test urine for proteinuria
- Measure and plot symphysis-fundal height
- Offer screening for gestational Diabetes if possible
- Offer a second screening for anemia
- Offer anti-D to rhesus negative women where available and indicated

30-36 Weeks

- Review, discuss and document the results of screening tests undertaken at 28 weeks :
- Measure blood pressure and test urine for proteinuria
- Measure and plot symphysis-fundal height
- Reassess planned pattern of care for the pregnancy and identify women who need additional care

Remember
Second Trimester

- First Trimester screening missed - Quadruple test
- USG for structural Anomalies
- Screening for GDM

36-40 weeks

- Measure blood pressure and test urine for proteinuria
- Measure and plot symphysis-fundal height
- check position of baby
- For women whose babies are in the breech presentation consider external cephalic version where expertise is available or refer to a district hospital for further management
- Review ultrasound scans report if placenta extended over the internal cervical os at previous ultrasound and if needed refer to a district hospital for further management.

After 40 weeks

- For women who have not given birth by 41 weeks - Closer antepartam vigilance
- Measure blood pressure and test urine for proteinuria
- Measure and plot symphysis-fundal height
- Check position of baby
- Review and if needed refer to a district hospital for further management
- Consider induction if inducible and favorable cervix

Additional Antenatal care

1. Underweight (BMI less than 18 at first contact)
2. Obesity (BMI 35 or more at first contact)
3. Extremes of age
4. Anaemia
5. Cardiac disease
6. Hypertension (essential as well as pregnancy induced)
7. Renal disease
8. Thyroid, diabetes and other endocrine disorders
9. Epilepsy requiring anticonvulsant drugs
10. Asthma and other respiratory disorders
11. Hematological disorder
12. HIV or HBV infected
13. Drug use such as heroin, cocaine (including crack cocaine) and ecstasy
14. Autoimmune disorders
15. Psychiatric disorders
16. Malignant disease
17. Women who have experienced any of the following in previous pregnancies -

    - Recurrent pregnancy loss
    - Preterm birth
    - Severe pre-eclampsia, HELLP syndrome or eclampsia
    - Rhesus isoimmunisation or other significant blood group antibodies
    - Uterine surgery including caesarean section, myomectomy or cone biopsy
    - Antepartum or postpartum haemorrhage
    - Previous MRP

Antenatal care for uncomplicated pregnancies - Screening

National Institute of Health and Care Excellence

Pregnant woman Screening	1. Anaemia and blood group	Anaemia – at booking and at 28 weeks Blood group and Rh D status - early pregnancy If Rh D negative – offer partner testing
	2. Infection	Asymptomatic bacteriuria – Mid stream urine culture - Early pregnancy Screening for Hepatitis B Virus Screening for HIV Screening for Syphilis Routine antenatal Screening NOT offered for o Asymptomatic Bacterial vaginosis o Hepatitis C virus o Cytomegalo virus o Toxoplasmosis o Group B Streptococcus
	3. Down's syndrome	Combined test – NT + B HCG + PAPPA - 11 TO 13+ 6 WEEKS For women booking later in pregnancy – Triple or Quadruple test between 15 – 20 weeks Routine anomaly scan – for soft markers – 18 – 20 + 6 weeks
	4. Haemoglobinopathies	Screening for sickle cell disease and thalassemia – In early pregnancy
	5. Structural fetal anomalies	Ultrasound screening between 18 - 20 + 6 weeks
	6. Pre - eclampsia	Blood pressure measurement and urine analysis for protein – at each antenatal visit

Screening for Gestational Diabetes Mellitus

- DIPSI recommends non-fasting Oral Glucose Tolerance Test (OGTT) with 75g of glucose
  - cut-off of plasma glucose of ≥ 140 mg/dl after 2 hours
- WHO recommends a fasting OGTT after 75g glucose
  - cut-off plasma glucose of ≥ 140 mg/dl after 2 hours.

VACCINATION CHART FOR PREGNANT WOMEN

FOGSI INTERNATIONAL WOMEN'S HEALTH SUMMIT				
Vaccine	Before pregnancy	During pregnancy	After pregnancy	No. of doses and route (IM-intramuscular, SC-subcutaneous)
Hepatitis B	Catch up vaccine in those with no history or incomplete vaccination	Yes, if indicated	Yes, if indicated	3 doses (0, 1 and 6 months) IM
Human papillomavirus (HPV)	To be considered if not given earlier. In case of pregnancy next dose to be delayed	No	Recommended immediately postpartum if not immunized earlier	3 doses (0, 1or 2 and 6 months) IM
Influenza (Inactivated)	Yes	Yes	Yes	1 dose, IM
Rubella	Catch up vaccine in those with no history or incomplete vaccination. Pregnancy should be avoided within 3 months of vaccination	No	Recommended immediately postpartum if not immunized earlier	2 dose (0 and 1 month), SC
Tdap	Yes, if indicated	Yes, vaccinate during each pregnancy ideally between 27 and 36 weeks of gestation	Recommended immediately postpartum if not immunized earlier	1 dose, IM
Tetanus	Yes, if indicated	From 2nd trimester	Recommended immediately postpartum if not immunized earlier	1 dose, IM
Varicella	Catch up vaccine in those with no history or incomplete vaccination. Avoid conception for 4 weeks	No	Recommended immediately postpartum if not immunized earlier	2 dose (0 and 1 month), SC

Please Note,

FOGSI recommends immunization against tetanus, diphteria, pertussis and influenza during pregnancy.

4.1 Two doses of tetanus toxoid injection at least 28 days apart are to be given to all pregnant mothers commencing from second trimester. If the subsequent pregnancy occurs within 5 years only one booster is given.

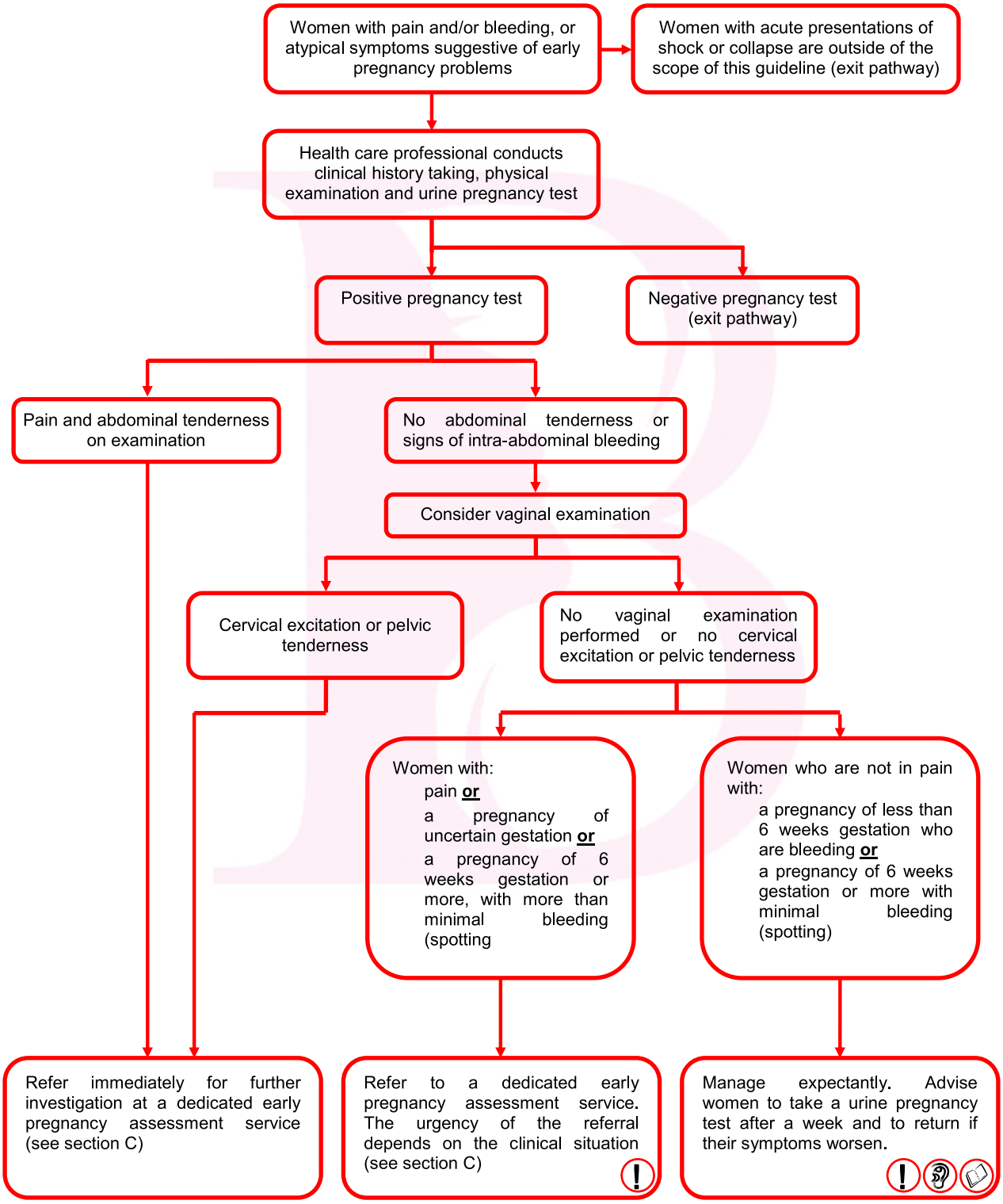
4.2 Tetanus diphtheria acellular pertussis (T-dap) vaccination can be considered instead of the second dose of tetanus toxoid to offer protection against diphtheria and pertussis in addition to tetanus.

