FEDERATION OF OBSTETRIC AND GYNAECOLOGICAL SOCIETIES OF INDIA

FOGSI

TOG Decision Tree CONCLAVE

ALGORITHMS

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Dydrogesterone Tablets IP 10mg

† Schindler AE. Progestational effects of dydrogesterone *in vitro*, *in vivo* and on the human endometrium. *Maturitas*. 2009;65(1):S3-S11.
* Data on file. ‡ Internal calculations based on Quintiles IMS database, IMS Health Analytics Link MAT03 2017.

Abbreviated Prescribing Information. Dydrogesterone Tablets IP. Duphaston® Composition: Each white film-coated tablet contains: Dydrogesterone IP 10 mg. Excipients q.s. Colour: Titanium dioxide IP. **Indications:** Progesterone deficiencies, Treatment of progesterone deficiencies such as: • Treatment of dysmenorrhoea • Treatment of endometriosis • Treatment of secondary amenorrhoea • Treatment of irregular cycles • Treatment of dysfunctional uterine bleeding • Treatment of pre-menstrual syndrome • Treatment of threatened and habitual abortion • Treatment of infertility due to luteal insufficiency. Hormone replacement therapy - To counteract the effects of unopposed oestrogen on the endometrium in hormone replacement therapy for women with disorders due to natural or surgical induced menopause with an intact uterus. **Dosage and Administration:** Dosages, treatment schedule and duration of treatment may be adapted to the severity of the dysfunction and the clinical response. Dysmenorrhoea: 10 or 20 mg dydrogesterone per day from day 5 to day 25 of the menstrual cycle. Endometriosis: 10 to 30 mg dydrogesterone per day from day 5 to day 25 of the cycle or continuously. Dysfunctional uterine bleeding: When treatment is started to arrest a bleeding episode, 20 or 30 mg dydrogesterone per day is to be given for up to 10 days. For continuous treatment, 10 or 20 mg dydrogesterone per day should be given during the Second half of the menstrual cycle. The starting day and the number of treatment days will depend on the individual cycle length. Withdrawal bleeding occurs if the endometrium has been adequately primed with either endogenous or exogenous estrogen. Secondary amenorrhoea: 10 or 20 mg dydrogesterone per day, to be given daily for 14 days during the second half of the theoretical menstrual cycle to produce an optimum secretory transformation of an endometrium that has been adequately primed with either endogenous or exogenous estrogen. Pre-menstrual syndrome: 10 mg dydrogesterone twice daily starting with the second half of the menstrual cycle until the first day of the next cycle. The starting day and the number of treatment days will depend on the individual cycle length. Irregular cycles: 10 or 20 mg dydrogesterone per day starting with the second half of the menstrual cycle until the first day of the next cycle. The starting day and the number of treatment days will depend on the individual cycle length. Threatened abortion: An initial dose of up to 40 mg dydrogesterone may be given followed by 20 or 30mg per day until symptoms remit. Habitual abortion: 10 mg dydrogesterone twice daily until the twentieth week of pregnancy. Infertility due to luteal insufficiency: 10 or 20 mg dydrogesterone daily starting with the Second half of the menstrual cycle until the first day of the next cycle. Treatment should be maintained for at least three consecutive cycles. Hormone replacement therapy: Continuous sequential therapy: An estrogen is dosed continuously and one tablet of 10 mg dydrogesterone is added for the last 14 days of every 28 day cycle, in a sequential manner. Cyclic therapy: When an estrogen is dosed cyclically with a treatment-free interval, usually 21 days on and 7 days off. One tablet of 10 mg dydrogesterone is added for the last 12-14 days of estrogen therapy depending on the clinical response, the dosage can subsequently be adjusted to 20 mg dydrogesterone per day There is no relevant use of dydrogesterone before menarche. The safety and efficacy of dydrogesterone in adolescents aged 12-18 years has not been established. Currently available data are described in section 4.8 and 5.1, but no recommendation on a posology can be made. **Contraindications:** Known hypersensitivity to the active substance or to any of the excipients. Known or suspected progestogen dependent neoplasms. Undiagnosed vaginal bleeding. Contraindications for the use of estrogens when used in combination with dydrogesterone. **Warnings and Precautions:** Before initiating dydrogesterone treatment for abnormal bleeding, the etiology for the bleeding should be clarified. Breakthrough bleeding and spotting may occur during the first months of treatment. If breakthrough bleeding or spotting appears after some time on therapy, or continues after treatment has been discontinued, the reason should be investigated, which may include endometrial biopsy to exclude endometrial malignancy. **Pregnancy and Lactation:** Pregnancy: It is estimated that more than 10 million pregnancies have been exposed to dydrogesterone. So far there were no indications of a harmful effect of dydrogesterone use during pregnancy. Some progestogens have been reported in the literature to be associated with an increased risk of hypospadias. However due to confounding factors during pregnancy, no definitive conclusion can be drawn regarding the contribution of progestogens to hypospadias. Clinical studies, where a limited number of women were treated with dydrogesterone early in pregnancy, have not shown any increase in risk. No other epidemiological data are hitherto available. Effects in non-clinical embryo-fetal and post-natal development studies were in line with the pharmacological profile. Untoward effects occurred only at exposures which exceeded the maximum human exposure considerably, indicating little relevance to clinical use. Dydrogesterone can be used during pregnancy if clearly indicated. Breastfeeding: No data exist on excretion of dydrogesterone in mother's milk. Experience with other progestogens indicates that progestogens and the metabolites pass to mother's milk in small quantities. Whether there is a risk to the child is not known. Therefore, dydrogesterone should not be used during the lactation period. Fertility: There is no evidence that dydrogesterone decreases fertility at therapeutic dose. **Adverse Reactions:** The most commonly reported adverse drug reactions of patients treated with dydrogesterone in clinical trials of indications without estrogen treatment are migraines/headache, nausea, menstrual disorders and breast pain/tenderness. Undesirable effects that are associated with an estrogen-progestogen treatment : Breast cancer, endometrial hyperplasia, endometrial carcinoma, ovarian cancer • Venous thromboembolism • Myocardial infarction, coronary artery disease, ischemic stroke. Issued on: 3/4/14. Source: Prepared based on full prescribing information (version 03) dated 13/03/2015.

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INDDUST01729B2 02 Nov 2017

President's Message

From the desk of Dr. Rishma Dhillon Pai – President, FOGSI 2017

Dear Colleagues,

It is a matter of pride and honor for me to present to you this 'Times of Gynaecology – Decision Tree'. It started as a thought in my mind, to put together a concise, clear and systematic algorithm on important subjects in obstetrics and gynecology. This has germinated and bloomed into a wonderful publication on eleven different topics being presented to you in a simple systematic format.

75 expert gynecologists from across the length and breadth of India got together for two days and brain stormed in groups and together - to bring out this decision tree. Two days of intense debate, discussions, disagreements and consensus, at the end of which these algorithms were put together. They were further modified and then are being brought to you. These of course are only opinions of our experts and not recommendations or guidelines and are only meant to give you all a systematic flow chart to follow, using your own expertise to make final judgements.

I would like to thank Abbott and Science Integra for felicitating these discussions and helping integrate the entire decision tree.

I hope you enjoy reading this decision tree, as much as we enjoyed putting it together.

"The key to pursuing excellence is to embrace an organic, long-term learning process, and not to live in a shell of static, safe mediocrity. Usually, growth comes at the expense of previous comfort or safety." — Josh Waitzkin

Best wishes!

Dr. Rishma Dhillon Pai

President 2017 - Federation of Obstetrics & Gynaecological Societies of India (FOGSI)
President (Elect- 2018) – Indian Society for Assisted Reproduction (ISAR)
Hon. Gen. Secretary - Indian Association of Gynaecological Endoscopists (IAGE)
Hon. Gen. Secretary- Mumbai Obstetrics and Gynaecological Society
Board Member - World Endometriosis Society (WES)

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TOG Decision Tree CONCLAVE

LUTEAL PHASE SUPPORT IN INTRAUTERINE INSEMINATION

Moderators : Dr. Nandita Palshetkar, Dr. Pratap Kumar
Panel Members : Dr. Jayam Kannan, Dr. Charumati Pekhale, Dr. Sunita Arora, Dr. Pritimala Gangurde, Dr. Anu Chawla

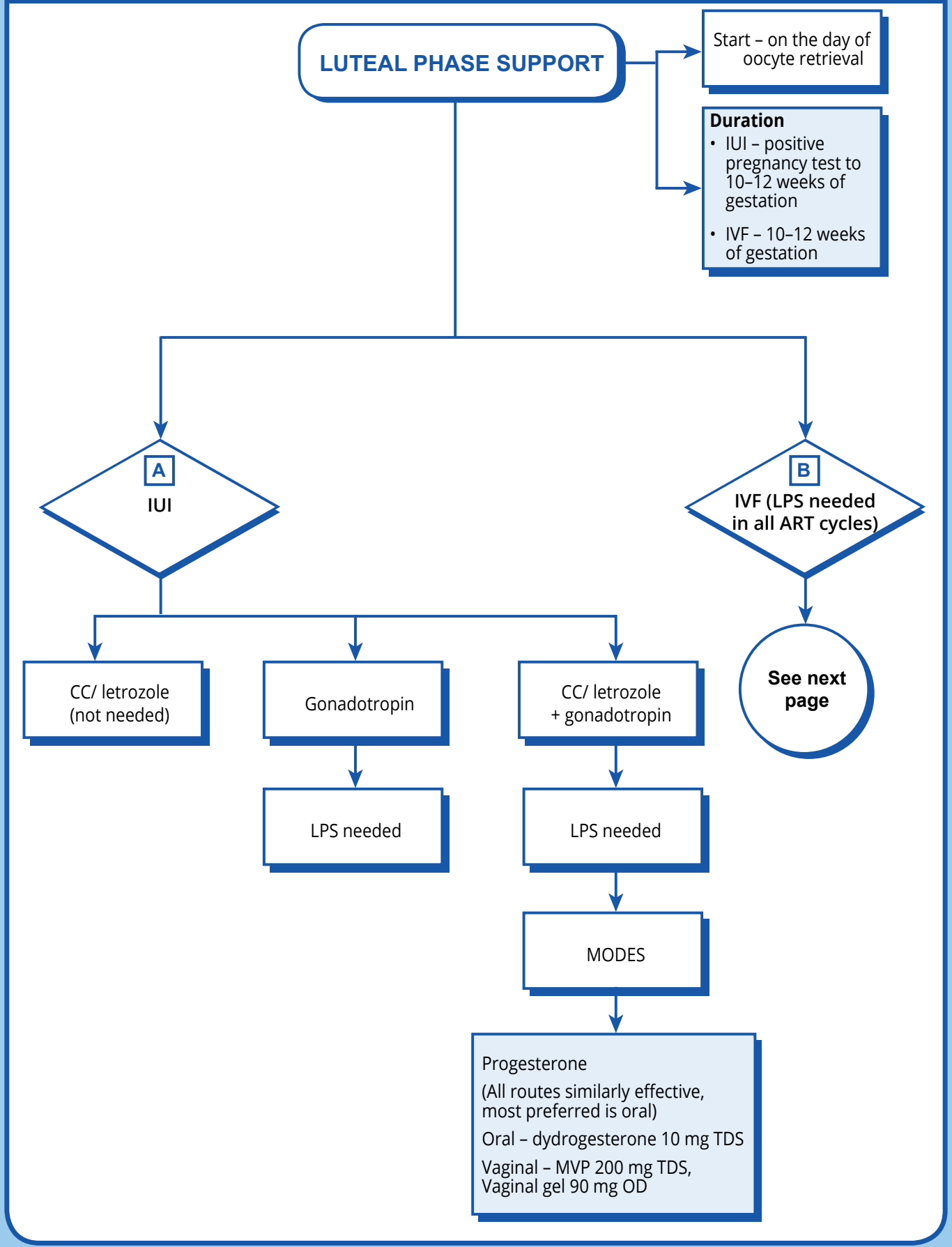
Preface

Intrauterine insemination (IUI) enhances the probability of pregnancy in sub fertile couples. The success of IUI depends on various factors including quality of the luteal phase; and deficiency in this phase is associated with insufficient production of progesterone that is essential for embryo implantation and maintenance of early pregnancy. The clinical conditions that manifest as luteal phase deficiency (LPD) status are stress, polycystic ovary syndrome (PCOS), aging, ovulation stimulation, ovulation induction with or without gonadotropin releasing hormone (GnRH) agonists, and assistant reproductive technologies (ART).

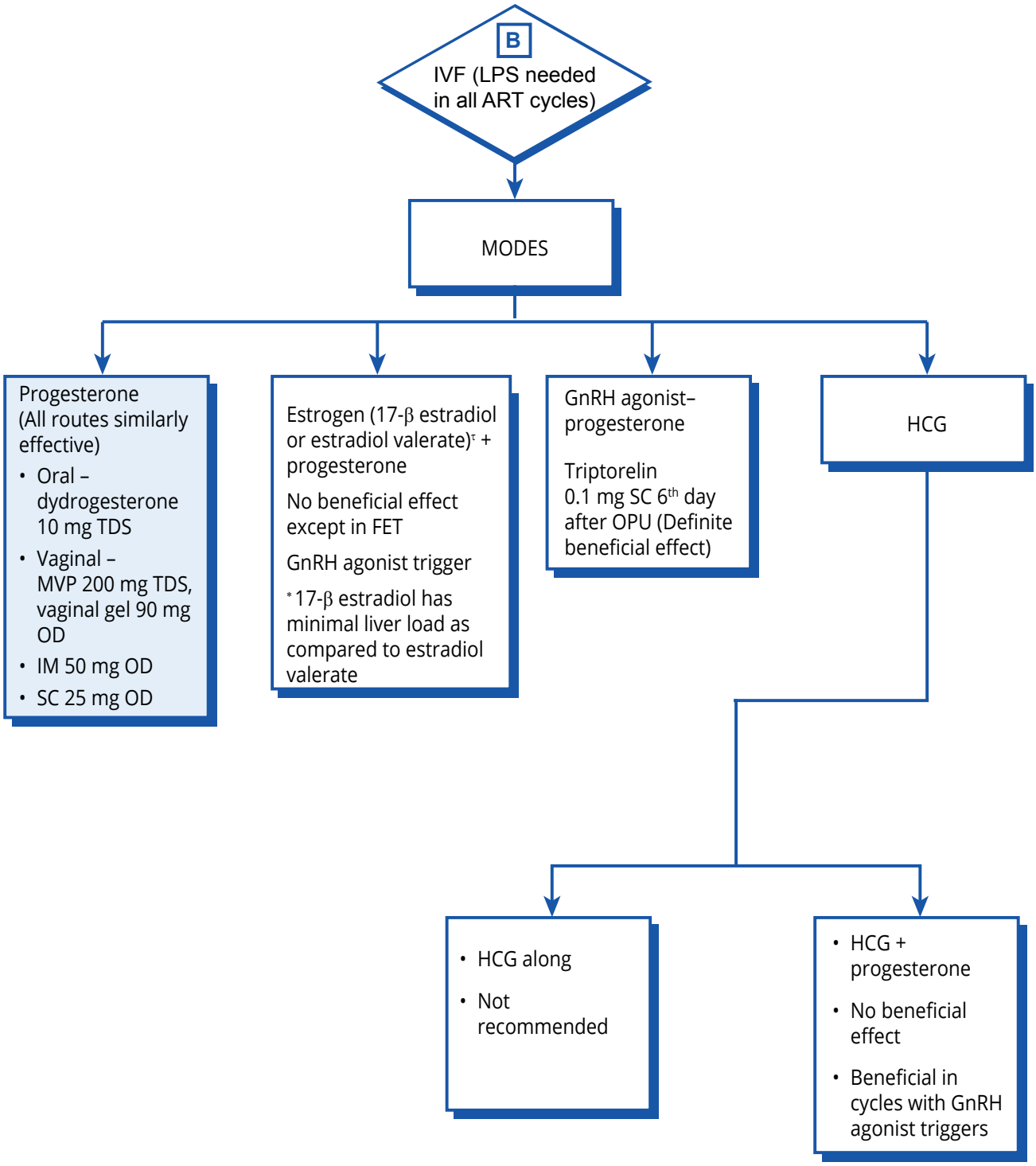
The medication to support luteal phase include progesterones, estrogens, and human chorionic gonadotrophin (hCG). There is an on going debate on optimal luteal phase support with many physicians favoring the use of hCG, despite the risk of ovarian hyper-stimulation syndrome (OHSS).

The aim is of the FOGSI team is to uncover a protocol which is simple, effective, and acceptable to the patients.

LUTEAL PHASE SUPPORT IN INTRAUTERINE INSEMINATION



LUTEAL PHASE SUPPORT IN INTRAUTERINE INSEMINATION



ART: assisted reproductive technology; CC: clomiphene citrate; GnRH: gonadotropin-releasing hormone; HCG: human chronic gonadotropin; FET: frozen embryo transfer; IM: intramuscular; IUI: intrauterine insemination; IVF: in-vitro fertilization; LPS: luteal phase support; MVP: micronized vaginal progesterone; OD: once daily; OPU: ovum pick-up; SC: subcutaneous; TDS: trice daily dosing; IUI: intrauterine insemination; IVF: in-vitro fertilization.

*Dusterberg B et al. All pharmacokinetics and biotransformation of Estradiol Valerate in Ovariectomized women. Horm Res. 1985; 21:145-54.

INFERTILITY

Moderators : Dr. Rishma Pai, Dr. Sudha Tandon
Panel Members : Dr. Hrishikesh Pai , Dr. Nikita Lad, Dr. Meenu Handa, Dr. Sarita Sukhija, Dr. Kedar Padte

Preface

Infertility is the inability to achieve pregnancy after 12 months of regular, unprotected intercourse. Infertility is estimated to affect one in seven to one in eight couples of reproductive age, with male infertility being responsible for 20% of the cases.

Since, around 85% of couples conceive spontaneously within 12 months of regular intercourse, identifying those who would benefit from infertility evaluation is important. Older women (>35 years) or couples with known risk factors for infertility may require evaluation at 6 months. Moreover, anxiety over infertility may increase stress and decrease libido, further complicating the problem; hence, formal counseling is encouraged for couples experiencing infertility. However, physicians need to be familiar with the workup and prognosis for the infertile couples.

The flowchart guides through the process of approach to an infertile couple, the necessary diagnosis and management strategies are provided as a practical guide for infertility treatment.

FEMALE FACTOR INFERTILITY

Infertility is defined as the inability to conceive despite regular sexual intercourse without using contraception for one year*.

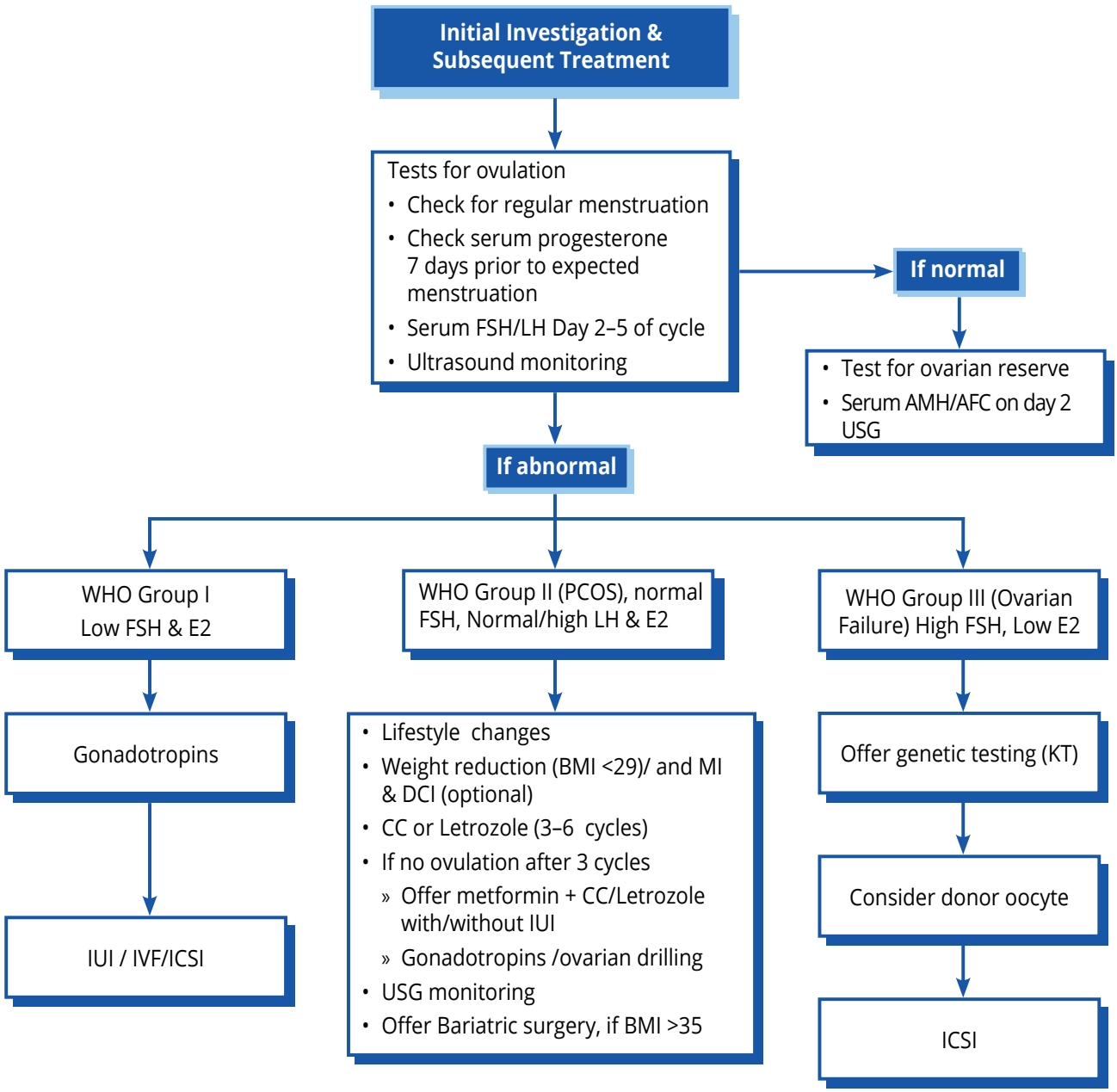
Preliminary Assessment

- Age of both partners
- Duration of infertility: duration of infertility and contraceptive use
- Lifestyle: timing of sexual intercourse, alcohol, smoking, drugs, occupation, and stress
- Menstrual/medical/surgical/sexual history and physical examination of both partners
- Obesity/ low body weight

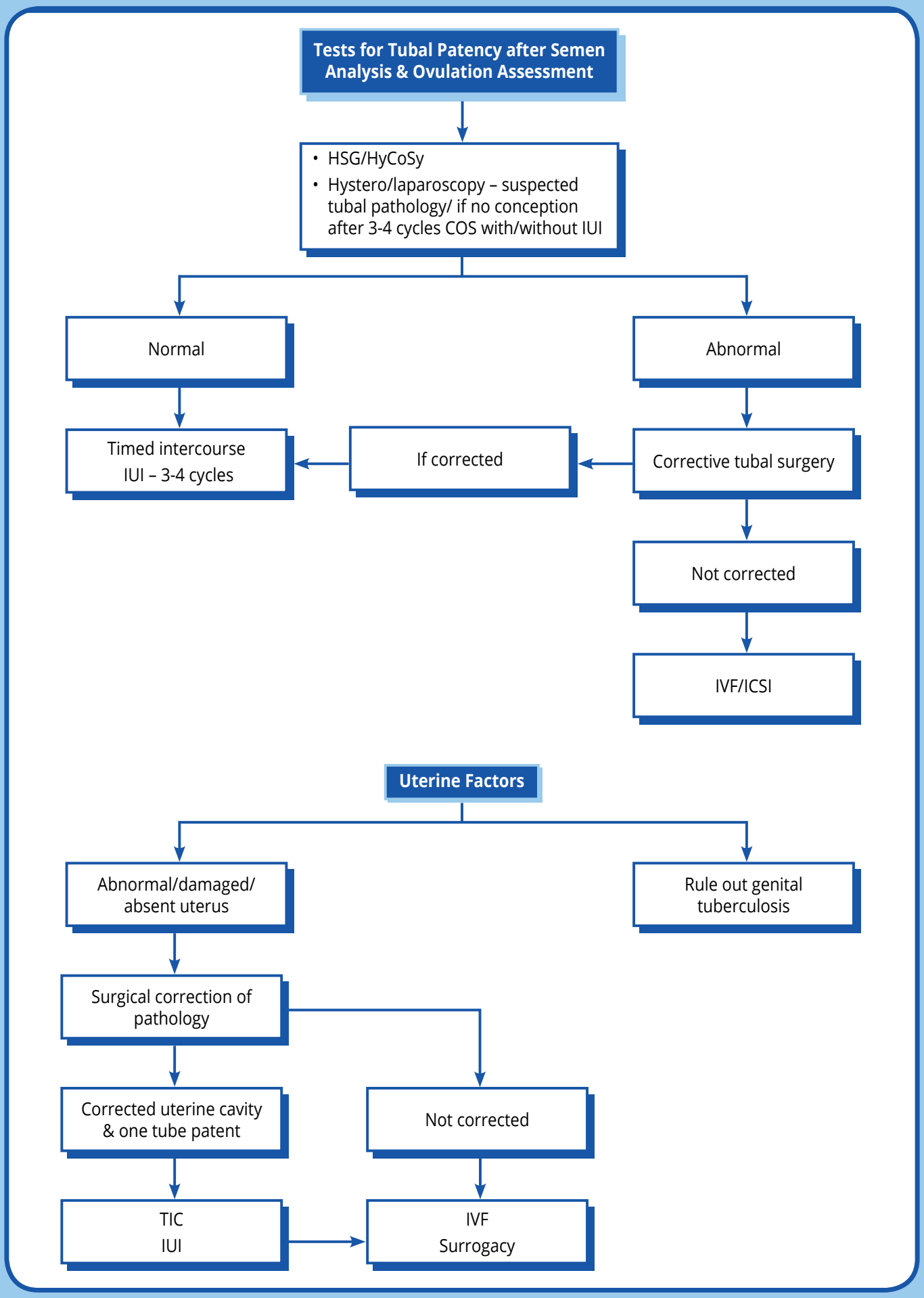
Preliminary Health

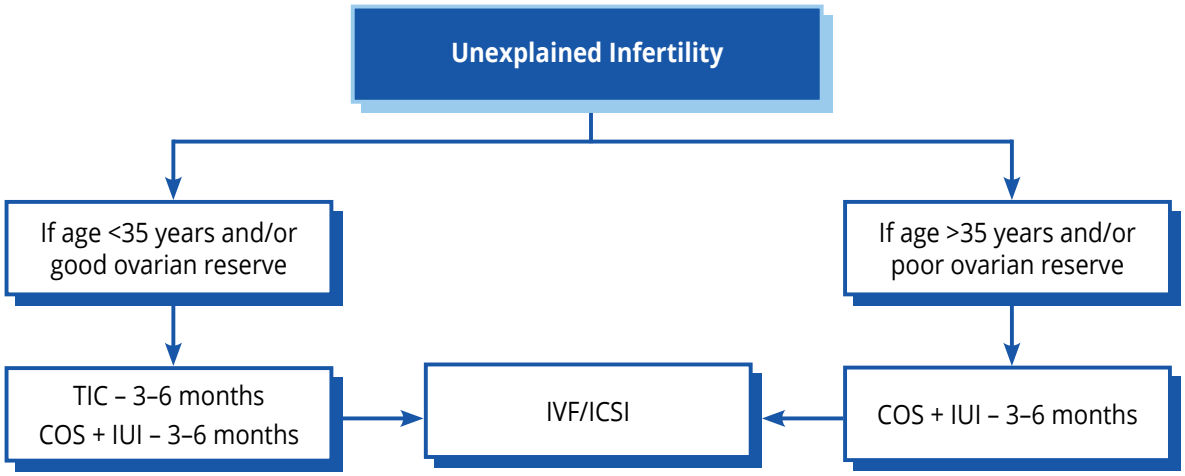
- Folate
- Rubella: if negative , vaccinate the female and wait for 1 month (RCOG)
- Thyroid
- Prolactin
- Thalassemia test of either one of the partner.
- AMH and AFC are recommended and HIV, HBsAg, and Anti-HCV are compulsory for all

*NICE



AMH: anti-Mullerian hormone; AFC: antral follicular count; BMI: body mass index; CC: clomiphene citrate; E2: estradiol; FSH: follicle-stimulating hormone; LH: luteinizing hormone; MI & DCI: Myo-inositol & D-chiro-inositol; PCOS: polycystic ovary syndrome; HBsAg: hepatitis B surface antigen; HCV: hepatitis C virus; HIV: human immunodeficiency virus; ICSI: intracytoplasmic sperm injection; RCOG: Royal College of Obstetricians and Gynaecologists; USG:ultrasonography; WHO: World Health Organization.


Tests for Tubal Patency after Semen Analysis & Ovulation Assessment
• HSG/HyCoSy
• Hystero/laparoscopy – suspected tubal pathology/ if no conception after 3-4 cycles COS with/without IUI
Normal
Abnormal
Timed intercourse IUI – 3-4 cycles
If corrected
Corrective tubal surgery
Not corrected
IVF/ICSI
Uterine Factors
Abnormal/damaged/ absent uterus
Rule out genital tuberculosis
Surgical correction of pathology
Corrected uterine cavity & one tube patent
Not corrected
TIC IUI
IVF Surrogacy



COS: controlled ovarian stimulation; HyCoSy: hystero salpingo contrast sonography; HSG: hysterosalpingogram; ICSI: intracytoplasmic sperm injection; IUI: intrauterine insemination; IVF: in-vitro fertilization; TIC: timed intercourse.

MALE FACTOR INFERTILITY

Infertility is defined as the inability to conceive despite regular sexual intercourse without using contraception for one year*.

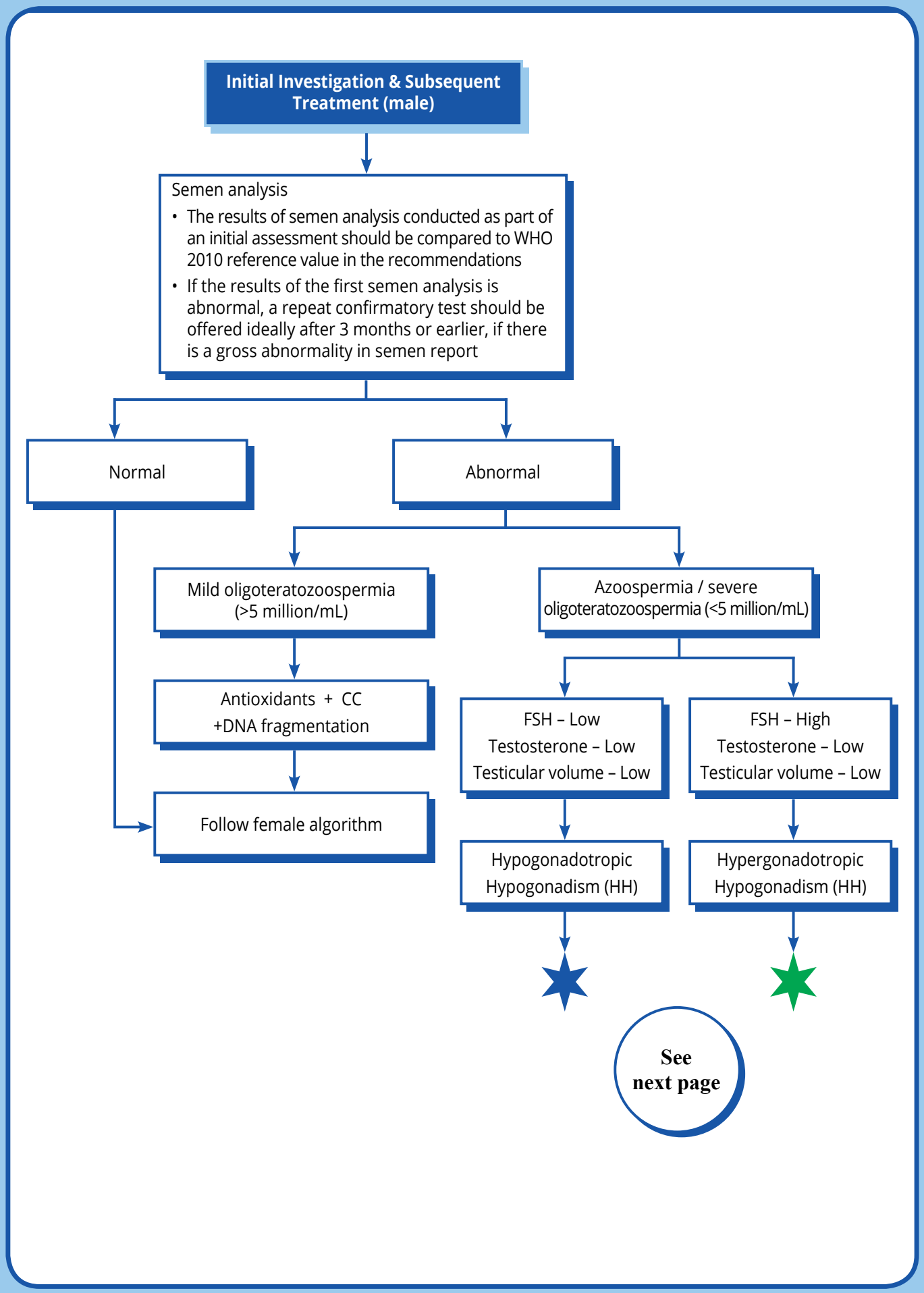
Preliminary Assessment

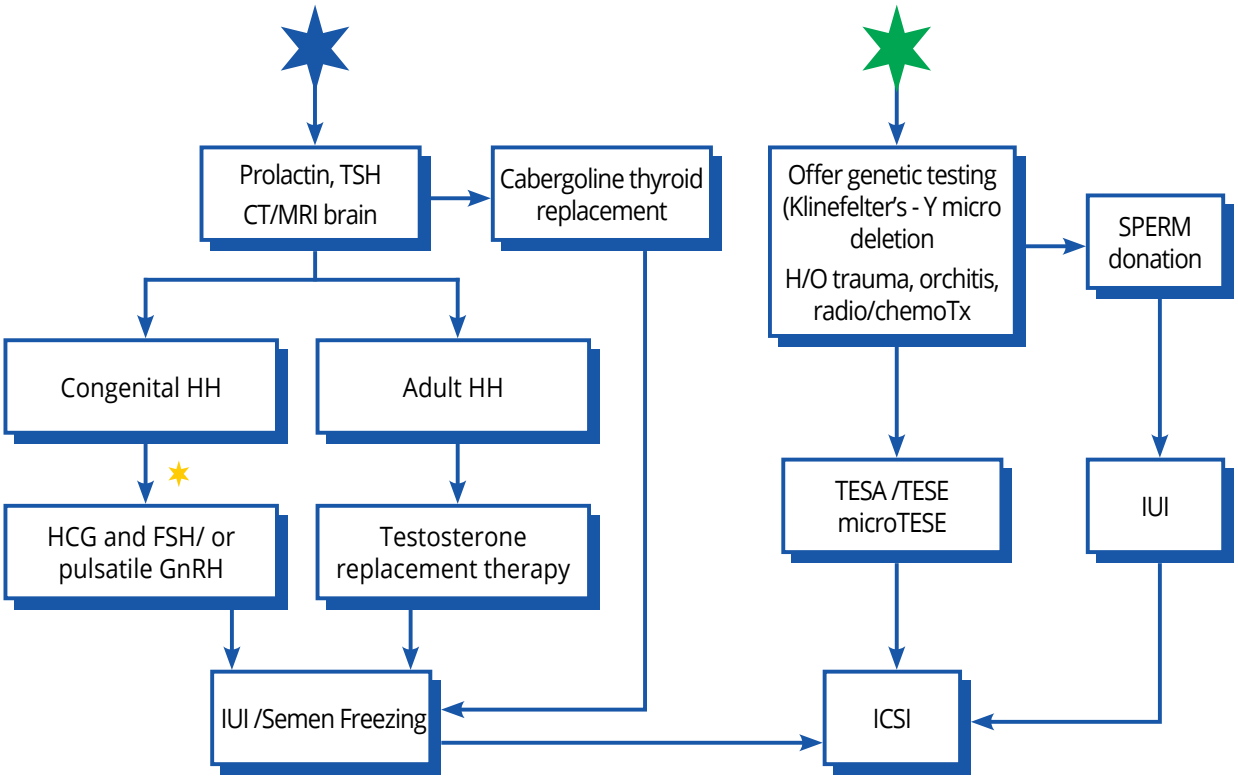
- Age of both partners
- Duration of infertility: duration of infertility and contraceptive use
- Lifestyle: timing of sexual intercourse, alcohol, smoking, drugs, occupation, and stress.
- Menstrual/medical/surgical/sexual history and physical examination of both partners
- Obesity/low body weight