4.2.1. The regular pertussis vaccine is contraindicated in pregnancy.

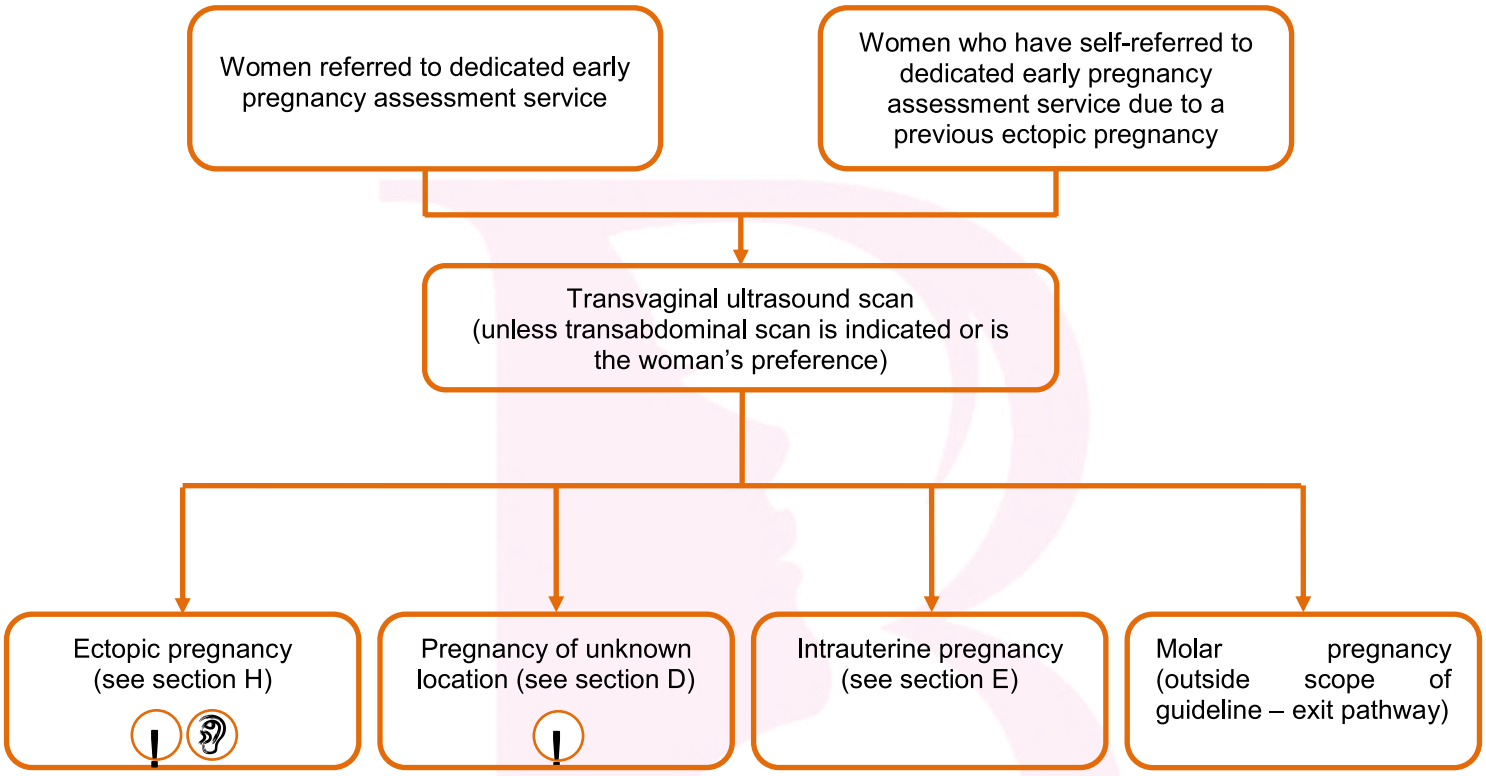
4.2.2. (Tdvac) tetanus and diptheria vaccination can be an alternative if T-dap is not available