Preliminary Health

- Folate
- Rubella: If negative , vaccinate the female and wait for 1 month (RCOG)
- Thyroid
- Prolactin
- Thalassemia test of either one of the partner
- AMH and AFC are recommended and HIV, HBsAg and Anti HCV are compulsory for all

*NICE

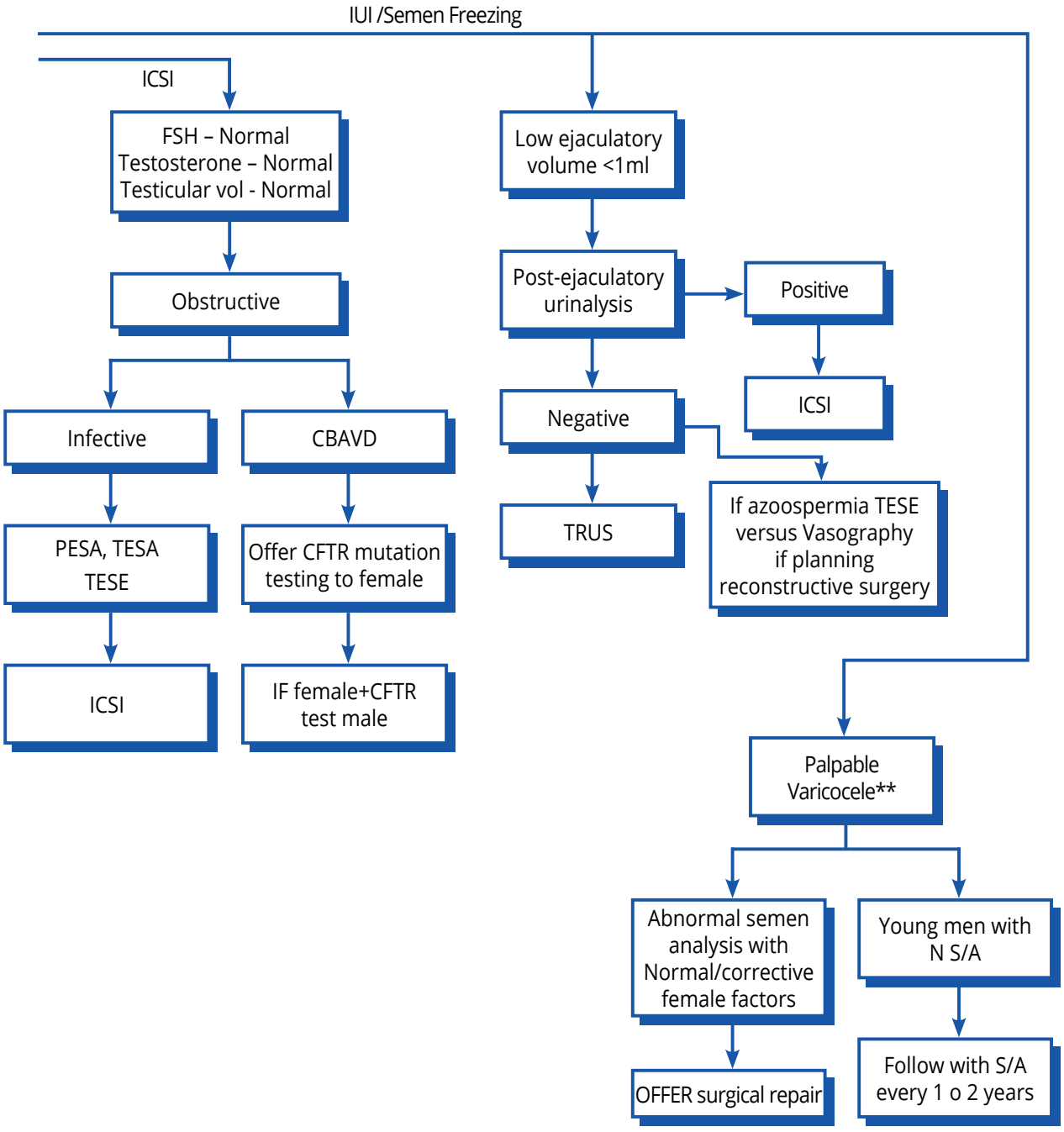

Initial Investigation & Subsequent Treatment (male)
Semen analysis
• The results of semen analysis conducted as part of an initial assessment should be compared to WHO 2010 reference value in the recommendations
• If the results of the first semen analysis is abnormal, a repeat confirmatory test should be offered ideally after 3 months or earlier, if there is a gross abnormality in semen report
Normal
Abnormal
Mild oligoteratozoospermia (>5 million/mL)
Azoospermia / severe oligoteratozoospermia (<5 million/mL)
Antioxidants + CC +DNA fragmentation
Follow female algorithm
FSH – Low
Testosterone – Low
Testicular volume – Low
FSH – High
Testosterone – Low
Testicular volume – Low
Hypogonadotropic Hypogonadism (HH)
Hypergonadotropic Hypogonadism (HH)
See next page



1 Sperm concentration >15x106/mL, motility >42%, morphology >4%

Optional

EUA update 2015



AMH: anti-Mullerian hormone; AFC: antral follicular count; CAVD: congenital absence of the vas deferens; CC: clomiphene citrate; CT: computed tomography; CFTR: cystic fibrosis transmembrane conductance regulator; DNA: deoxyribonucleic acid; FSH: follicle-stimulating hormone; HBsAg: hepatitis B surface antigen; HCV: hepatitis C virus; HCG: human chronic gonadotropin; HIV: human immunodeficiency virus; ICSI: intracytoplasmic sperm injection; IUI: intrauterine insemination; MRI: magnetic resonance imaging; PESA: Percutaneous epididymal sperm aspiration; RCOG: Royal College of Obstetricians and Gynaecologists; TRUS: transrectal ultrasound; TESE: testicular sperm extraction; TESA: testicular / epididymal sperm aspiration; TSH: Thyroid-stimulating hormone; WHO: World Health Organization.

SCREENING IN PREGNANCY

Moderators : Dr. Narendra Malhotra, Dr. Mala Arora
Panel Members : Dr. Ranjana Khanna, Dr. Pragya Mishra, Dr. Abha Rani Sinha, Dr. Navneet Magon, Dr. Ganpat Sawant

Preface

Pregnancy is a normal physiological process and any intervention that is offered to the pregnant or expectant mother should have known benefits and should be acceptable to the woman. Screening in pregnancy is the process of surveying a population of women with markers and defined screening cut-off levels, to identify those at higher risk for a particular disorder. All pregnant women, regardless of age, should be offered, through an informed counselling process, the option of a prenatal screening test for the most common clinically significant fetal aneuploidies in addition to a second trimester ultrasound for dating, assessment of fetal anatomy, and detection of multiples.

During the entire antenatal period, clinician should remain alert to risk factors, signs or symptoms of conditions that may affect the health of a pregnant woman such as pre-eclampsia and diabetes. Screening tests assess the degree of risk, or chance, of a fetus that may potentially have certain common birth defects, but there is no certainty that the baby born will actually have the problem. If a pregnant women has a positive screening result, she should have genetic counseling and undergo one of two invasive diagnostic tests, that have greater accuracy and reliability than genetic screening alone.

The FOGSI protocol has been arrived at after careful consideration of evidences to achieve best practice for screening of women of all pregnancies and provides information for decision making about appropriate treatment in specific circumstances.

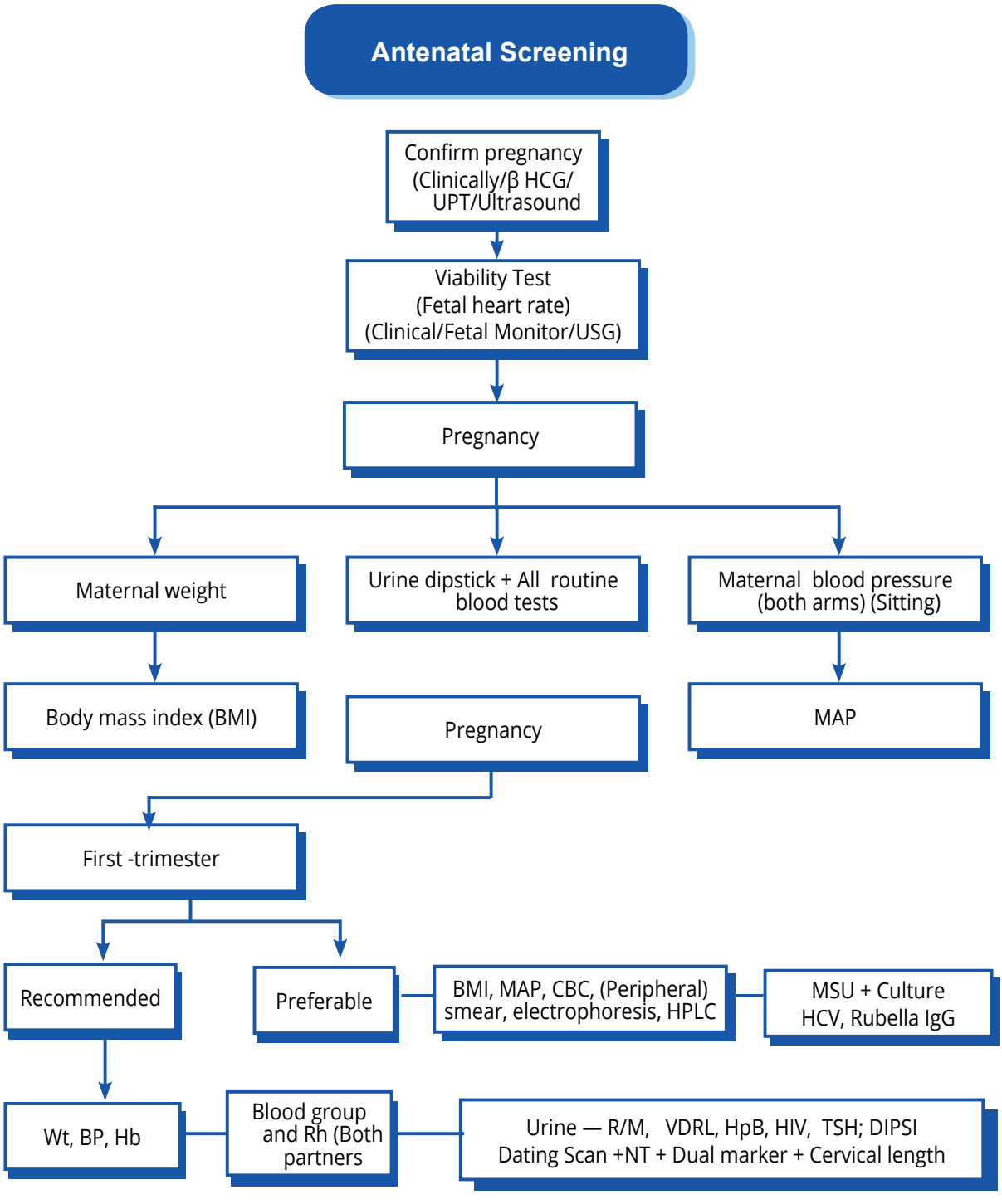
SCREENING IN PREGNANCY

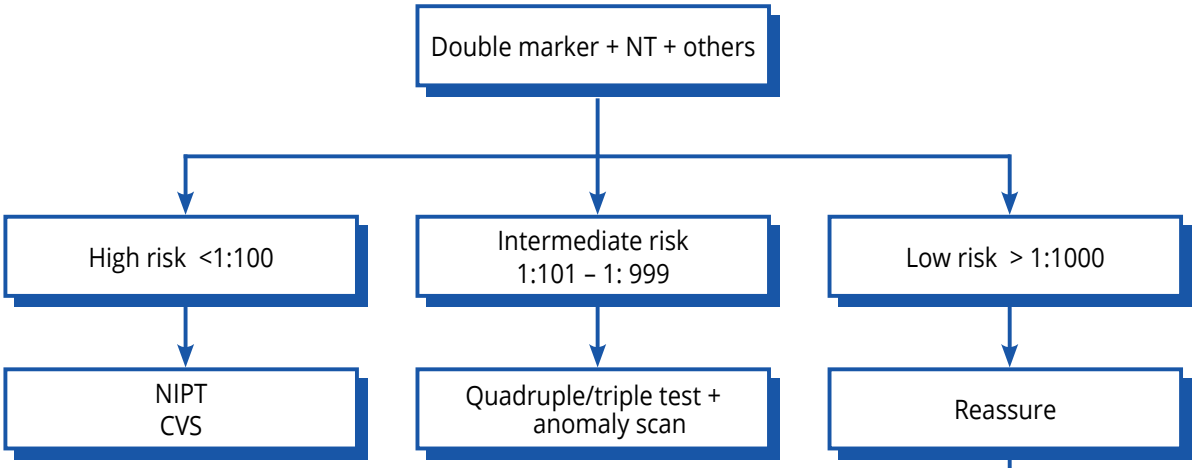
(Recommended three antenatal visits, [preferable 5])

At booking general physical exam heart/lungs/breast/abdomen

In all trimesters

- Maternal weight/BMI
- Blood pressure/mean arterial pressure
- Urine dipstick (albumin, sugar)





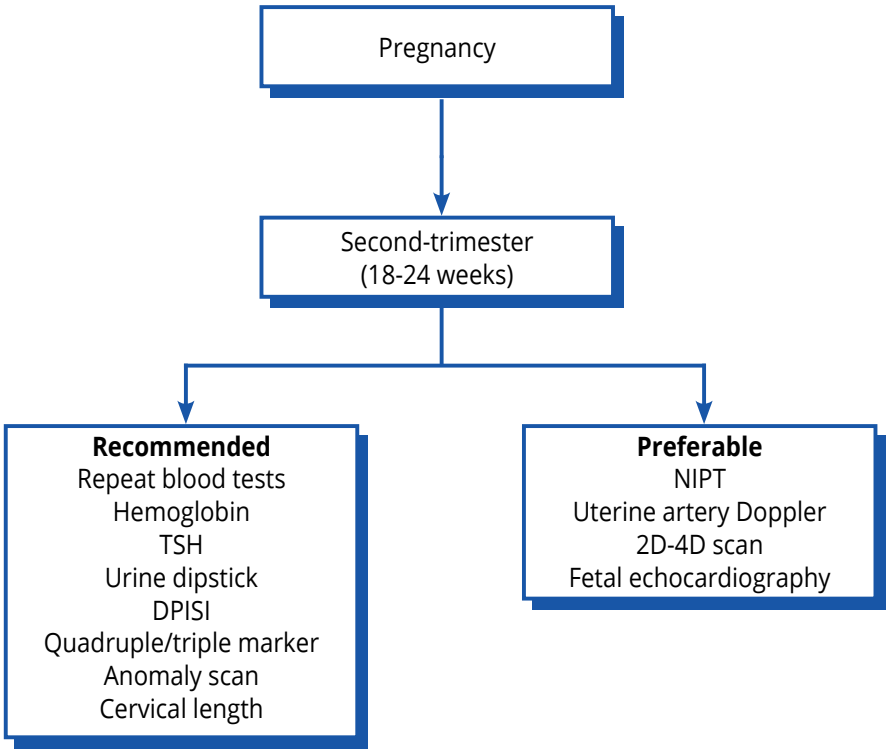
BP: blood pressure; CBC: complete blood count; Hb: hemoglobin; HCV: hepatitis C virus; HPLC: high performance liquid chromatography; MSU: midstream urine; NT: nuchal translucency; R/M: routine microscopy; OGTT: oral glucose tolerance test; TSH: thyroid stimulating hormone; UPT: uterine pregnancy test; USG: ultrasonography; Wt: weight.