National Institute of Health and Care Excellence

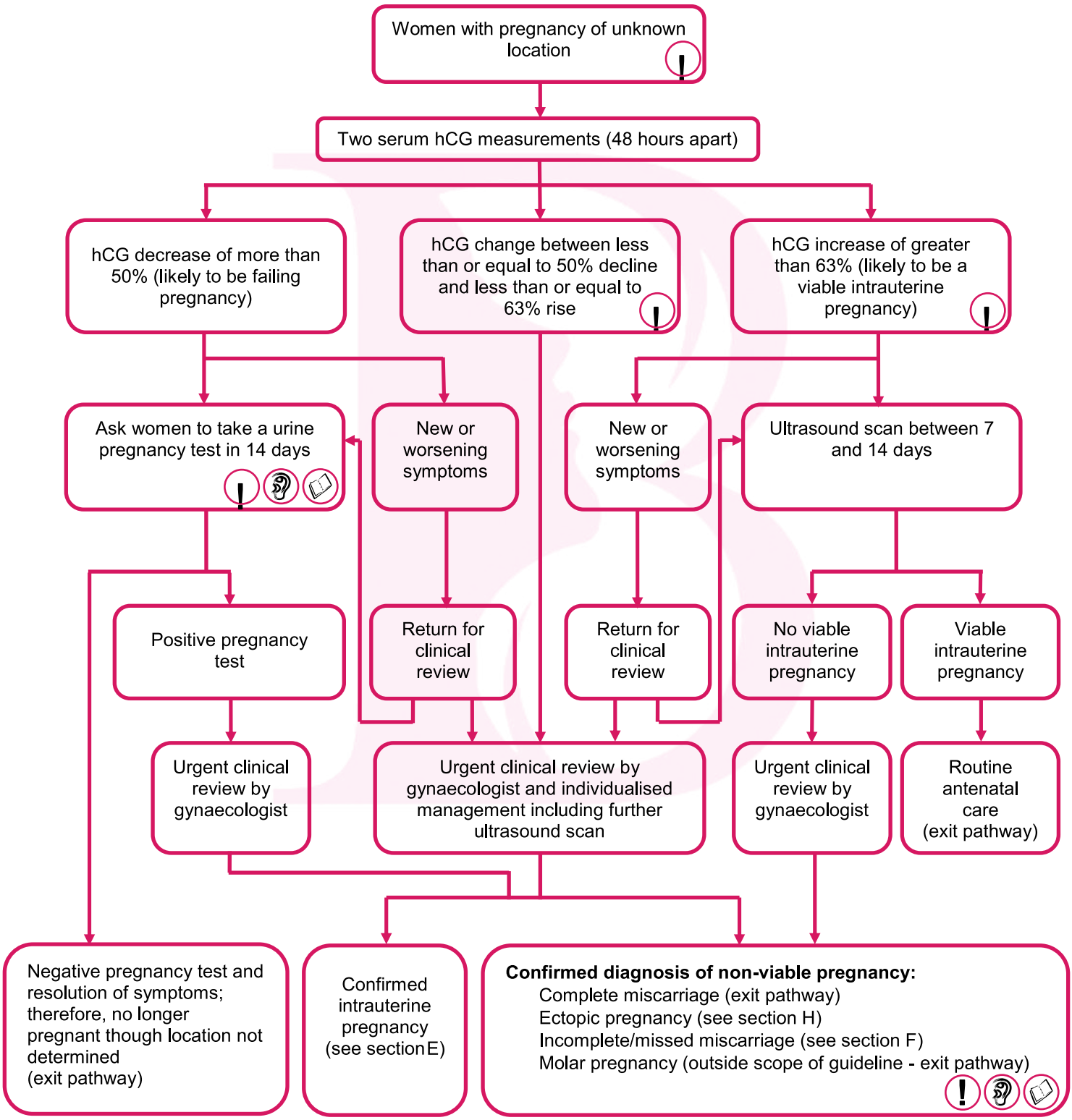
A. Initial clinical assessment



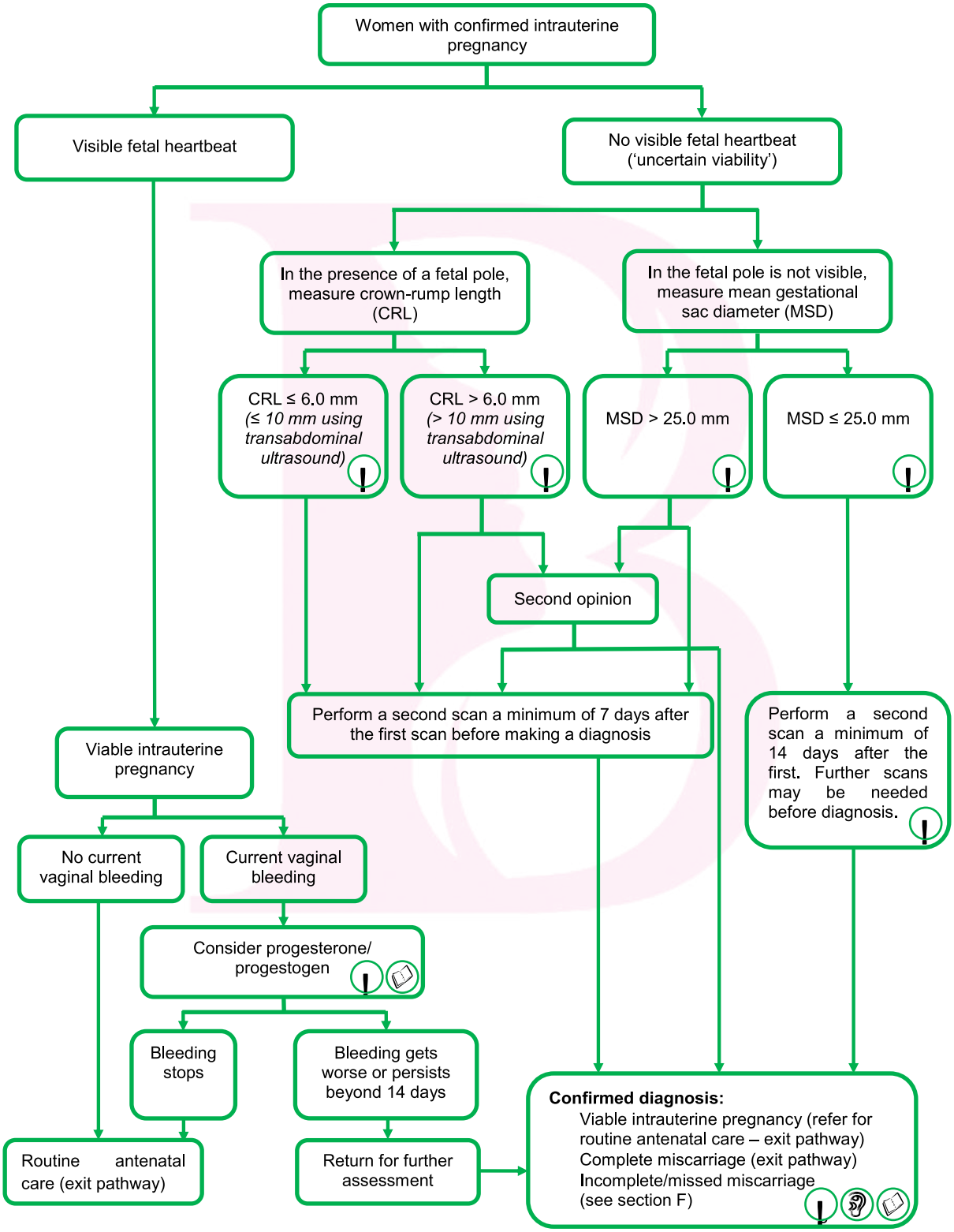
B. Initial ultrasound scan



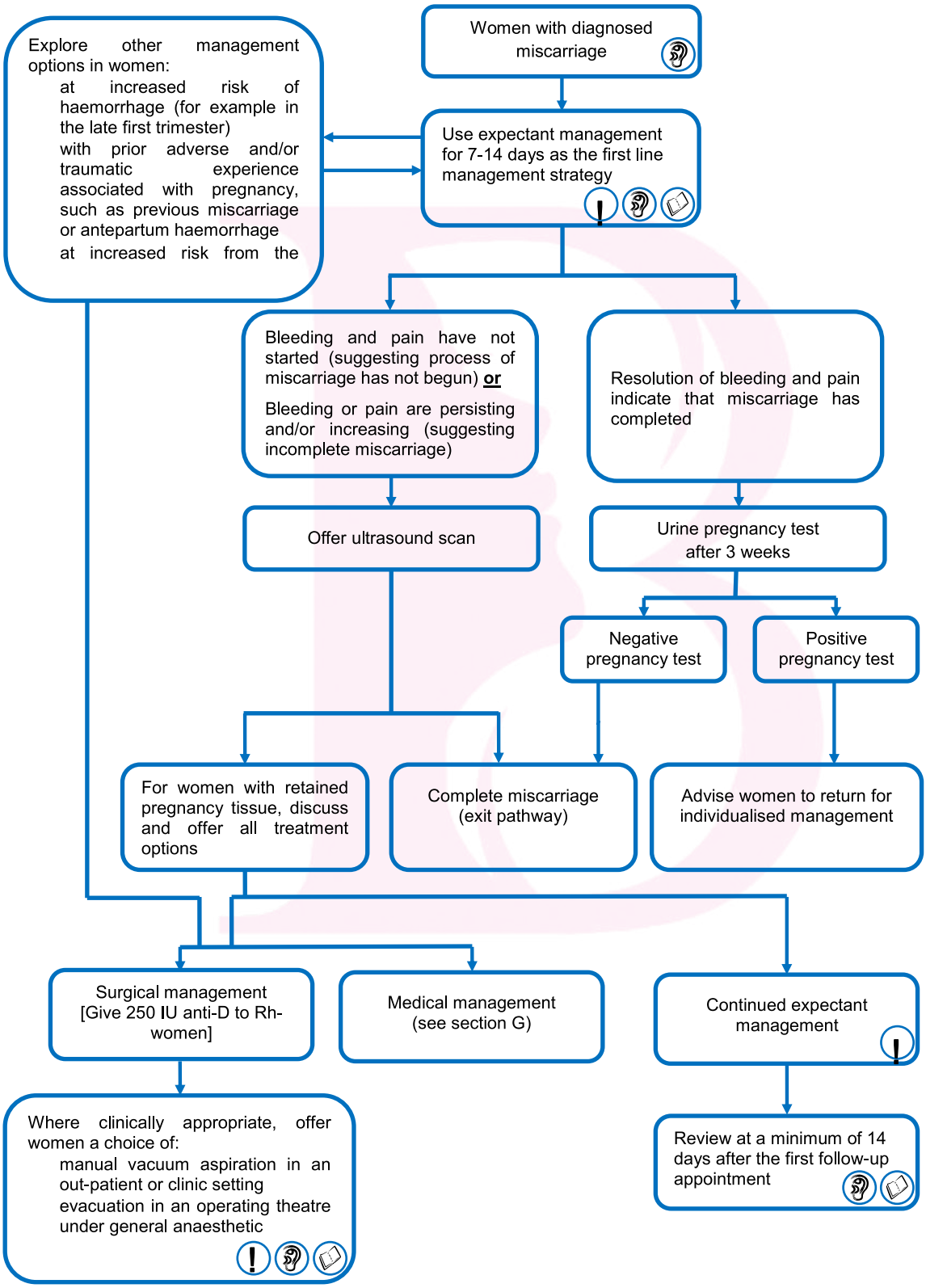
C. Pregnancy of unknown location (PUL)



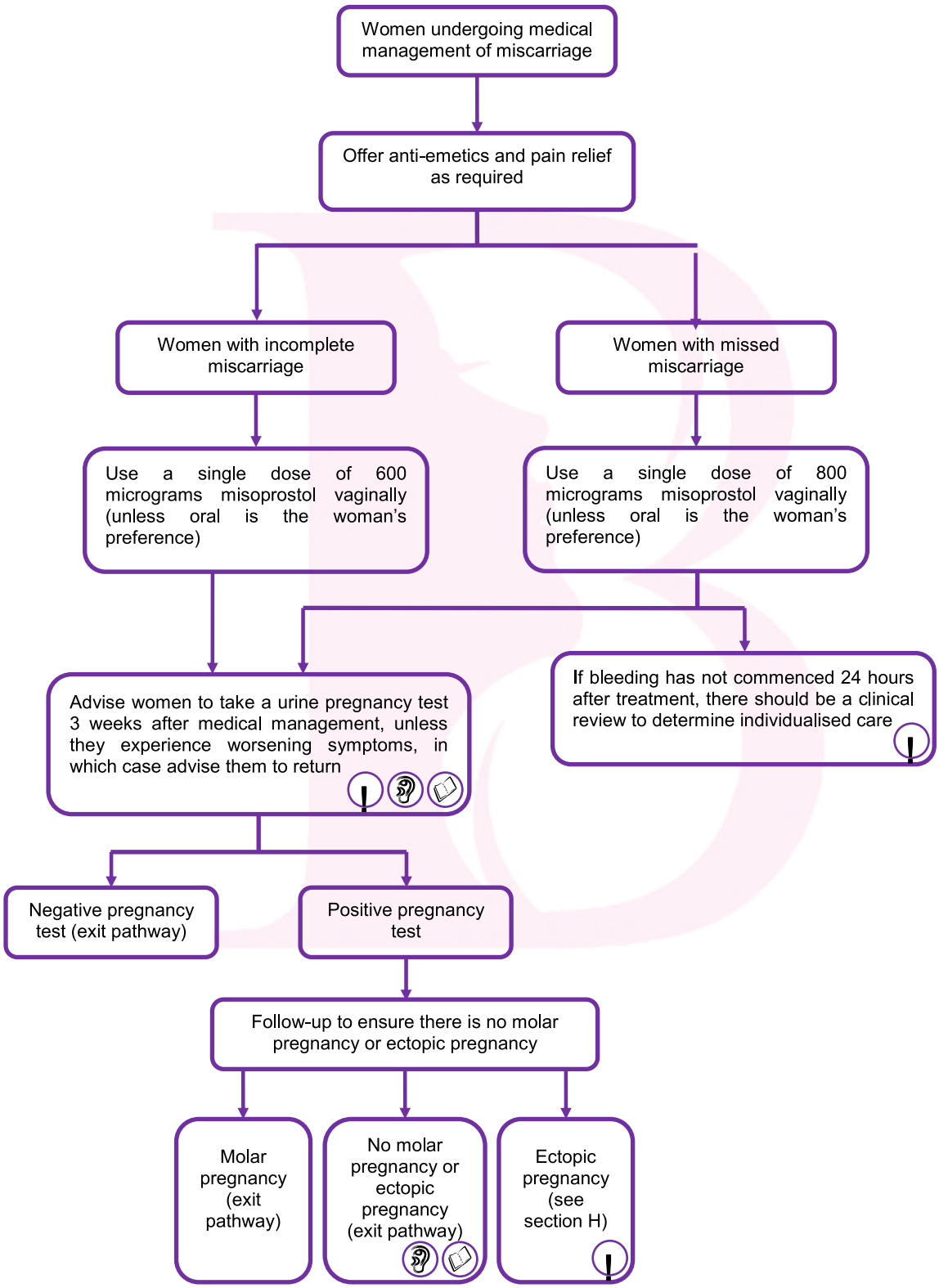
D. Intrauterine pregnancy



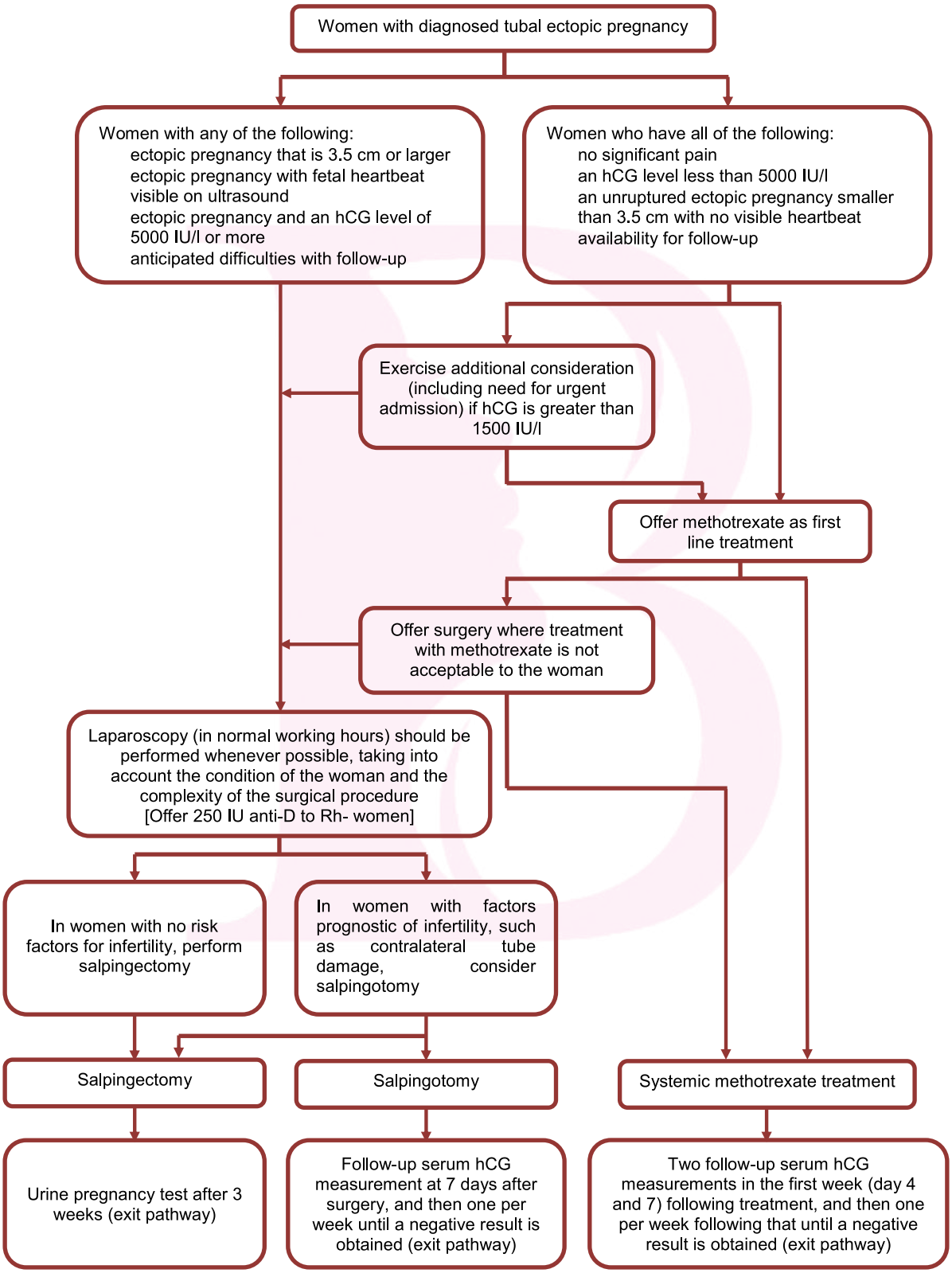
E. Management of miscarriage



F. Medical management of miscarriage



G. Ectopic pregnancy



RCOG Green Top Guideline

- Recurrent miscarriage - loss of three or more consecutive pregnancies,
- Affects 1% of couples trying to conceive

Recommended investigations

- All women with recurrent first-trimester miscarriage and all women with one or more second-trimester miscarriage should be screened before pregnancy for antiphospholipid antibodies.
- Cytogenetic analysis should be performed on products of conception of the third and subsequent consecutive miscarriage(s). Parental peripheral blood karyotyping of both partners should be performed in couples with recurrent miscarriage where testing of products of conception reports an unbalanced structural chromosomal abnormality
- All women with recurrent first-trimester miscarriage and all women with one or more second-trimester miscarriages should have a pelvic ultrasound to assess uterine anatomy. Suspected uterine anomalies may require further investigations to confirm the diagnosis, using hysteroscopy, laparoscopy or three-dimensional pelvic ultrasound
- Women with second-trimester miscarriage should be screened for inherited thrombophilias including factor V Leiden, factor II (prothrombin) gene mutation and protein S.