ANTENATAL CHECKLIST

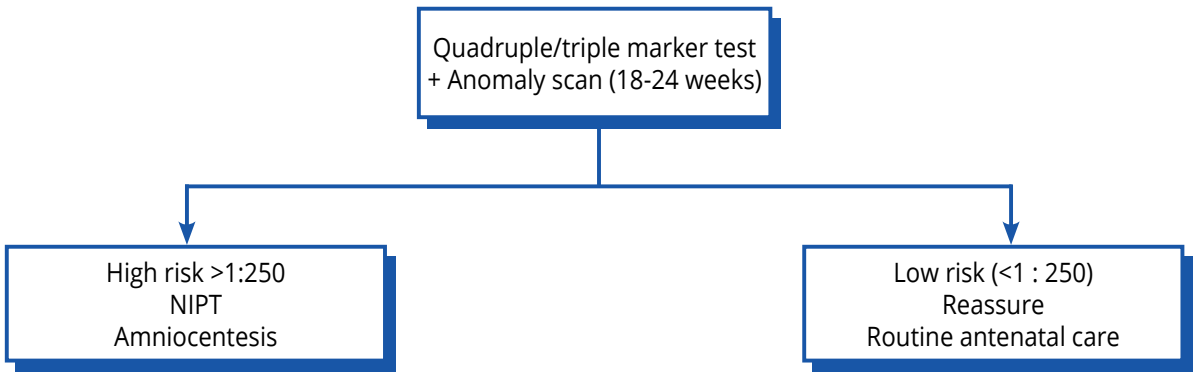
First Trimester	Recommended	Preferable
	Weight	BMI
	Blood pressure	Mean arterial pressure
	Hemoglobin	Complete blood count/ Peripheral smear/Hb Electrophoresis/ HPLC
	Blood group ABO & Rh (both partners)	
	Urine routine	MSU + culture
	VDRL/ Hep B / HIV	HCV / Rubella IgG
	TSH	Thyroid function test / thyroid antibodies Vitamin D
	DIPSI test 75 gms 2 hours blood sugar	HbA1C / OGTT/ 6 point blood sugar test
	Dating scan + NT Double marker (free β HCG + PAPP A[1]) (Contingent Screen[2])	Cervical length Uterine artery Doppler NIPT Placental Growth Factor[1] (PLGF)
	Per speculum exam	Pap smear, bacterial vaginosis and chlamydia screen

[1] Low levels predict pre ecclampsia
[2] Low risk no further test (1 : 1000)
Intermediate risk (101 : 999) to proceed to second trimester screening vs NIPT
High risk (1 : 100) to go for NIPT / CVS

SECOND TRIMESTER

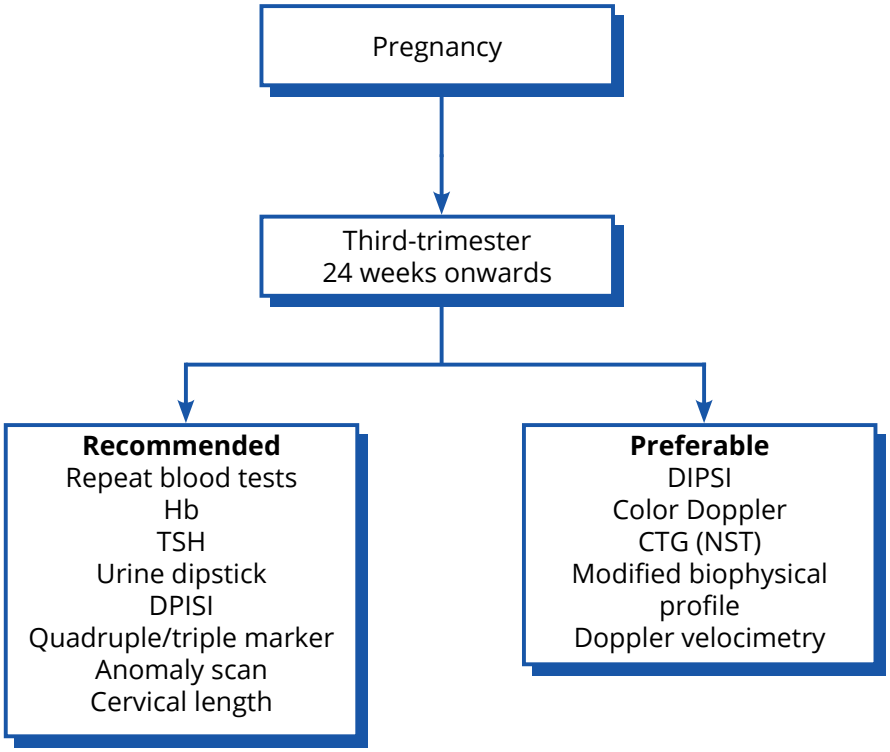


Second Trimester	Recommended	Preferable
18-24 weeks	Repeat bloods (Hb / blood sugar / TSH) & urine test as indicated	
	Quadruple OR Triple marker	NIPT
	Anomaly scan	3D/4D scan/ Fetal Echo Uterine artery Doppler
	Cervical length	
	DIPSI screen 75 gms 2 hour blood sugar	6 points blood sugar HbA1C



DIPSI: Diabetes in Pregnancy Study Group India; HbA1c: hemoglobin A1c; NIPT: non-invasive prenatal tests; TSH: Thyroid-stimulating hormone.

THIRD TRIMESTER



Third Trimester	Recommended	Preferable
24 weeks onwards	Repeat DIPSI screen TSH/Hb/ urine	HbA1C
	Growth scan with liquor volume and placental localisation	Fetal Doppler velocimetry
	Fetal movement count (6 in 2 hours post-prandial)	CTG (NST) Modified biophysical score Doppler velocimetry

BP: blood pressure; BMI: body mass index; CBC: complete blood count;, CTG (NST): ; CVS: ; DIPSI: ; GCT: Glucose Challenge Test; Hb: hemoglobin, HbA1C: hemoglobin A1C, Hep B: hepatitis B virus, HCV: hepatitis C virus; HIV: human Immune deficiency virus; HPLC: high performance liquid chromatography; HbA1C: hemoglobin A1C, R/M: Routine microscopy, MAP: , MSU: midstream urine; NT Scan: nuchal translucency scan; NIPT: Non invasive prenatal testing; OGTT: Oral glucose tolerance test; PAPP A: pregnancy-associated plasma protein A; PlGF: placental growth factor; TSH: thyroid stimulating hormone; VDRL: Venereal Diseases Research Laboratory Test; Wt: weight.

MENOPAUSE

Moderators : Dr. Maninder Ahuja / Madhuri Patel
Panel Members : Dr. Niranjan Chavan, Dr. Mandakini Megh, Dr. Vineet Mishra, Dr. Rajnikant Contractor

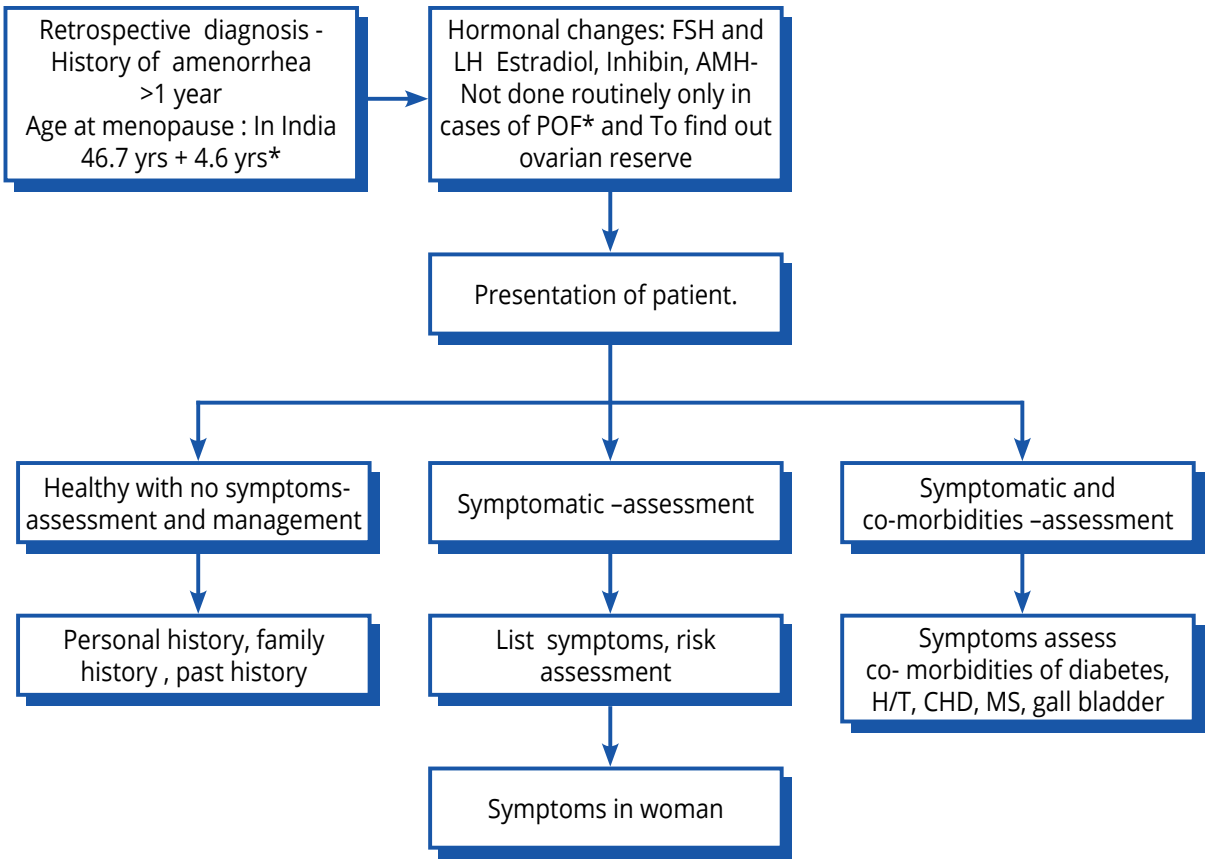
Preface

Menopause is a biological stage in a woman's life marked by cessation of menstruation and associated with infertility. A woman not menstruating for one year after her last period is termed as being postmenopausal. Reduced estrogen levels associated with menopause affects the body by causing vasomotor, musculoskeletal, urogenital, and psychological symptoms. It also has a profound effect on the bone and the cardiovascular system, which can significantly affect a woman's quality of life. Therefore, women need to know about the available therapeutic options, their risks and benefits in order to make an informed decision for effective treatment. The following flowchart helps in the diagnosis and guides the process of the management and treatment of menopause symptoms.

MENOPAUSE

- Define menopause
- Types of menopause
- Diagnosis of menopause
- Initial assessment at menopause
- Classifying women to plan management
- MHT

MENOPAUSE



AMH: anti-Mullerian hormone; CHD: coronary heart disease; FSH: follicle-stimulating hormone; H/T: hypertension; LH: luteinizing hormone; MHT: menopausal hormone therapy; MS: metabolic syndrome; POF: premature ovarian failure.

MENOPAUSE DEFINITION

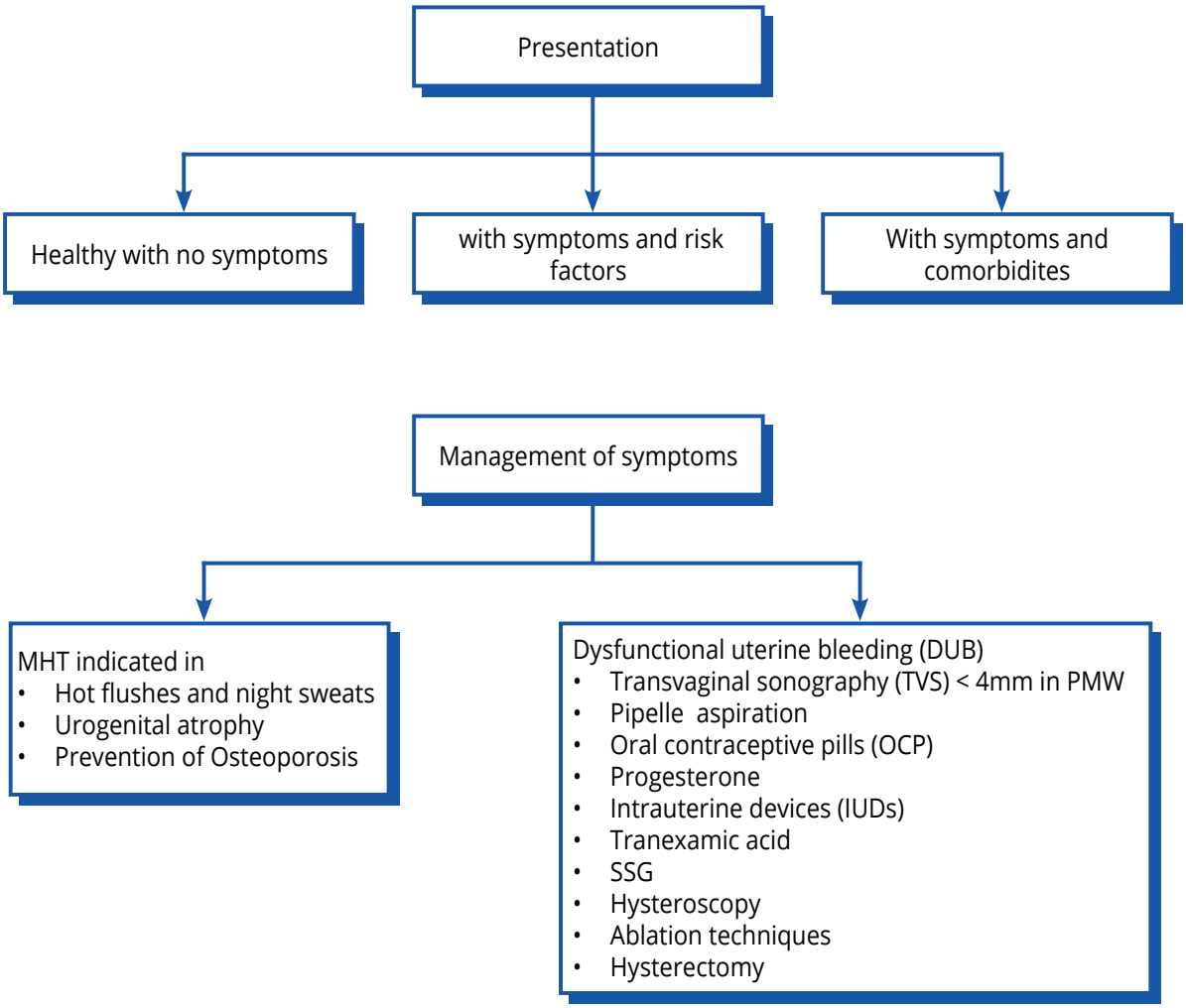
- Twelve months of amenorrhea
- Retrospective diagnosis
- Diminution of ovarian hormones estradiol and raised follicle-stimulating hormone (FSH) and luteinizing hormone (LH)
- No independent biological marker
- Objective sensitive marker: Irregular cycles
- Average age in India is 46.5 years and rest of world is 52 years
- Can be premature before 40 years, natural or surgical

No need to conduct tests routinely to diagnose menopause

HORMONAL CHANGES

- FSH ↑
- LH ↑
- Antimullerian hormone (AMH) ↑
- Inhibin↑
- Estradiol↓
- Estrogen becomes main hormone
- Ovaries go on producing androgens – androstenedione till 65 years↓

Routine diagnosis is by clinical history



MANAGEMENT OF HEALTHY MENOPAUSAL WOMAN WITH NO SYMPTOMS

- Education
- Counseling
- Documentation in mid-life OPD card and assessment of risk factors
- Lifestyle modifications, weight control, and nutrition
- Vitamin D 800–1200 IU
- Calcium 1200 mg
- Vitamin B12 supplementation
- Moderate alcohol, no smoking
- Exercise, aerobics, range of movement, resistance, and weight training, stretching, yoga, and meditation

SYMPTOMS IN PERIMENOPAUSE AND MENOPAUSE

Early symptoms

Vasomotor: Hot flashes, night sweats mood disturbances, and irritability

Menstrual: Irregular cycles, first short and then long AUB

Intermediate symptoms

Musculoskeletal

Aches and pains, arthralgia

Urogenital atrophy, itching of vagina, dryness, frequency of urine, dyspareunia, and low libido

Late symptoms

Osteoporosis, metabolic syndrome, CHD, cancers, and Alzheimer's disease

BASIC UNIVERSAL ASSESSMENT OF ALL WOMEN IN PERIMENOPAUSE AND MENOPAUSE

Documentation in mid-life OPD card

Personal history:

- Last menstrual period, age of menarche
- PCOD, OH, hypertension, PIH, diabetes , CHD, fracture, thromoboembolic, cancer
- Diet and physical activity,
- Sleep, sexual diseases, CKD or liver disease,
- Gall bladder or pancreas problem
- OCP use or MHT use or OCT,
- Alcohol or drug use,
- Eye or hearing problem

Family history of CHD, hypertension, diabetes, breast cancer, colon cancer, ovarian cancer, dementia , Alzheimer's disease, and fragility fractures

UNIVERSAL ASSESSMENT

Physical examination

- Height
- Weight
- BMI
- Blood pressure
- Waist measurement
- Gait
- Eye
- Hearing
- Hand shake
- Breast, chest, P/A P/V / P/S
- TVS

Investigations

- Hb, BS
- HbA1c
- TSH
- Lipid Profile
- If indicated, KFTs, LFTs
- PAP/LBC/VIA
- Mammography after 42 years or US breast
- DEXA scan if more than 5 years after menopause and earlier if risk factors

Call for re-evaluation every year and loss of height is very important.

MANAGEMENT OF VASOMOTOR SYMPTOMS

General

Loose clothing, dress in layers, cool air, and avoid hot spicy food

Menopausal hormone therapy

Within 10 years of menopause or before 60 years of age

After counseling and assessment for risk of MHT, stroke, DVT or any other co-morbidity where MHT is contraindicated.

CO-MORBIDITIES

Assess for risk factors or presence of:

- Diabetes
- Hypertension
- CHD
- Cancers and treated cancers of ovary, cervical, and endometrium
- Thyroid
- Osteoporosis
- Kidney and liver disease
- Dementia
- Gall bladder and pancreas, if symptomatic

Call for re-evaluation every year and loss of height is very important

MHT

If indicated

- For hot flushes , night sweats, irritability, insomnia because of hot flushes
- For urogenital syndrome vaginal route
- For prevention of osteoporosis

TYPES OF MHT

- Estrogen alone when no uterus
- Combination of estrogen-progesterone
- Selective estrogen receptor modulators (SERMs)
- Tibolone/selective tissue estrogenic activity regulator (STEAR)
- TSEC–bezadoxiphene + CEE for osteoporosis and if risk of breast cancer
- Ospemifene for urogenital atrophy

ROUTES OF ADMINISTRATIONS

- Oral
- Transdermal spray
- Patches
- Gel
- Vaginal tablets
- Creams
- Intramuscular
- Intrauterine device

HOW MHT

- Estrogen alone continuous,if no uterus
- Estrogen+ progesterone sequential, when uterus is there – within 1 year of menopause
- Continuous combined in later menopause
- SERMS when risk of breast cancer and osteoporosis risk is there. Can cause increased hot flashes so not given before menopause.
- OCP is in POF and in AUB and contraception in perimenopause

ESTROGENS SALTS

Natural estrogens

- 17 β-estradiol tab (17 β-estradiol has minimal liver load as compared to estradiol valerate and CEE)
- Estradiol valerate tab
- Estrone cream
- Estriol
- CEE tablets and vaginal cream

Synthetic estrogens

- Ethinyl estradiol is 750–1,000 times more potent than natural estrogens
- Enhances hepatic effects that increases synthesis of clotting factors, angiotensin, and SHBG

PROGESTERONE

- Given when uterus is present, to prevent endometrial hyperplasia of because of estrogens
- Not needed when vaginal route of estrogens are given

Types of progesterone

- Dydrogesterone
- Micronized progesterone (preferred as less thrombogenic and < risk of breast cancer)
- Levonorgestrel/IUD
- Tibolone
- Medroxyprogesterone acetate (not lipid friendly, increased risk of breast cancer)
- Cyproterone acetate, dienogest, and drospirenone (in OCP)

MHT: HOW LONG AND WHEN?

- Within 10 years of menopause and before 60 years of age
- For shortest periods for the relief of symptoms
- For hot flashes, it can be continued beyond 60 years with proper counselling
- Vaginal route daily for 2 weeks and then twice weekly for 1 year.
- If patient needs more, than it can be used for longer periods with counselling

PROGESTERONE

- Given when uterus is present, to prevent endometrial hyperplasia of because of estrogens
- Not needed when vaginal route of estrogens is given

Types of progesterone

- Dydrogesterone + estrogen (safe)
- Micronized progesterone (preferred as less thrombogenic and < risk of breast cancer)
- Levonorgestrel/IUD
- Tibolone
- Medroxyprogesterone acetate (not lipid friendly, increased risk of breast cancer)
- Cyproterone acetate, dienogest, and drospirenone (in OCP)

DURATION OF THERAPY

Premature menopause

- Up to natural age of menopause
- Further continuation of therapy according to the indication and need

Natural menopause

- Safety data of EPT therapy with CEE+MPA is 3–5 years, with ET safety data for use is 7 years of treatment with 4 years follow up
- 17-β estradiol and dydrogesterone can be given 3–5 years

According to the Indian Menopause Society (2013), International Menopause Society (2016), and the North American Menopause Society (2012):

- MHT should begin within 10 years of menopause or <60 years of age
- Premature menopause: MHT upto natural age of menopause 3–5 years
- Continuation of therapy should be decided at the discretion of the well-informed woman and her health professional

CONTRAINDICATIONS TO MHT

- Known or suspected estrogen-sensitive malignant conditions
- Undiagnosed genital bleeding
- Untreated endometrial hyperplasia
- Previous idiopathic or current venous thromboembolism
- Active or recent arterial thromboembolic disease
- Untreated hypertension
- Active liver disease
- Known hypersensitivity to the active substances of MHT or to the excipients
- Porphyria cutanea tarda (absolute contraindication)

NON-HORMONAL TREATMENTS

Non-hormonal treatments for relief of menopausal symptoms

- Gabapentin: 300 mg TID × 6 weeks–3 months
- Venlafaxine: 25–75 mg/day
- Paroxetine: 7.5–20 mg/day
- Fluoxetine: 10–20 mg/day
- Isoflavones: 70 mg–100 mg daily × 6 weeks–3 months (equal producer patients have to be identified)
- Lycopene: 18–24 mg daily
- Isoflavones, bioidentical hormones

DOSAGE OF MHT

Choice of

- Ultra low dosage
- Low dosage
- Normal dosage

EXCEPTIONS TO LOW DOSAGE

- Premature ovarian failure
- Severe osteoporosis
- Predominance of psychological problems, e.g. climacteric depression

DOSAGE

- 17 β-estradiol oral, mg/day: Ultra low dosage: 0.5, low dose: 1, normal: 2, high: 4 mg
- CEE oral, mg/day: Ultra low dosage: 0.15, low dosage: 3-4.5, normal: 0.625, high: 1.2 mg
- Estradiol valerate oral, mg/day: Low: 1, high: 2 mg
- Transdermal 17 β-estradiol µgm: Ultra low dosage: 14, low dose: 25, normal: 50, high:100 µgm

NON-ORAL TRANSDERMAL ROUTE INDICATIONS

- Transdermal estrogen has a neutral effect on triglycerides, C-reactive protein, and sex hormone binding globulin
- Triglyceridemia
- Hyperlipidemia
- Increased C-reactive protein
- Migraine
- Diabetes
- DVT
- Gall bladder disease,
- Smoking
- Controlled hypertension
- Personal preference

PROGESTERONE

- Dydrogesterone
- MPA
- Micronised progesterone
- Norethisterone
- Cyproterone acetate
- Dienogest
- Select dydrogesterone or micronized progesterone, early reports of neutral effect on breast cancer
- Metabolically friendly

Androgenic progesterone

- Blunt positive effect of estrogens on lipids, implicated in breast cancer, and CVD
- Used for hemostatic control in DUB

PROGESTERONE USE IN SURGICAL MENOPAUSE

- After endometriosis surgery with hysterectomy to take care of residual tissue
- After supracervical hysterectomy
- After ablation technique on endometrium

USE OF LEVONORGESTREL IN IUD

- During perimenopause
- Contraception
- Control of bleeding: AUB
- Women with side effects for oral progestogens

DOSE OF PROGESTERONE

- Dydrogesterone 10–20 mg/day
- For conversion of endometrium micronized progesterone 100–200 mg
- MPA 5–10 mg /day
- Levonorgestrel 0.20 mcg
- Norethisterone 1.25–2.5 mg

SERM: SELECTIVE ESTROGEN RECEPTOR MODULATORS

- A drug that acts like estrogen on some tissues but blocks the effect of estrogen on other tissues
- Used in osteoporosis, positive effect on bone

MHT AND BREAST

- Risk not increased in first-time hormone users [GRADE A]
- The MHT attributable risk is small and decreases when treatment stops [B]
- 17 β-estradiol has negligible risk of breast cancer
- The increased risk is primarily associated with the addition of a synthetic progestogen to estrogen therapy and to duration of use [B]
- The risk may be lower with micronized progesterone or dydrogesterone [C]
- Any possible increased risk associated with MHT may be decreased by selecting women with lower baseline risk including low breast density and by providing education on preventive lifestyle measures (reducing weight, reducing alcohol intake, and increasing physical activity) [D]

ESTROGEN-ANDROGEN COMBINATION

- Continued VMS despite estrogen replacement
- Decreased well-being despite estrogen replacement
- Surgical menopause
- Acquired sexual desire dysfunction
- In India, androgen formulations for use at menopause are unavailable Tibolone is a good alternative

ENDOMETRIAL SURVEILLANCE

- Endometrial thickness of ≤ 4 mm in TVS do not require endometrial sampling
- Endometrial thickness is > 4 mm on TVS: endometrial sampling
- Endometrium thickness =6 mm on TVS with homogeneous and normal morphology, women on hormonal therapy and hypertensive medication is acceptable
- Homogenous endometrium and local thickening even with thin endometrium needs investigation by Pipelle aspirations and HPE or hysteroscopy directed biopsy

INDICATIONS FOR DEXA SCAN

- All women 5 years beyond the age of natural menopause
- Women less than 5 years since menopause with a particular risk factor
- Women with fragility fractures
- Women in menopause transition with secondary causes
- Radiological evidence of osteopenia and presence of vertebral compression fractures
- Before initiating pharmacotherapy for osteoporosis
- The interval testing should be based on calculated individual risk, mostly be scheduled between 1 and 5 years later

VENOUS THROMBOEMBOLISM AND MHT

- Oral estrogen is contraindicated in women with a personal history of VTE [A]
- Transdermal estrogen should be first choice in obese women with VMS [B]
- VTE risk increases with age and with thrombophilic disorders
- The risk of VTE increases with oral MHT but is rare below 60 years of age
- Two times more VT risk is associated with CEE*

WE DON'T NEED THROMBOPHILIA PROFILE BEFORE STARTING MHT

CHECK LIST

- Mid life OPD card
- Breast self exam card
- Cuscos speculum and light
- Cx cancer screening kits
- 5% Acetic acid
- Colposcope (if possible)

*Smith N et al. JAMA Intern Med. 2014;174(1):25-31.

RISK FACTORS FOR OSTEOPOROSIS

Non modifiable

- Female
- Menopause
- H/O fragility #
- H/O fragility# in family

Modifiable

- Physical activity: muscle building exercises
- BMI
- Smoking
- Alcohol >3 drinks/day
- Calcium
- Sun exposure
- Fall prevention

RISK OF DVT

- Previous history of DVT during pregnancy, prolonged bed rest or surgery
- High risk profession like air hostess
- Personal history or family history
- Known thrombophilia (F5 Leiden, Protein C, antithrombin III)

RISK OF DIABETES MELLITUS

Non modifiable

- Hypertension
- Dyslipidemia
- Polycystic ovary syndrome
- Physical inactivity
- Obesity

Modifiable

- Advancing age
- Endogenous estrogens
- Late menopause
- Nulliparity and Infertility
- Genetic factor

RISK OF ALZHEIMER

Modifiable

- Physical inactivity
- Diabetes
- Hypertension
- Dyslipidaemia
- Smoking
- Obesity
- Depression
- Stress & social engagement
- Diet
- Poly pharmacy and thyroid medications

Non modifiable

- Age
- Family history
- Genetic factor apolipoprotein (APOE)
- Auto-immune diseases
- Head trauma
- Traumatic brain injury

RISK OF BREAST CANCER

Modifiable

- Age at first child
- Breastfeeding
- BMI
- Alcohol
- Hormone Therapy?

Non modifiable

- Age and gender
- Benign breast disease
- Family history of inherited cancers
- BRCA1 & BRCA2
- Menstrual history: Ages at menarche and menopause
- Breast density on mammogram
- Medical history of Hodgkin's lymphoma

RISK FACTORS OF ENDOMETERIAL CANCER

Modifiable

- Obesity
- Diabetes
- Hypertension
- Polycystic ovarian syndrome
- Unopposed estrogen therapy

Non Modifiable

- Advancing Age
- Endogenous estrogens
- Late menopause
- Nulliparity and infertility
- Genetic factor

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3. North American Menopause Society, 2012.
4. Indian Menopause Society.
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AUB: abnormal uterine bleeding, CEE: conjugated equine estrogen CHD: coronary heart disease, CKD: chronic kidney disease, CVD: cardiovascular disease, DUB: dysfunctional uterine bleeding, DVT: deep vein thrombosis EPT: estrogen and progesterone therapy Hb: hemoglobin, HbA1c : Hemoglobin A1c; HPE: histopathological evaluation IUD: Intrauterine devic KFTs: Kidney functions tests, LFTs: liver function tests, MHT: menopausal hormone therapy, OCP: Oral contraceptive pill, OPD: outpatient department; PAP/LBC: Pap smear and liquid-based cytology; PCOD: Polycystic ovary syndrome, PIH: pregnancy-induced hypertension, POF: premature ovarian failure; SHBG: Sex hormone–binding globulin TSEC: Tissue-selective estrogen complex TSH: Thyroid-stimulating hormone TVS: Transvaginal sonography; VIA: visual inspection with acetic acid; VMS: vasomotor symptoms.

VACCINATION

Moderators : Dr. Sarita Bhalerao, Dr. Neerja Bhatla
Panel Members : Dr. Kawita Bapat, Dr. Arun Nayak, Dr. M C Patel, Dr. Krishnendu Gupta

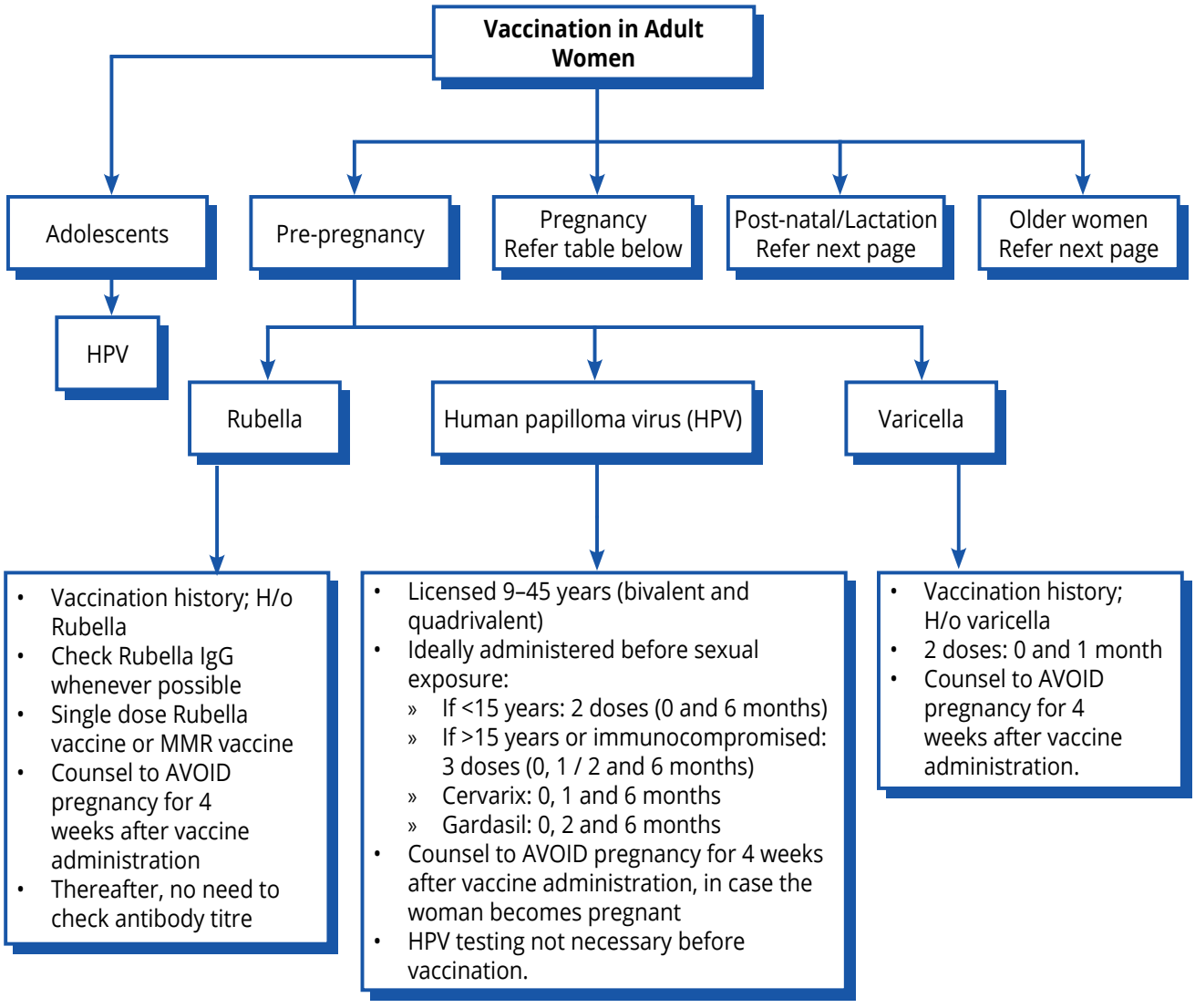
Preface

Immunization of a pregnant woman enables a number of important health benefits for both mother and the baby. Vaccine-preventable diseases have been shown to cause significant morbidity and mortality among maternal, neonatal, and young infant. Furthermore, some of these infections can be serious enough to waste pregnancy, or affect the infant post delivery.

Vaccination of the pregnant women has been shown to strengthen her immune systems to fight off serious infectious diseases. It helps in protecting the mother from infections and this immunity passes to her infant during pregnancy, keeping the child safe during the first few months of life.

The fear that fetus can be at risk after vaccination of the mother during pregnancy has no scientific bases. There have been no study to show if there is risk for fetus after maternal vaccination with inactivated vaccines or bacterial vaccines or toxoids. Since live vaccine poses a theoretical risk to a developing fetus, all live vaccines should be avoided during pregnancy.

Lack of awareness of risk and benefits of vaccination during pregnancy is a common barrier for its use.



- All vaccines are optional
- FOGSI recommends HPV vaccination inn all adolescents for protection against cancer of cervix

PREGNANCY

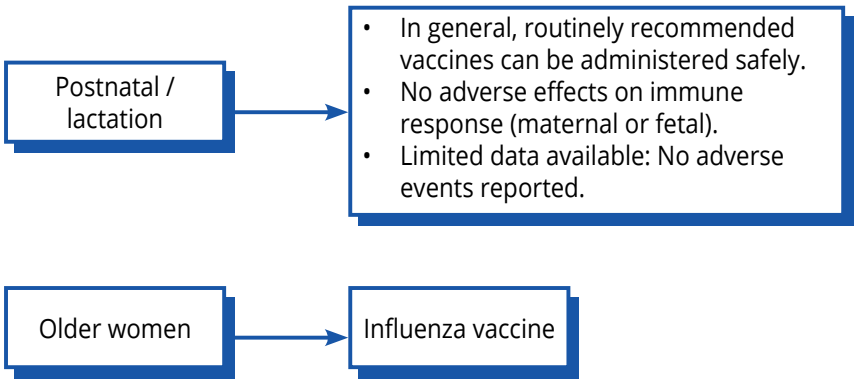
Strongly recommended	Recommended	Not recommended
TT:2 doses or Tdap	Influenza vaccine (during flu season) Intramuscular after first trimester	HPV MMR Varicella

TT
- 1st dose: Between 16–20 weeks, 2nd dose: After 4–6 weeks after the 1st dose.

Tdap
- Can replace TT (wherever available)
- Single dose replaces both doses of TT: Administered 28–36 weeks, if previously immunized
- If not immunized: 2 doses of TT and 1 dose of Tdap.

Recommended vaccines under "Special Situations"

- Rabies: Where the benefits outweigh the risks involved
- Hepatitis A
- Hepatitis B
- Cholera
- Typhoid



COUNSELLING

- The lady must be counseled properly clearly explaining the benefits and side-effects of the concerned vaccine; consent must be obtained.
- AEFI (Adverse Events Following Immunization) reporting: Risk of anaphylaxis must be explained.

ADVERSE EVENTS FOLLOWING IMMUNIZATION

- Mild reactions (common): Injection site pain, redness, swelling, induration.
- Moderate reactions (occasional): Fever, headache, myalgia, joint pains, lymph node swelling, and gastrointestinal disorders.
- Severe reactions (rare): Circulatory reactions, chills, paresthesia, allergic reactions, and anaphylaxis.

HPV: human papillomavirus; IgG: immunoglobulin G; MMR: Measles, mumps, and rubell.

Documentation must be made regarding that the "patient and accompanying relatives, if present, were properly counseled about the potential benefits and risks of the vaccine prior to administration".