Treatment options

- Pregnant women with antiphospholipid syndrome should be considered for treatment with low-dose aspirin plus heparin to prevent further miscarriage.
- Neither corticosteroids nor intravenous immunoglobulin therapy improve the live birth rate of women with recurrent miscarriage associated with

antiphospholipid antibodies compared with other treatment modalities; their use may provoke significant maternal and fetal morbidity.

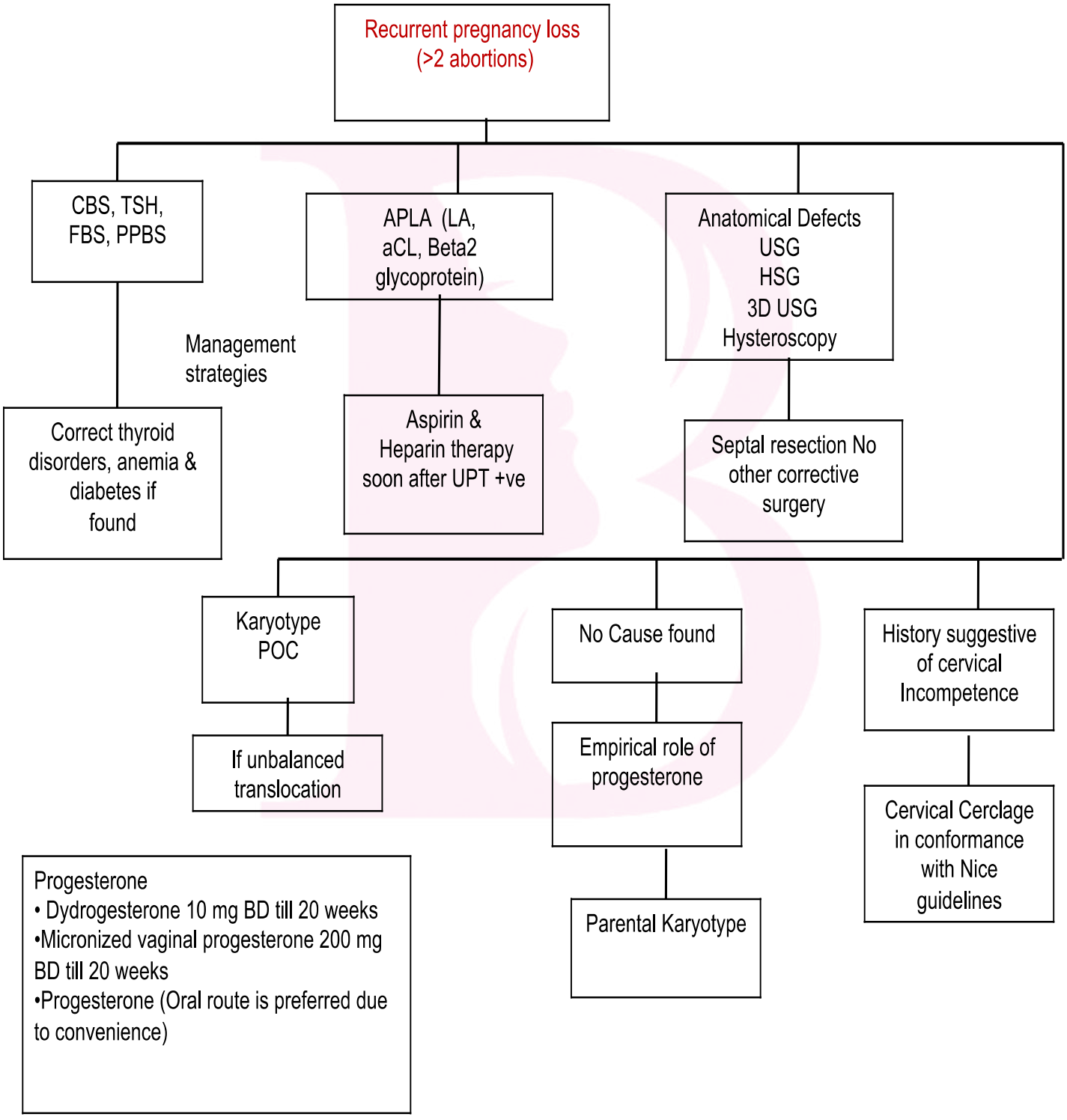
- The finding of an abnormal parental karyotype should prompt referral to a clinical geneticist
- Preimplantation genetic screening with in vitro fertilisation treatment in women with unexplained recurrent miscarriage does not improve live birth rates.
- not undergone a history-indicated cerclage may be offered serial cervical sonographic surveillance. In women with a singleton pregnancy and a history of one second-trimester miscarriage attributable to cervical factors, an ultrasound-indicated cerclage should be offered if a cervical length of 25 mm or less is detected by transvaginal scan before 24 weeks of gestation.

- There is insufficient evidence to evaluate the effect of progesterone supplementation in pregnancy to prevent a miscarriage in women with recurrent miscarriage.
- There is insufficient evidence to evaluate the effect of human chorionic gonadotrophin supplementation in pregnancy to prevent a miscarriage in women with recurrent miscarriage.
- Suppression of high luteinising hormone levels among ovulatory women with recurrent miscarriage and polycystic ovaries does not improve the live birth rate.
- There is insufficient evidence to evaluate the effect of metformin supplementation in pregnancy to prevent a miscarriage in women with recurrent miscarriage.
- Paternal cell immunisation, third-party donor leucocytes, trophoblast membranes and intravenous immunoglobulin in women with previous unexplained recurrent miscarriage does not improve the live birth rate.