HYPERTENSIVE DISORDERS IN PREGNANCY

Moderators : Dr. Suchitra Pandit / Dr. Pratima Mittal
Panel Members : Dr. Ashis Mukhopadhyay, Dr. Atul Munshi, Dr. Sudhir Shah, Dr. Nita Thakre, Dr. Alpesh Gandhi

Preface

Hypertensive disorders during pregnancy (HDP) are a major cause of maternal morbidity and mortality and are known to complicate about 3-10% of all pregnancies. About 10-15% of all maternal deaths are contributed by hypertensive disorders of pregnancy especially in the developing world.

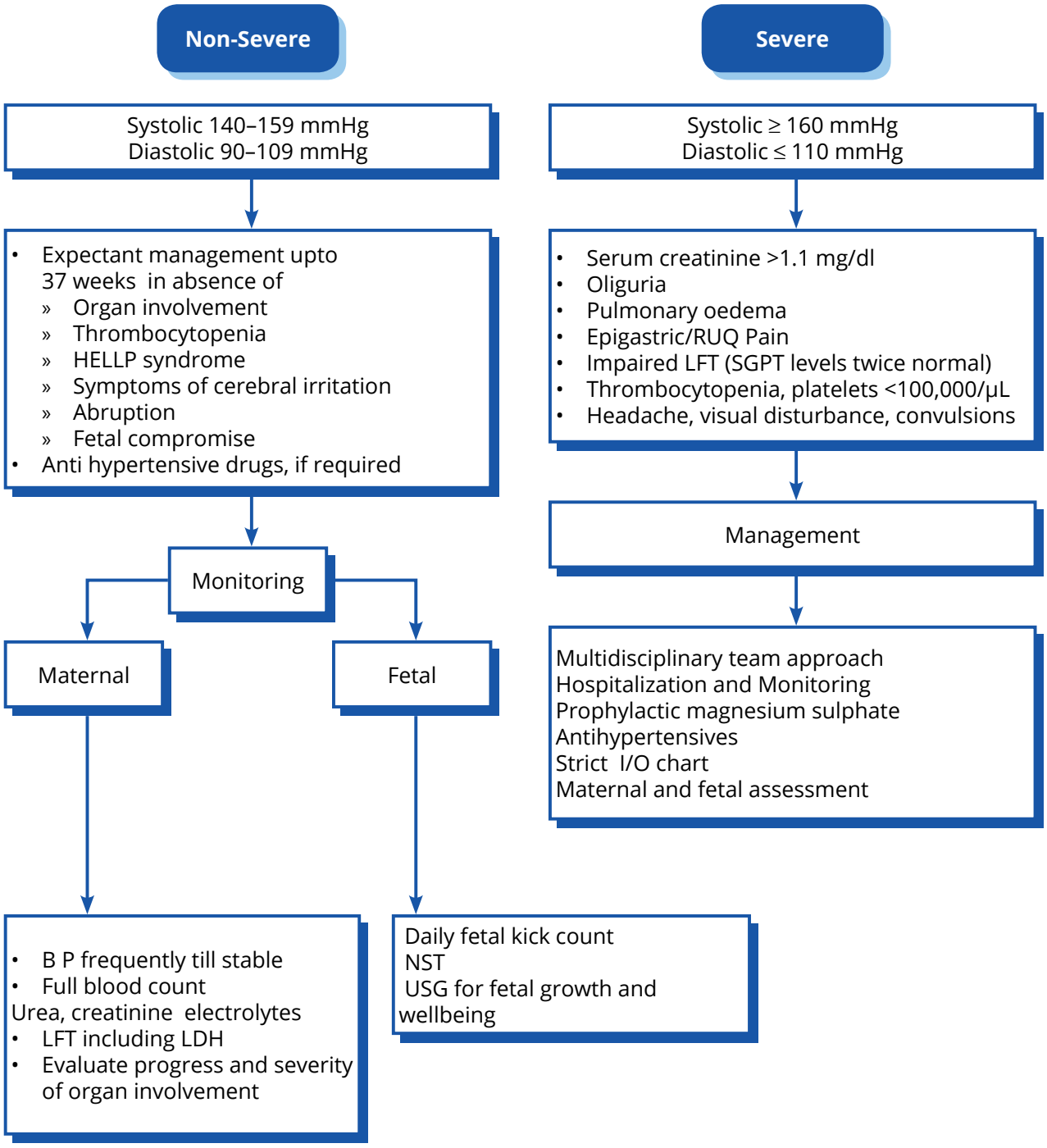
Preeclampsia and eclampsia has been seen to occur, most often after 20 weeks of gestation.

A noteworthy feature is that the prevalence of hypertension during pregnancy has been seen to be significantly higher in women with previous history of cesarean section (17.6 vs 6.5%) as compared to women with no history of cesarean section. A significantly higher rate of prior cesarean section were recorded in women with chronic hypertension as compared to normotensive women.

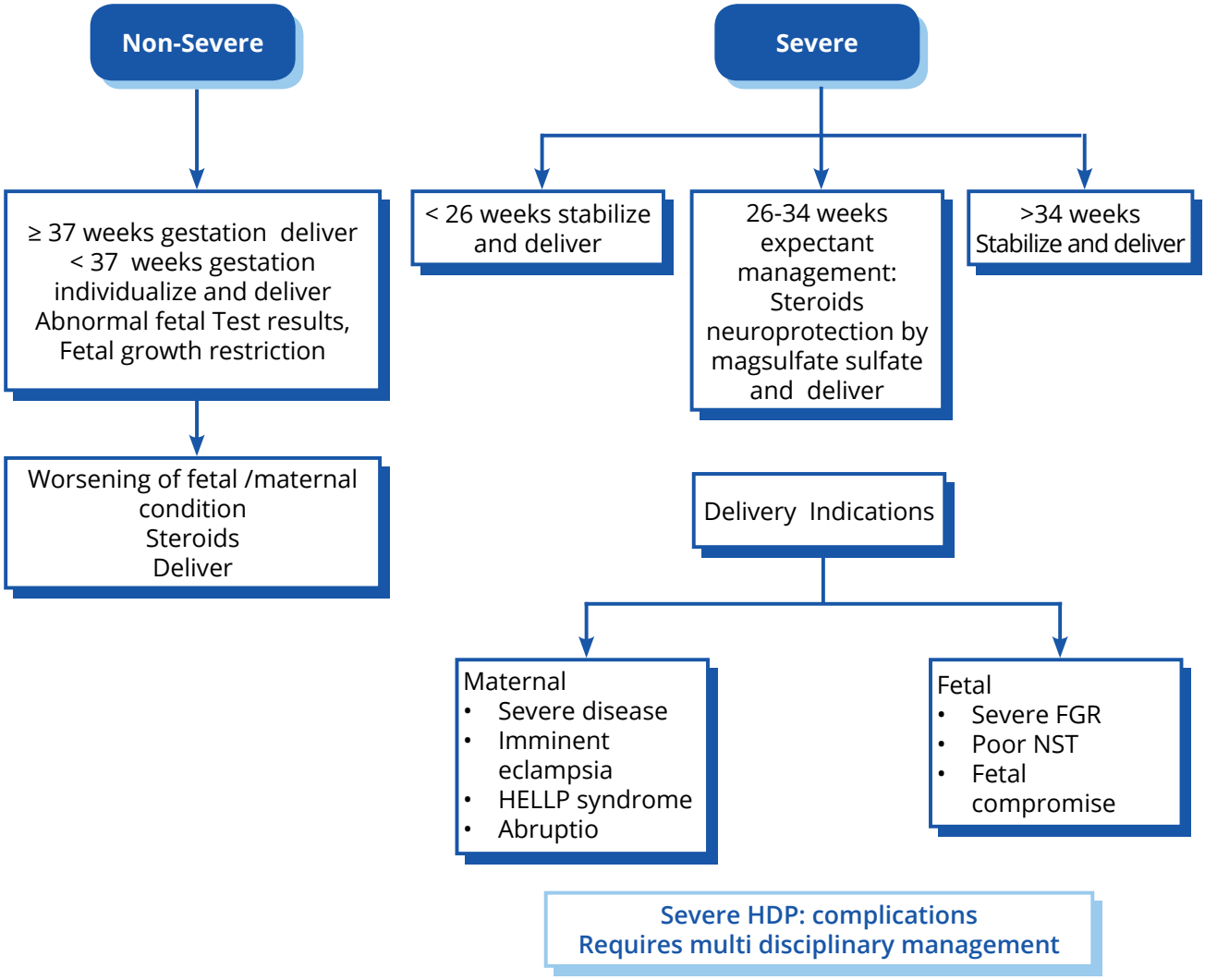
The complications of HDP which are responsible for maternal morbidity and mortality include cerebro-vascular accidents, acute renal failure and pulmonary edema, all of which are potentially preventable. So, the need of the hour is to enable an effective screening strategy to diagnose hypertension during pregnancy and also to device a comprehensive protocol for management of such cases.

HYPERTENSIVE DISORDERS IN PREGNANCY

Classification	Prevention and Prediction	Diagnostic Evaluation
• Gestational Hypertension • Preeclampsia/eclampsia • Chronic hypertension • Preclampsia superimposed on hypertension	Risk Identification: age >40; < 20 • BMI >30 • Family history of preeclampsia • Inter-pregnancy interval >10 yrs • Nulliparity • H/O Prev HDP,CKD, diabetes, APLS, Autoimmune disease • Multiple pregnancy • Gestational trophoblastic disease Prevention by: Low Dose Aspirin from 12 weeks Calcium supplementation 1 gm BD Prediction uterine artery Doppler in high risk cases	• Signs: Hypertension Rapid weight gain Progressive edema • Warning S/S: » Headache » Epigastric pain » Visual disturbances » Oliguria • Proteinuria/protein: creatinine ratio in urine • Full blood count with platelets • Urea, creatinine electrolytes • LFT including LDH **Categorize: Non severe severe**


Non-Severe
Systolic 140–159 mmHg
Diastolic 90–109 mmHg
• Expectant management upto 37 weeks in absence of
» Organ involvement
» Thrombocytopenia
» HELLP syndrome
» Symptoms of cerebral irritation
» Abruption
» Fetal compromise
• Anti hypertensive drugs, if required
Monitoring
Maternal
Fetal
• B P frequently till stable
• Full blood count
Urea, creatinine electrolytes
• LFT including LDH
• Evaluate progress and severity of organ involvement
Daily fetal kick count
NST
USG for fetal growth and wellbeing
Severe
Systolic ≥ 160 mmHg
Diastolic ≤ 110 mmHg
• Serum creatinine >1.1 mg/dl
• Oliguria
• Pulmonary oedema
• Epigastric/RUQ Pain
• Impaired LFT (SGPT levels twice normal)
• Thrombocytopenia, platelets <100,000/µL
• Headache, visual disturbance, convulsions
Management
Multidisciplinary team approach
Hospitalization and Monitoring
Prophylactic magnesium sulphate
Antihypertensives
Strict I/O chart
Maternal and fetal assessment

HYPERTENSIVE DISORDERS: OBSTETRIC MANAGEMENT



SEVERE HDP: COMPLICATIONS
REQUIRES MULTI DISCIPLINARY MANAGEMENT

- Eclampsia
- HELLP syndrome
- Neurological complications
- Pulmonary edema
- Acute kidney injury
- Peripartum cardiomyopathy
- Disseminated intravascular coagulation
- Multi-organ failure

HDP: MANAGEMENT: ANTIHYPERTENSIVE DRUG

Non-Severe

Start drugs when DBP >100 mm Hg

- Tab Labetalol 200 mg 6 to 8 hourly
- Tab Nifedipine10 to 20 mg thrice a day
- Tab Methyldopa 250 to 500 mg 6-8 hrly

if available and patient is already having it can be stopped if BP controlled with above drugs

Severe

Avoid drastic and sudden lowering of BP.

Maintain DBP : 90-100 mm Hg

Systolic
DBP > 110 mm Hg

- Inj Labetalol
- Tab Nifedipine
- Inj Hydralazine

→ Starting at lower doses. incremental

- Inj Labetalol : 20 mg IV, if no response then 40-80mg every 20-30 min, max of 220 mg : for infusion: 1-2 mg/min
- Hydralazine (5 mg IV bolus then if needed, 5–10 mg IV every 10-20 min to a maximum of 45 mg) (FIGO 2016)
- Nifedipine tablet (10 mg orally every 20-30 min to a maximum of 30 mg) (FIGO 2016)

NOTE :

- No sublingual Nifedipine
- No Frusemide
- Avoid drastic and sudden lowering of BP.
- Can use Nifedipine + Magnesium sulphate, but with caution
- Prior to transfer to tertiary care start IV line and give Inj magnesium sulphate

APLS: antiphospholipid antibodies; BP: blood pressure; CBC: complete blood count; CRP: C-reactive protein; CKD: chronic kidney disease; DBP: diastolic blood pressure; FGR: fetal growth restriction; HDP: hypertensive disorders of pregnancy; HELLP: Hemolysis, elevated liver enzymes, low platelet count syndrome; LDH: lactate dehydrogenase; LFT: liver function tests; LSCS: lower (uterine) segment Caesarean section; NST: Non-Stress test; RFT: renal function tests; RUQ: right upper quadrant; SGPT: serum glutamic pyruvic transaminase; USG: ultrasonography.

MANAGEMENT OF A PREGNANT WOMAN PRESENTING WITH ECLAMPSIA

Shout for help! IV access (no.16 to 18 cannula)

Place woman on her left side to reduce risk of aspiration of secretions, vomitus and blood

Assess breathing

- Check airway and intubate, if required
  - Rapidly evaluate vital sign (pulse, BP, and temperature). If pulse not palpable, CPR initiated, and resuscitate
  - If breathing, given oxygen at 4-6 L/min by mask or nasal cannulae Examine neck for rigidity

Simultaneouly, take patient's history from relatives

Post convulsion: clean mouth and throat, continue IV infusion at maximum of 80 ml/hr. Catheterize patient and I/O chart

- Investigation: Blood group, CBC with platelets, sugar, LFT, RFT

Start Magnesium sulphate

- Magnesium sulfate loading dose: 4 g IV as 8 ml of 50% solution diluted in 12 mL saline over 5 minutes. 10 gm of 50% solution, 5 g in each buttock as deep IM injection (can add 1 mL of lignocaine in same syringe. Maintenance dose of 5 gms IM 4 hourly on alternate buttock

Start anti hypertensive drugs if diastolic BP>100 mmHg

Provide ongoing care

- Labetolol -10-20 mg IV, then 20-80 mg every 20-30 min, max of 220 mg: for infusion: 1-2 mg/min
  Nifedipine 10-30 mg PO, repeat in 45 min if needed
  Hydralazine Inj. 5 mg IV or IM, later 5-10 mg every 30 min once BP is controlled repeat every 3 hours to a max 5 doses

- Monitor vital sign (pulse, BP & respiration > 16/min), patellar reflexes and urinary output > 30ml/hr
- Maintain strict fluid balance chart to prevent fluid overload.
- Provide maintenance dose of anti-convulsive and anti- hypertensive drugs
- Auscultate lung base hourly for rales (indication of pulmonary edema)
- Plan delivery, Monitor progress of labour, LSCS for obstetric indication

POSTPARTUM HEMORRHAGE

Moderators : Dr. Vanita Raut, Dr. S. Shanthakumari
Panel Members : Dr. M G Hiremath, Dr. Saraogi, Dr. Mahesh Gupta, Dr. Dipak Bhagde, Dr. M. Krishna Kumari

Preface

Postpartum hemorrhage is generally considered as ≥500 ml of blood loss within 24 hours after birth, while severe PPH is blood loss ≥1000 ml within 24 hours. It is the most common cause of maternal death worldwide. Most cases of PPH associated morbidity and mortality occur in the first 24 hours following delivery, whereas other few cases of PPH also occur due to abnormal or excessive bleeding from the birth canal between 24 hours and 12 weeks postnatally. Blood loss post-delivery is rarely measured in clinical practice, hence there is lack of clarity. Measuring blood loss may improve the care and outcome for women. Grand multiparity and multiple gestations are known risk factors for PPH. Moreover, it may occur in women without identifiable clinical or historical risk factors. Therefore, it is recommended that active management of the third stage of labor should be offered to all women during childbirth. Preventing delays in the diagnosis and treatment improves the chances of survival. The following demonstrates the "care pathway" for management of PPH, as a practical guide for clinicians.

POSTPARTUM HAEMORRHAGE (PPH)

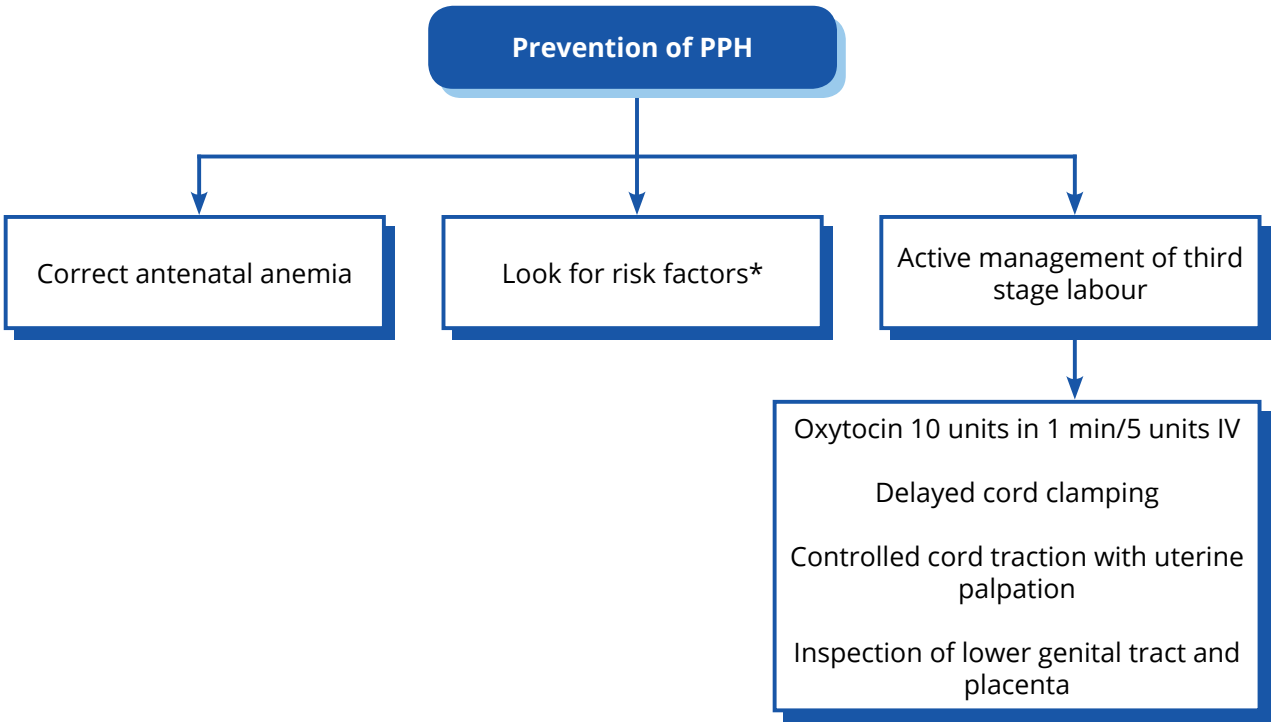
Definition

Any bleeding after the delivery of a baby that may affect the hemodynamic status/vital parameters of the mother.

Blood loss: Vaginal delivery >500 ml; caesarean section >1000 ml

Types

- Early
- Late (primary/secondary)



*PPH can occur without any risk factor

MANAGEMENT OF POST-PARTUM HEMORRHAGE

All components should be carried out simultaneously. Try to establish cause of PPH.

Prevention of PPH

Communication

- Inform patient and relatives
- Call for Help- obstetrician and anaesthetist
- Alert OT, ICU, Blood bank

Assessment

1. Clinical
- Pulse, BP,
- Respiratory rate
- Input/output

2. Assess Blood Loss

3. Investigations
- CBC
- Grouping and cross matching
- Bedside clot testing
- Coagulation studies
- Platelet count
- PT - INR
- aPTT
- Fibrinogen
- Renal and liver functions

Resuscitation

- ABC approach
- 100% oxygen at 10-15 L/min
- 16 G cannula x 2
- Urinary catheter

Replace

- 3.5 L of warmed fluid initially
- 2L crystalloid followed by crystalloid/ colloid
- Blood transfusion group specific/ O -ve
- Coagulation factors
  - » FFP
  - » Cryoprecipitate
  - » Platelets
- Massive transfusion protocol (MTP)

Arrest

- **Uterine massage**
- **Bimanual uterine compression-AORTIC Compressium**
- **Drugs**
- **Uterotonics**
  - » Oxytocin
  - » 10U IM / 5U IV followed by 20–40U IV in 500–1000ml at 125mL/hr
  - » Ergometrine every 5 mins, 5 doses, 0.25–0.5mg IV/mcg IM
  - » Misoprostol 400–800 mcg rectal
  - » Carboprost 0.25 mg IM every 15 mins, max 8 doses
- **Tranexamic acid 1g IV**
- **Surgical intervention**
  - » Removal of retained placenta
  - » Repair of tears
  - » Uterine packing
  - » Balloon tamponade
  - » Brace sutures
  - » Step in devascularisation
  - » Arterial embolization
- **Hysterectomy**

aPPT: activated partial thromboplastin time; BP: blood pressure; CBC: complete blood count; FFP: fresh frozen plasma; ICU: intensive care unit; OT: operation theater; PT-INR: prothrombin time-and international normalized ratio.

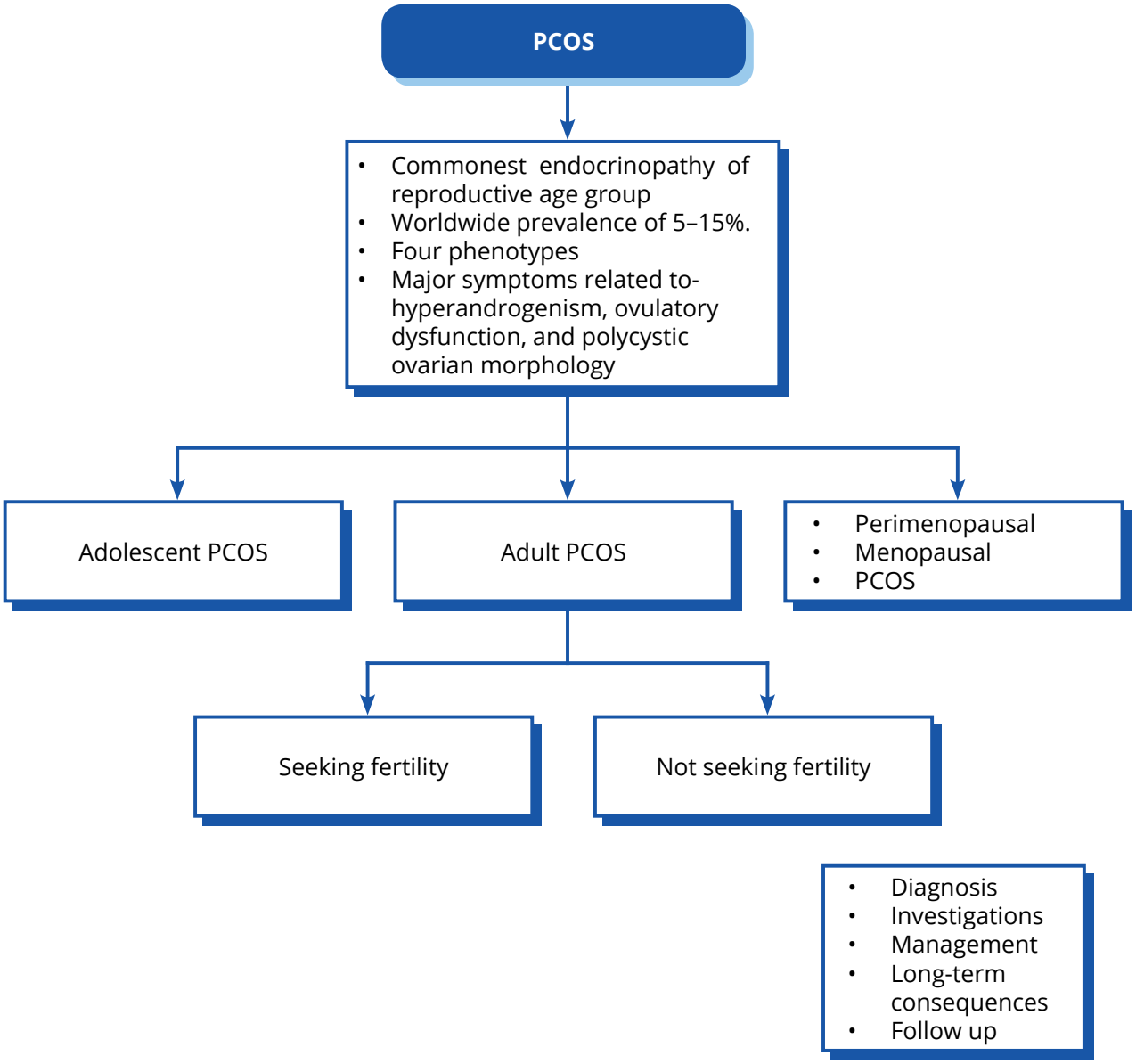
POLYCYSTIC OVARY SYNDROME

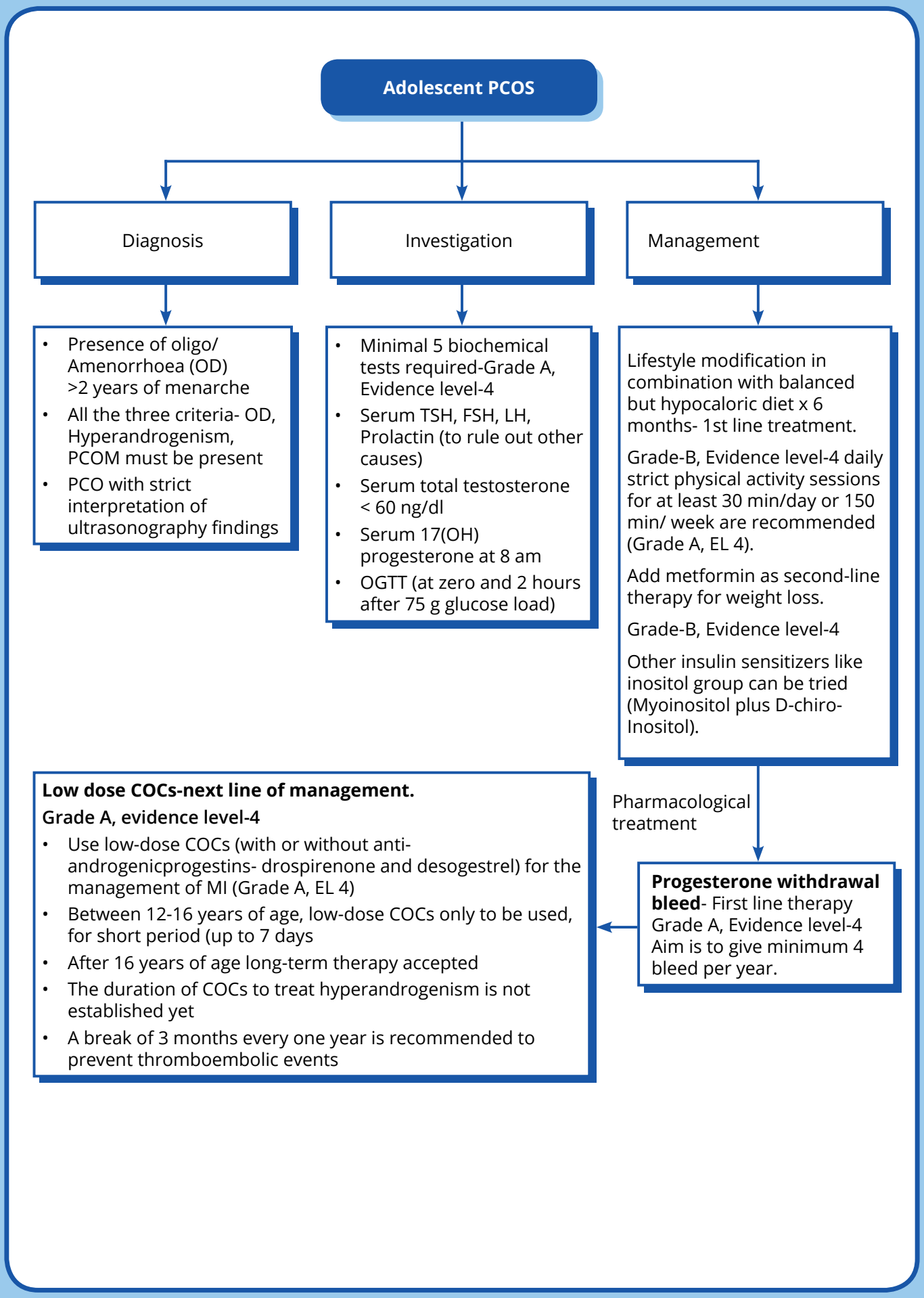
Moderators : Dr. Jaideep Malhotra, Dr. Kuldeep Jain
Panel Members : Dr. Vinita Singh, Dr. H. P. Pattnaik, Dr. A. Charmila, Dr. Seema Pandey, Dr. Sushma Pandey

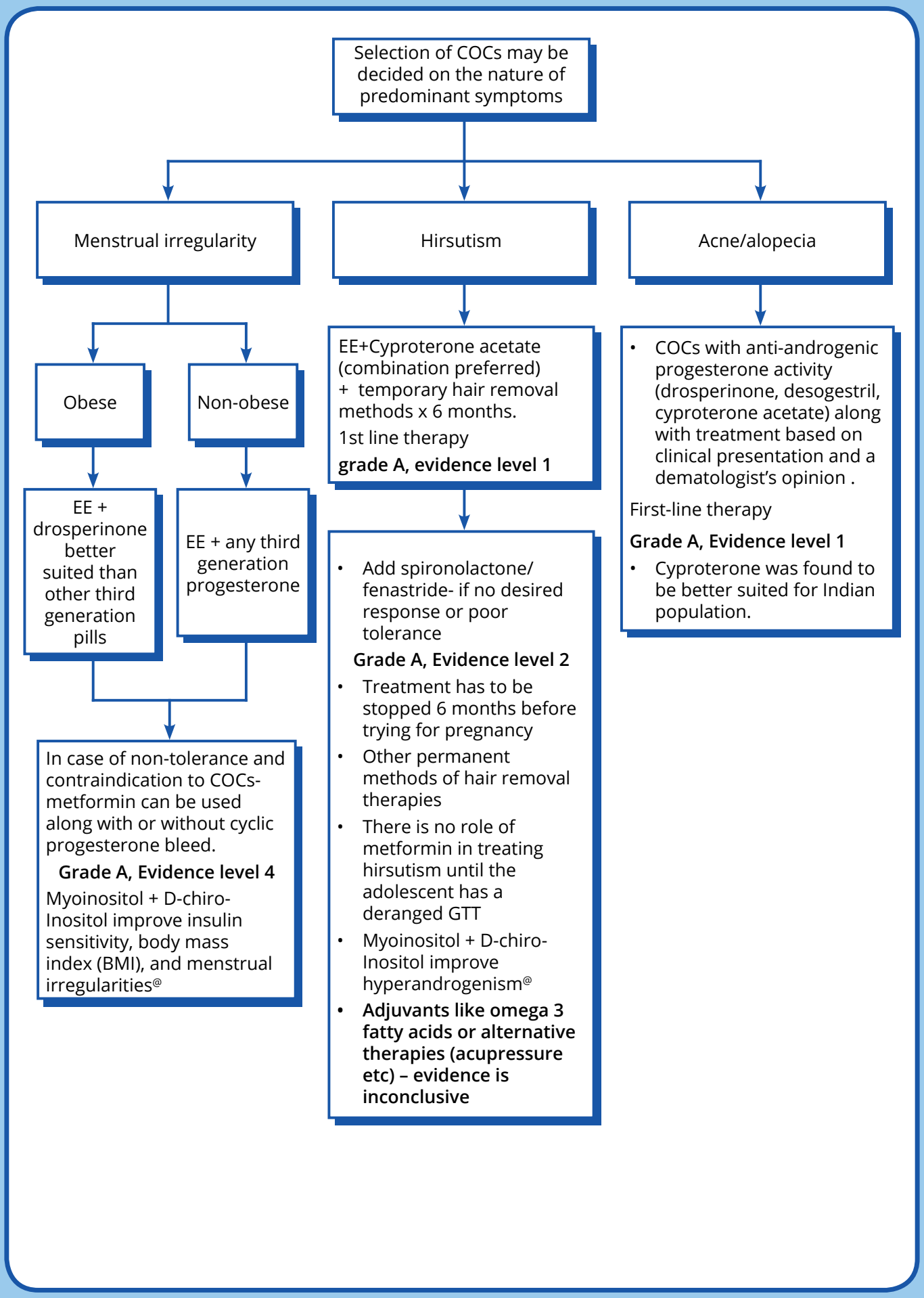
Preface

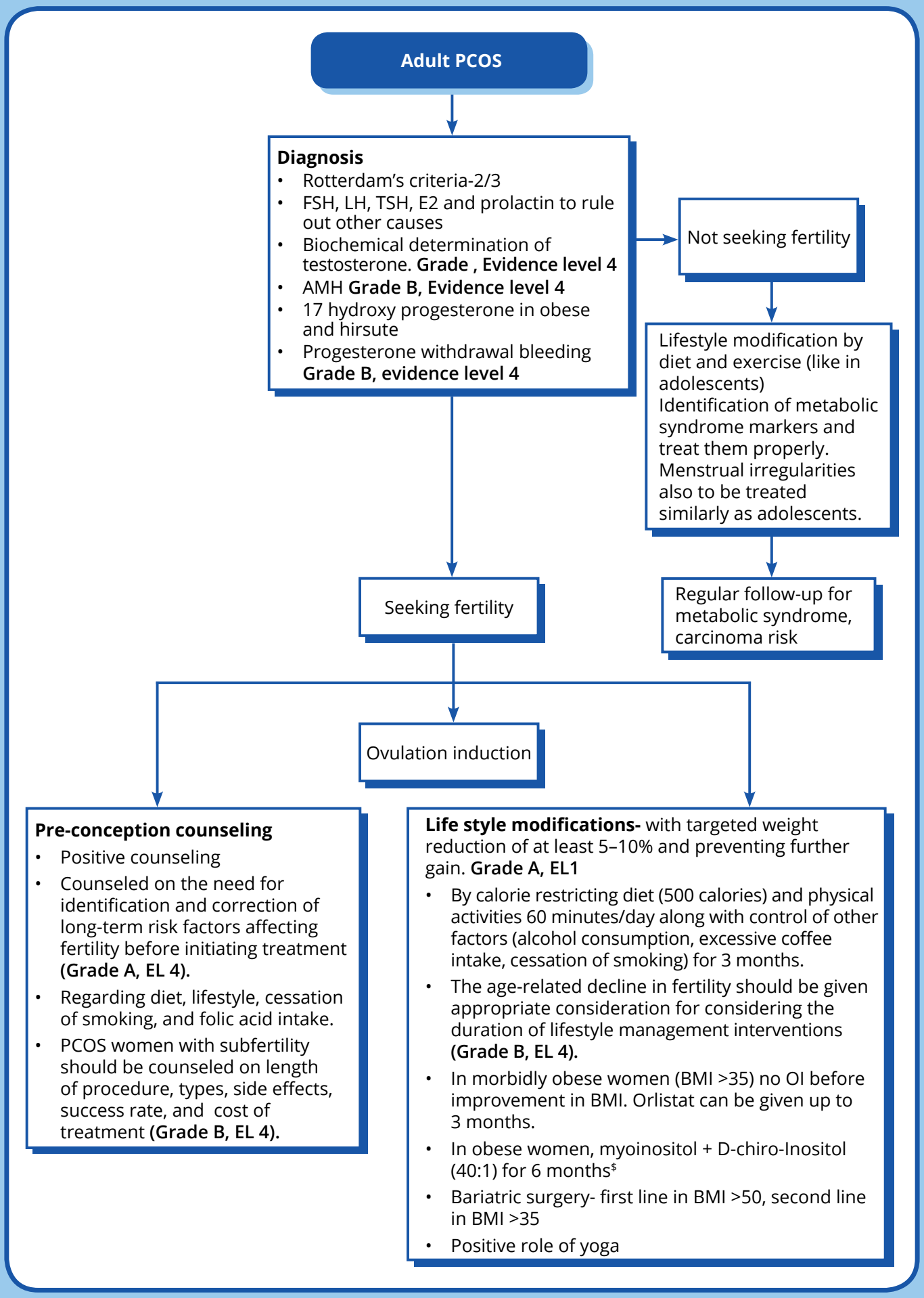
Polycystic ovary syndrome (PCOS) is one of the most common endocrine disorders in women of reproductive age with prevalence estimates ranging from 2.2% to as high as 26%. This syndrome is a common disorder complicated by hyperandrogenism and chronic anovulatory infertility associated with clinical manifestations of oligomenorrhoea, hirsutism, and acne.