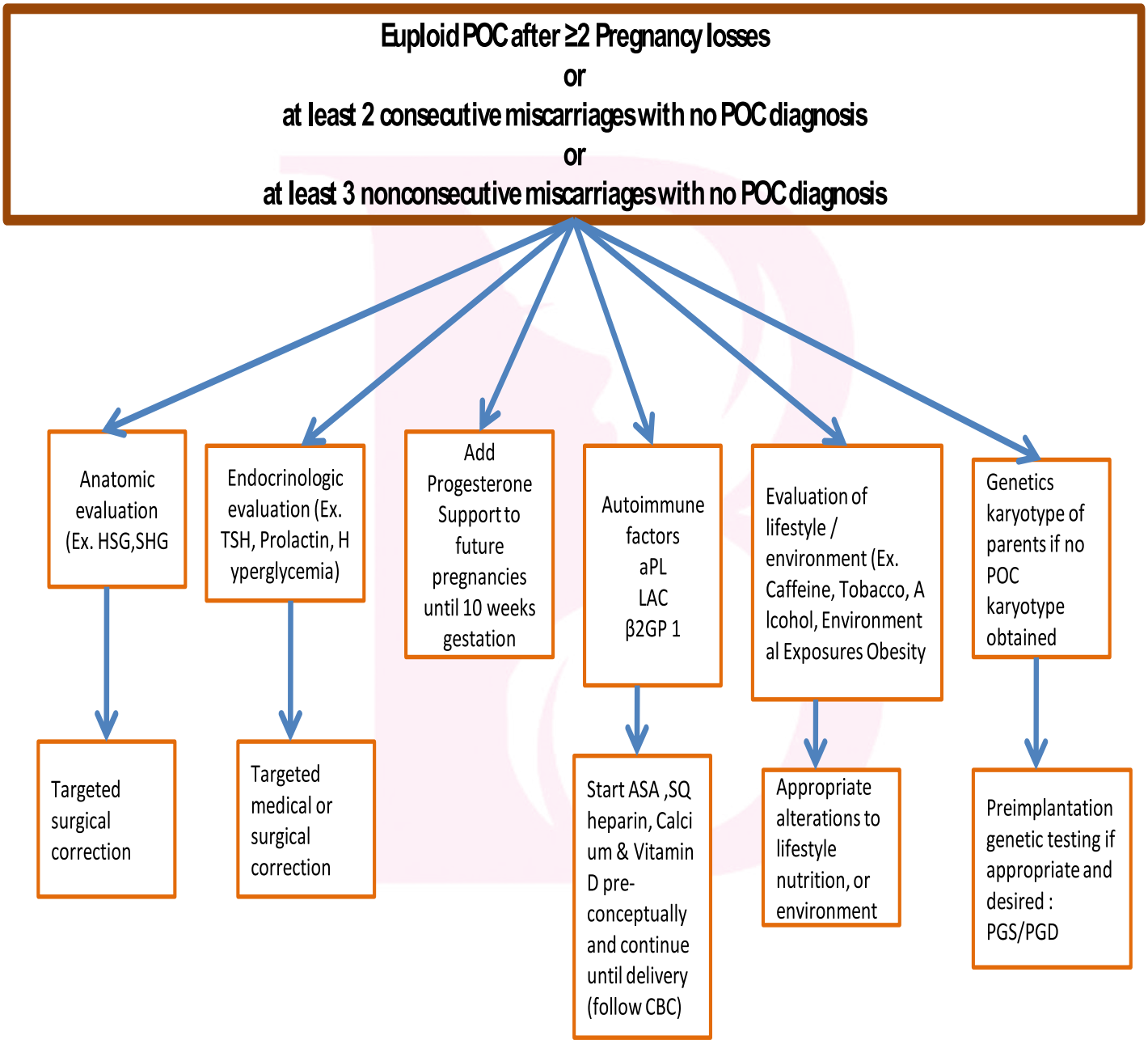
- There is insufficient evidence to evaluate the effect of heparin in pregnancy to prevent a miscarriage in women with recurrent first-trimester miscarriage associated with inherited thrombophilia. Heparin therapy during pregnancy may improve the live birth rate of women with second-trimester miscarriage associated with inherited thrombophilias.

- Women with unexplained recurrent miscarriage have an excellent prognosis for future pregnancy outcome without pharmacological intervention if offered supportive care alone in the setting of a dedicated early pregnancy assessment unit.

The flow charts summarize the causes and required investigations of Recurrent Pregnancy Loss (Courtesy - Dr. Mala Arora)

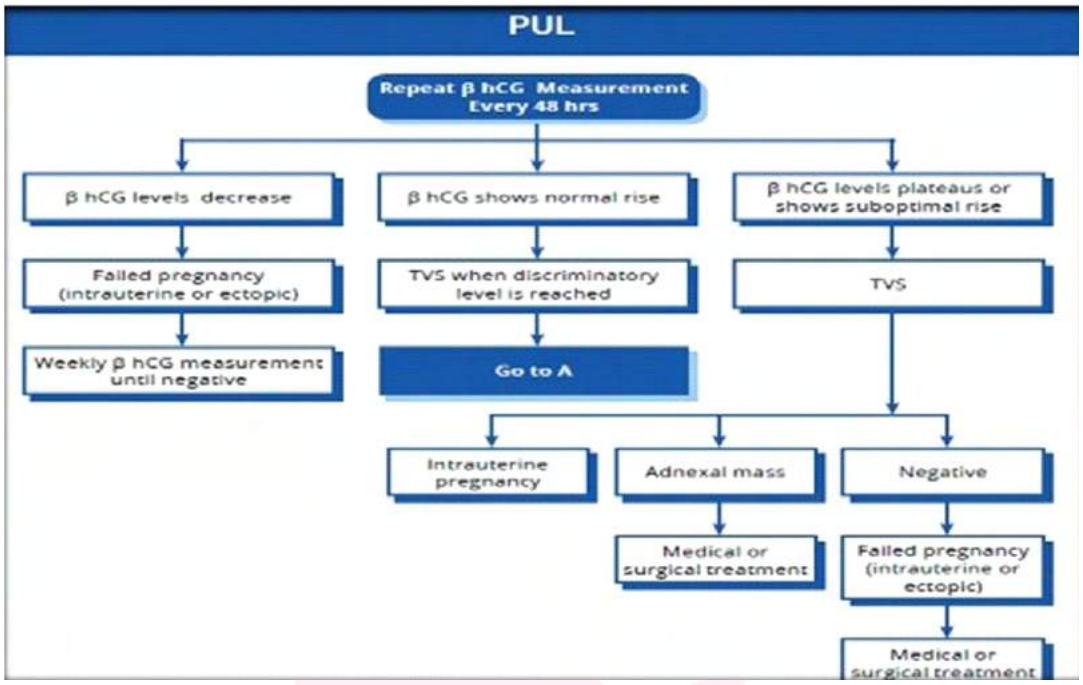


This flowchart summarises the treatment options available once a reason for RPL is identified (Courtesy - Dr. Mala Arora)



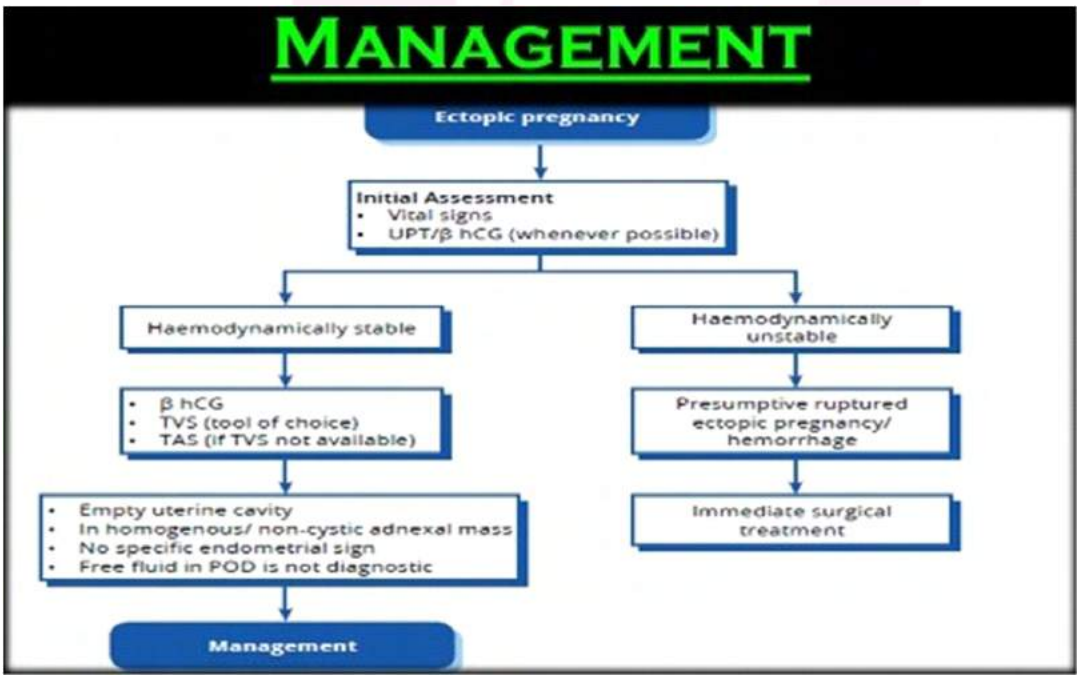
FOGSI TOG Conclave

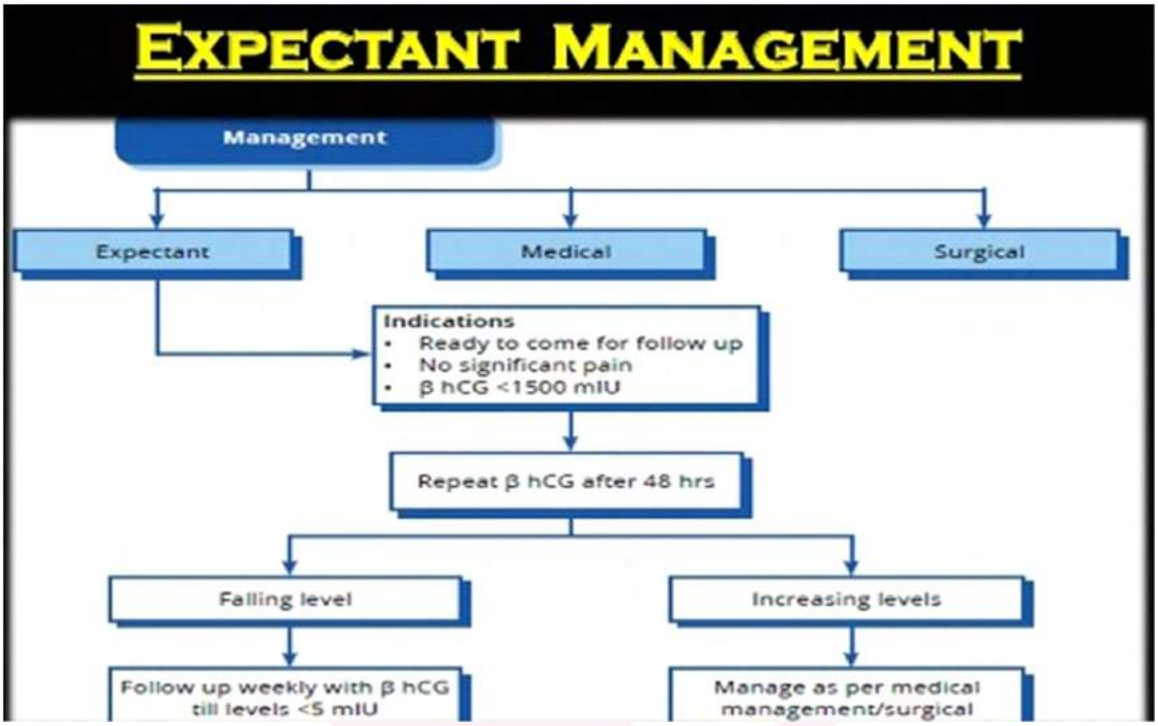
Pregnancy of Unknown location

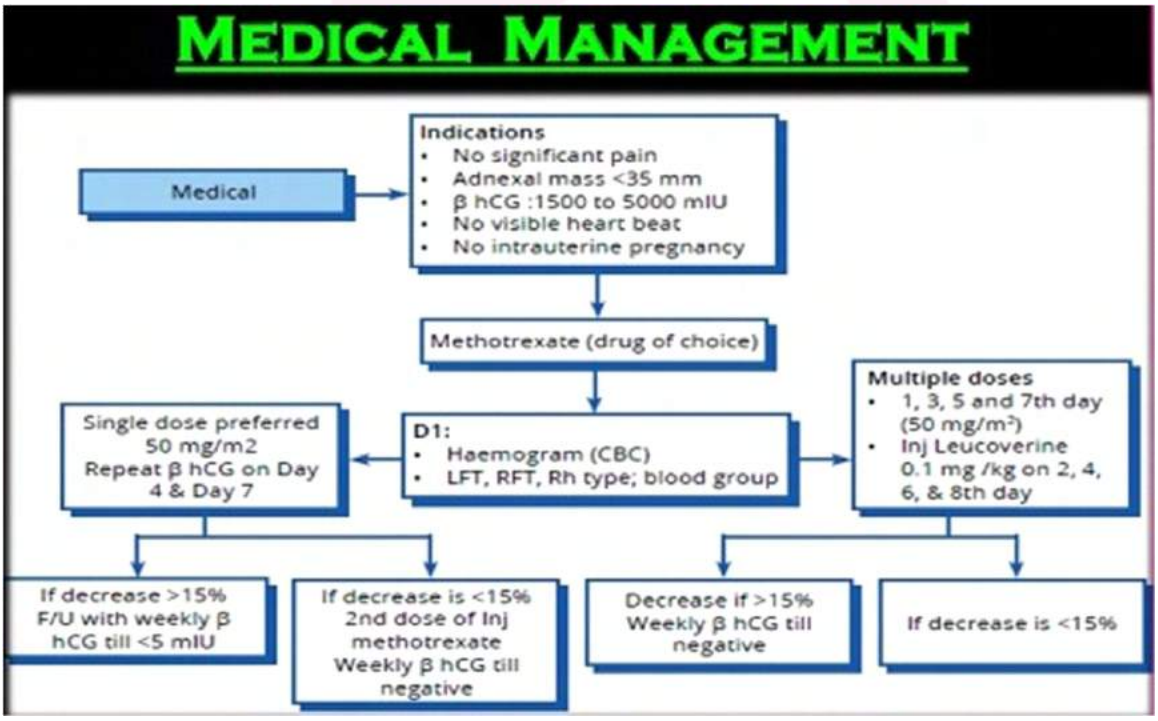


Discriminatory zone – serum hCG level above which a gestational sac should be visualised by ultrasound examination. It is 1500 – 2000 IU/L for TVS.

Management of Ectopic pregnancy




EXPECTANT MANAGEMENT
Management
Expectant
Medical
Surgical
Indications
• Ready to come for follow up
• No significant pain
• β hCG <1500 mIU
Repeat β hCG after 48 hrs
Falling level
Increasing levels
Follow up weekly with β hCG till levels <5 mIU
Manage as per medical management/surgical

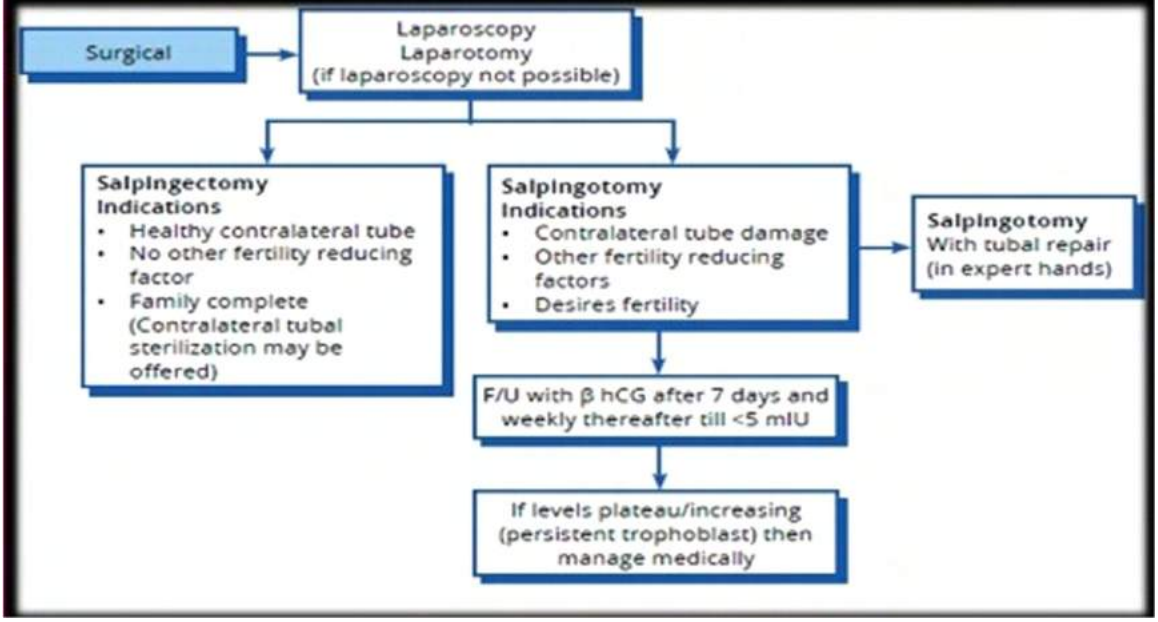

MEDICAL MANAGEMENT
Medical
Indications
• No significant pain
• Adnexal mass <35 mm
• β hCG :1500 to 5000 mIU
• No visible heart beat
• No intrauterine pregnancy
Methotrexate (drug of choice)
Single dose preferred 50 mg/m2 Repeat β hCG on Day 4 & Day 7
D1:
• Haemogram (CBC)
• LFT, RFT, Rh type; blood group
Multiple doses
• 1, 3, 5 and 7th day (50 mg/m²)
• Inj Leucoverine 0.1 mg /kg on 2, 4, 6, & 8th day
If decrease >15% F/U with weekly β hCG till <5 mIU
If decrease is <15% 2nd dose of Inj methotrexate Weekly β hCG till negative
Decrease if >15% Weekly β hCG till negative
If decrease is <15%

MULTIPLE DOSE MTX REGIMEN

Treatment day	Laboratory evaluation	Intervention
Pre-treatment	hCG, CBC with differential, liver function tests, Creatinine, blood type, and antibody screen	Rule out spontaneous abortion RhoGAM if Rh negative
1	hCG	MTX 1.0 mg/kg IM
2		LEU 0.1 mg/kg IM
3	hCG	MTX 1.0 mg/kg IM if <15% decline day 1 – day 3 if >15%, stop treatment and start surveillance
4		LEU 0.1 mg/kg IM
5	hCG	MTX 1.0 mg/kg IM if <15% decline day 3 – day 5 if >15%, stop treatment and start surveillance
6		LEU 0.1 mg/kg IM
7	hCG	MTX 1.0 mg/kg IM if <15% decline day 5 – day 7 if >15%, stop treatment and start surveillance
8		LEU 0.1 mg/kg IM

Note: surveillance every 7 days (until hCG < 5 mIU/mL), screening laboratory studies should be repeated every week after the last dose of MTX, CBC= complete blood count, MTX= methotrexate, IM=intramuscularly, LEU= leucovorin.

SURGICAL MANAGEMENT



RCOG Green Top Guideline

- The classic features of molar pregnancy are irregular vaginal bleeding, hyperemesis, excessive uterine enlargement and early failed pregnancy.
- Ultrasound examination is helpful in making a pre-evacuation diagnosis but the definitive diagnosis is made by histological examination of the products of conception.
- Suction curettage is the method of choice of evacuation for complete molar pregnancies
- Suction curettage is the method of choice of evacuation for partial molar pregnancies except when the size of the fetal parts deters the use of suction curettage and then medical evacuation can be used.
- A urinary pregnancy test should be performed 3 weeks after medical management of failed pregnancy if products of conception are not sent for histological examination.
- Anti-D prophylaxis is required following evacuation of a molar pregnancy
- Preparation of the cervix immediately prior to evacuation is safe - Prolonged cervical preparation, particularly with prostaglandins, should be avoided where possible to reduce the risk of embolisation of trophoblastic cells
- The use of oxytocic infusion prior to completion of the evacuation is not recommended. There is theoretical concern over the routine use of potent oxytocic agents because of the potential to embolise and disseminate trophoblastic tissue through the venous system.
- If the woman is experiencing significant haemorrhage prior to evacuation, surgical evacuation should be expedited and the need for oxytocin infusion weighed up against the risk of tumour embolisation.
- The histological assessment of material obtained from the medical or surgical management of all failed pregnancies is recommended to exclude trophoblastic neoplasia.

- Any woman who develops persistent vaginal bleeding after a pregnancy event is at risk of having GTN. A urine pregnancy test should be performed in all cases of persistent or irregular vaginal bleeding after a pregnancy event.
- In twin pregnancy where there is one viable fetus and the other pregnancy is molar, the woman should be counselled about the increased risk of perinatal morbidity and outcome for GTN. Prenatal invasive testing for fetal karyotype should be considered in cases where it is unclear if the pregnancy is a complete mole with a coexisting normal twin or a partial mole.
- If hCG has reverted to normal within 56 days of the pregnancy event then follow up will be for 6 months from the date of uterine evacuation. If hCG has not reverted to normal within 56 days of the pregnancy event then follow-up will be for 6 months from normalisation of the hCG level.
- All women should notify the screening centre at the end of any future pregnancy, whatever the outcome of the pregnancy. hCG levels are measured 6-8 weeks after the end of the pregnancy to exclude disease recurrence.
- Women with GTN may be treated either with single-agent or multi-agent chemotherapy for GTN. Treatment used is based on the FIGO 2000 scoring system for GTN.
- Women should be advised not to conceive until their follow-up is complete. Women who undergo chemotherapy are advised not to conceive for 1 year after completion of treatment.
- Women who receive chemotherapy for GTN are likely to have an earlier menopause. Women with high-risk GTN who require multi-agent chemotherapy which includes etoposide should be advised that they may be at increased risk of developing secondary cancers.
- Women with GTD should be advised to use barrier methods of contraception until hCG levels revert to normal. Once hCG level have normalised, the combined oral contraceptive pill may be used. Intrauterine contraceptive devices should not be used until hCG levels are normal to reduce the risk of uterine perforation.

FOGSI ICOG Good Clinical Practice Recommendation

Evaluation

- Determining the length of the pregnancy - Bimanual pelvic examination and recognition of other symptoms of pregnancy is usually adequate. Laboratory or ultrasound testing to confirm pregnancy / gestational age is not mandatory but may be used as per the clinician's discretion.
- Investigations- Hemoglobin, blood group, Rh typing, urine sugar and protein testing may be the minimum investigations that are to be performed.

Role of Ultrasound

- It is not mandatory to perform ultrasound before a medical termination of pregnancy.
- There are certain situations where ultrasound may be helpful before, during and after a surgical abortion.
- Ultrasound may be performed for dating a pregnancy with irregular cycles, lactational amenorrhoea, clinical discrepancy or uncertainty in examination and to exclude an ectopic gestation before a medical termination of pregnancy.

Consent for medical termination of pregnancy

- Consent as per form C of the MTP Act is mandatory.
- FOGSI suggests that an informed consent be obtained in a supplementary form.
- An adult woman who is not mentally ill can undergo MTP with only her own consent as provided under the MTP Act.

Medical Methods for Early Abortions

- FOGSI recognises the universal evidence on the effectiveness and safety of combining mifepristone - misoprostol for inducing abortion up to 63 days as approved for use by the Drug Controller of India
- Under existing laws medical methods can only be administered by Gynecologists and Registered Medical Practitioners recognized for performing MTPs by the MTP Act of 1971.
- The current recommendations for medical methods for early abortions are 200 mg mifepristone followed after 36 - 48 hours by 400 micrograms of oral or vaginal misoprostol up to 7 weeks or 800 micrograms of oral or vaginal misoprostol over 7 weeks

Pre- Procedure Priming of Cervix

- It is not mandatory to perform pre procedure priming for all patients. However in selected cases this may be effectively performed with the use of prostaglandins or their analogues.
- FOGSI recommendations - 400 micrograms of oral, sublingual or vaginal misoprostol 2 to 4 hours before the procedure for pre procedure priming of the cervix.
- In exceptional cases mechanical priming may be resorted to and is effective.

Anesthesia for surgical methods for early abortion

- The choice of the anesthesia should be at the discretion of the attending physician provider.
- Local anesthesia is a feasible method of providing pain relief during a surgical MTP.

Surgical Methods for Early Abortion

- Vacuum aspiration, manual or electric is the preferred method of choice for first trimester surgical termination.
- Manual vacuum aspiration and electrical vacuum aspiration are both equally effective.
- Manual aspiration has advantages where maintenance of equipment and reliable source of electricity are not available.
- FOGSI recommends against the routine use of D&C in first trimester terminations. However clinical discretion may be exercised.

Role of Antibiotics

- Routine use of antibiotics at the time of the surgical abortion procedure reduces the risk of post procedural infection.
- While routine use of antibiotics is not mandated with medical methods of abortion their use may be beneficial in nulliparas, in the presence of active vaginal infections and in high risk situations.

Complications of Abortion

- Possible complications include incomplete abortion, hemorrhage, infection, uterine perforation and anesthesia related complications.
- Failure to achieve abortion with continuation of pregnancy though rare can occur in women who have undergone surgical or medical methods of abortion.

Post Abortion Care and Contraception

- Post abortion care should emphasize in providing women with information to recognize early the complications of surgical abortion and instructing them to report early in case of such an event occurring.
- It is equally important to counsel the woman regarding the choice of contraception available.
- All contemporary contraceptive methods both temporary and permanent may be used at or immediately after surgical and medical abortion after confirming acceptance and suitability.
- A follow up visit within 7 days is recommended.
- The patient should report if she misses her periods beyond six weeks after the termination of pregnancy.
- All methods of contraception including intrauterine devices and hormonal contraceptives can be considered for use after abortion.