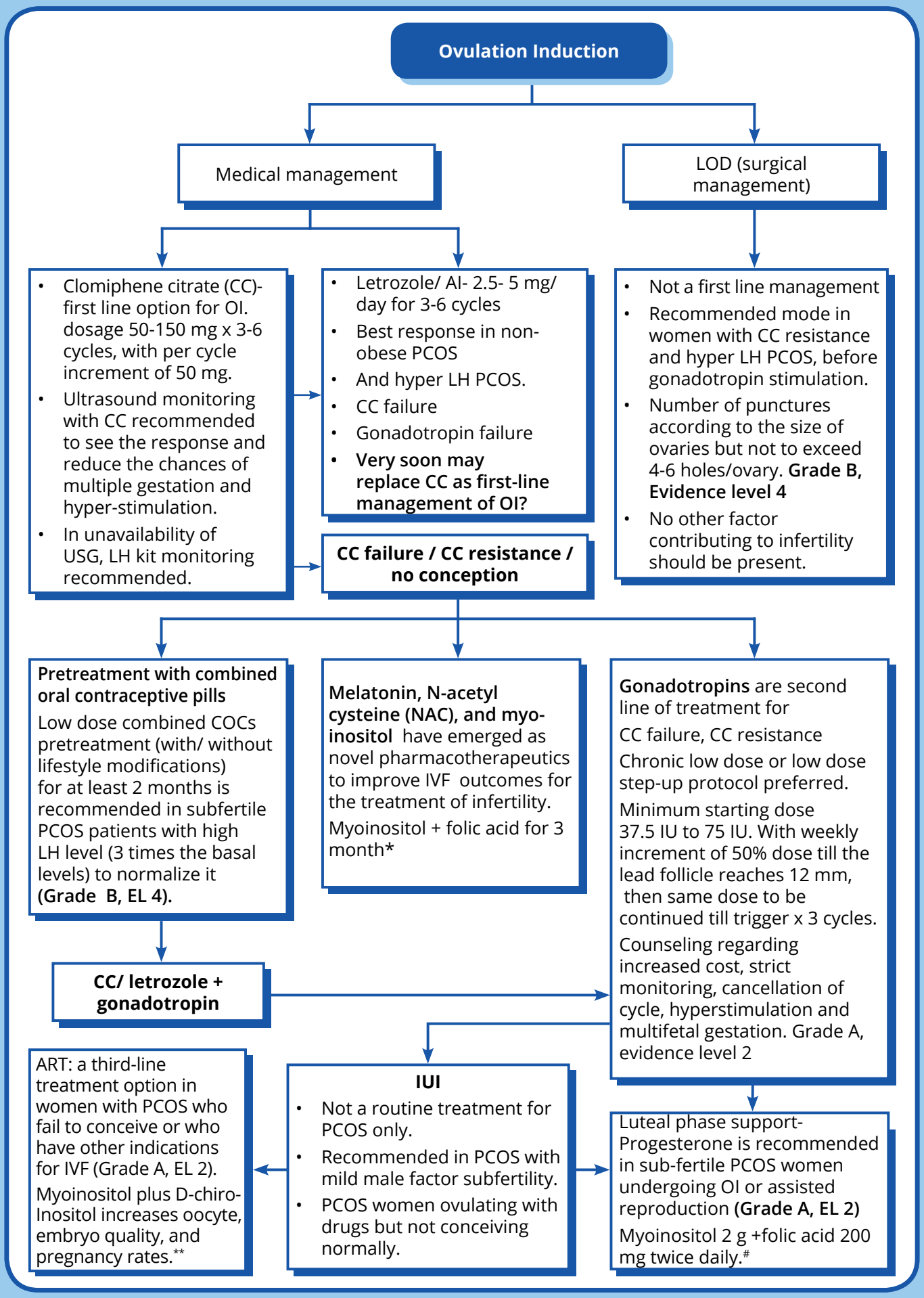
Women having PCOS are generally obese, exhibit an adverse cardiovascular risk profile, and have a higher prevalence of impaired glucose tolerance, type II diabetes, and sleep apnoea. These patients are also prone to high incidence of cardiometabolic syndrome involving hypertension, dyslipidaemia, visceral obesity, insulin resistance, and hyperinsulinaemia. Gynaecologists are observed to frequently diagnose PCOS; therefore in order to offer a holistic approach to the disorder, it is essential to have a good understanding of the long-term implications of the PCOS diagnosis. The healthcare professionals need to educate the women with PCOS regarding the possible long-term health risks and positive effects of lifestyle modifications. Those with PCOS before pregnancy should be diagnosed for gestational diabetes. The algorithm provided in this chapter guides through the process of diagnosis, investigations and management of adolescents, women and postmenopausal women with PCOS.

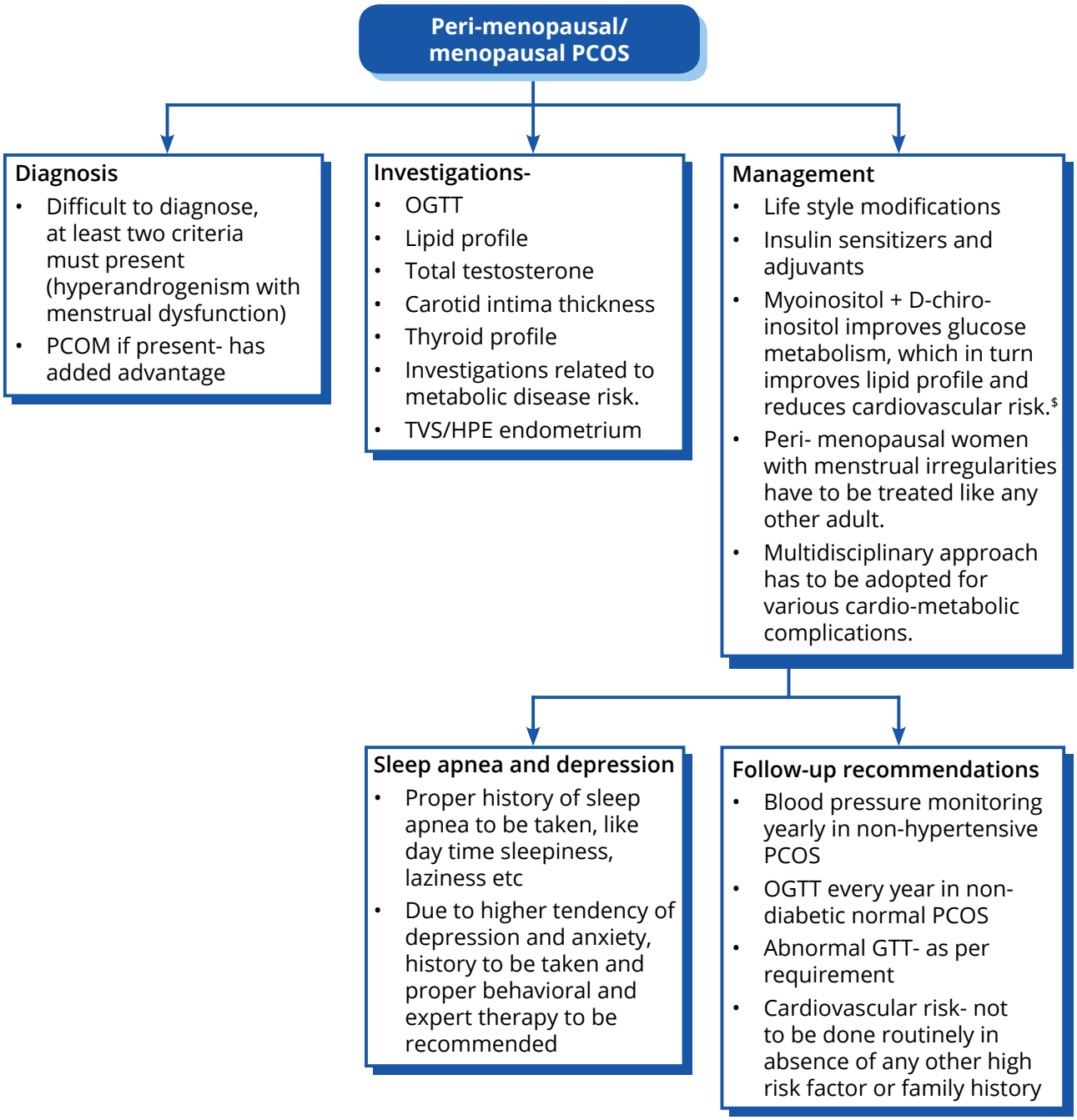

PCOS
• Commonest endocrinopathy of reproductive age group
• Worldwide prevalence of 5–15%.
• Four phenotypes
• Major symptoms related to- hyperandrogenism, ovulatory dysfunction, and polycystic ovarian morphology
Adolescent PCOS
Adult PCOS
• Perimenopausal
• Menopausal
• PCOS
Seeking fertility
Not seeking fertility
• Diagnosis
• Investigations
• Management
• Long-term consequences
• Follow up


Adolescent PCOS
Diagnosis
Investigation
Management
• Presence of oligo/ Amenorrhoea (OD) >2 years of menarche
• All the three criteria- OD, Hyperandrogenism, PCOM must be present
• PCO with strict interpretation of ultrasonography findings
• Minimal 5 biochemical tests required-Grade A, Evidence level-4
• Serum TSH, FSH, LH, Prolactin (to rule out other causes)
• Serum total testosterone < 60 ng/dl
• Serum 17(OH) progesterone at 8 am
• OGTT (at zero and 2 hours after 75 g glucose load)
Lifestyle modification in combination with balanced but hypocaloric diet x 6 months- 1st line treatment.
Grade-B, Evidence level-4 daily strict physical activity sessions for at least 30 min/day or 150 min/ week are recommended (Grade A, EL 4).
Add metformin as second-line therapy for weight loss.
Grade-B, Evidence level-4
Other insulin sensitizers like inositol group can be tried (Myoinositol plus D-chiro-Inositol).
Pharmacological treatment
Progesterone withdrawal bleed- First line therapy Grade A, Evidence level-4 Aim is to give minimum 4 bleed per year.
Low dose COCs-next line of management.
Grade A, evidence level-4
• Use low-dose COCs (with or without anti-androgenicprogestins- drospirenone and desogestrel) for the management of MI (Grade A, EL 4)
• Between 12-16 years of age, low-dose COCs only to be used, for short period (up to 7 days
• After 16 years of age long-term therapy accepted
• The duration of COCs to treat hyperandrogenism is not established yet
• A break of 3 months every one year is recommended to prevent thromboembolic events


Selection of COCs may be decided on the nature of predominant symptoms
Menstrual irregularity
Hirsutism
Acne/alopecia
Obese
Non-obese
EE + drosperinone better suited than other third generation pills
EE + any third generation progesterone
In case of non-tolerance and contraindication to COCs- metformin can be used along with or without cyclic progesterone bleed.
Grade A, Evidence level 4
Myoinositol + D-chiro-Inositol improve insulin sensitivity, body mass index (BMI), and menstrual irregularities@
EE+Cyproterone acetate (combination preferred) + temporary hair removal methods x 6 months.
1st line therapy
grade A, evidence level 1
• Add spironolactone/ fenastride- if no desired response or poor tolerance
Grade A, Evidence level 2
• Treatment has to be stopped 6 months before trying for pregnancy
• Other permanent methods of hair removal therapies
• There is no role of metformin in treating hirsutism until the adolescent has a deranged GTT
• Myoinositol + D-chiro-Inositol improve hyperandrogenism@
• Adjuvants like omega 3 fatty acids or alternative therapies (acupressure etc) – evidence is inconclusive
• COCs with anti-androgenic progesterone activity (drosperinone, desogestril, cyproterone acetate) along with treatment based on clinical presentation and a dematologist's opinion .
First-line therapy
Grade A, Evidence level 1
• Cyproterone was found to be better suited for Indian population.


Adult PCOS
Diagnosis
• Rotterdam's criteria-2/3
• FSH, LH, TSH, E2 and prolactin to rule out other causes
• Biochemical determination of testosterone. Grade , Evidence level 4
• AMH Grade B, Evidence level 4
• 17 hydroxy progesterone in obese and hirsute
• Progesterone withdrawal bleeding Grade B, evidence level 4
Not seeking fertility
Lifestyle modification by diet and exercise (like in adolescents)
Identification of metabolic syndrome markers and treat them properly.
Menstrual irregularities also to be treated similarly as adolescents.
Regular follow-up for metabolic syndrome, carcinoma risk
Seeking fertility
Ovulation induction
Pre-conception counseling
• Positive counseling
• Counseled on the need for identification and correction of long-term risk factors affecting fertility before initiating treatment (Grade A, EL 4).
• Regarding diet, lifestyle, cessation of smoking, and folic acid intake.
• PCOS women with subfertility should be counseled on length of procedure, types, side effects, success rate, and cost of treatment (Grade B, EL 4).
Life style modifications- with targeted weight reduction of at least 5–10% and preventing further gain. Grade A, EL1
• By calorie restricting diet (500 calories) and physical activities 60 minutes/day along with control of other factors (alcohol consumption, excessive coffee intake, cessation of smoking) for 3 months.
• The age-related decline in fertility should be given appropriate consideration for considering the duration of lifestyle management interventions (Grade B, EL 4).
• In morbidly obese women (BMI >35) no OI before improvement in BMI. Orlistat can be given up to 3 months.
• In obese women, myoinositol + D-chiro-Inositol (40:1) for 6 months$
• Bariatric surgery- first line in BMI >50, second line in BMI >35
• Positive role of yoga


Ovulation Induction
Medical management
LOD (surgical management)
• Clomiphene citrate (CC)- first line option for OI. dosage 50-150 mg x 3-6 cycles, with per cycle increment of 50 mg.
• Ultrasound monitoring with CC recommended to see the response and reduce the chances of multiple gestation and hyper-stimulation.
• In unavailability of USG, LH kit monitoring recommended.
• Letrozole/ AI- 2.5- 5 mg/ day for 3-6 cycles
• Best response in non-obese PCOS
• And hyper LH PCOS.
• CC failure
• Gonadotropin failure
• Very soon may replace CC as first-line management of OI?
• Not a first line management
• Recommended mode in women with CC resistance and hyper LH PCOS, before gonadotropin stimulation.
• Number of punctures according to the size of ovaries but not to exceed 4-6 holes/ovary. Grade B, Evidence level 4
• No other factor contributing to infertility should be present.
CC failure / CC resistance / no conception
Pretreatment with combined oral contraceptive pills
Low dose combined COCs pretreatment (with/ without lifestyle modifications) for at least 2 months is recommended in subfertile PCOS patients with high LH level (3 times the basal levels) to normalize it (Grade B, EL 4).
Melatonin, N-acetyl cysteine (NAC), and myo-inositol have emerged as novel pharmacotherapeutics to improve IVF outcomes for the treatment of infertility.
Myoinositol + folic acid for 3 month*
Gonadotropins are second line of treatment for
CC failure, CC resistance
Chronic low dose or low dose step-up protocol preferred.
Minimum starting dose 37.5 IU to 75 IU. With weekly increment of 50% dose till the lead follicle reaches 12 mm, then same dose to be continued till trigger x 3 cycles.
Counseling regarding increased cost, strict monitoring, cancellation of cycle, hyperstimulation and multifetal gestation. Grade A, evidence level 2
CC/ letrozole + gonadotropin
ART: a third-line treatment option in women with PCOS who fail to conceive or who have other indications for IVF (Grade A, EL 2).
Myoinositol plus D-chiro-Inositol increases oocyte, embryo quality, and pregnancy rates.**
IUI
• Not a routine treatment for PCOS only.
• Recommended in PCOS with mild male factor subfertility.
• PCOS women ovulating with drugs but not conceiving normally.
Luteal phase support- Progesterone is recommended in sub-fertile PCOS women undergoing OI or assisted reproduction (Grade A, EL 2)
Myoinositol 2 g +folic acid 200 mg twice daily.#



@ Kalra B, Kalra S, Sharma JB. The inositols and polycystic ovary syndrome. Indian J Endocr Metab. 2016;20:720-4.
*Regidor PA, Schindler AE. Myoinositol as a safe and alternative approach in the treatment of infertile PCOS women: A German Observational Study. Int J Endocrinol. 2016;2016:9537632.
** Colazingari S, Treglia M, Najjar R, et al. The combined therapy myo-inositol plus D-chiro-inositol, rather than D-chiro-inositol, is able to improve IVF outcomes: Results from a randomized controlled trial. Arch Gynecol Obstet. 2013;288(6):1405–411.
# Papaleo E, Unfer V, Baillargeon JP, et al. Myo-inositol in patients with polycystic ovary syndrome: A novel method for ovulation induction. Gynecol Endocrinol. 2007;23(12):700–03.
$ Minozzi M, Nordio M, Pajalich R. The Combined therapy myo-inositol plus D-Chiro-inositol, in a physiological ratio, reduces the cardiovascular risk by improving the lipid profile in PCOS patients. Eur Rev Med Pharmacol Sci. 2013;17(4):537–40.

AI: Aromatase Inhibitor; AMH: anti-Mullerian hormone; BMI: body mass index; COCs: combined oral contraceptive; E2: estradiol; EE: ethinylestradiol; FSH: follicle-stimulating hormone; GTT: glucose tolerance test; HPE: histopathological evaluation; IVF: in-vitro fertilization; LH: luteinizing hormone; LOD: laparoscopic ovarian drilling; OGTT: oral glucose tolerance test; OI: Ovulation Induction; PCOM: polycystic ovarian morphology; TSH: Thyroid-stimulating hormone; TVS: Transvaginal sonography; USG: ultrasonography.

REVERSIBLE CONTRACEPTION PRACTICE

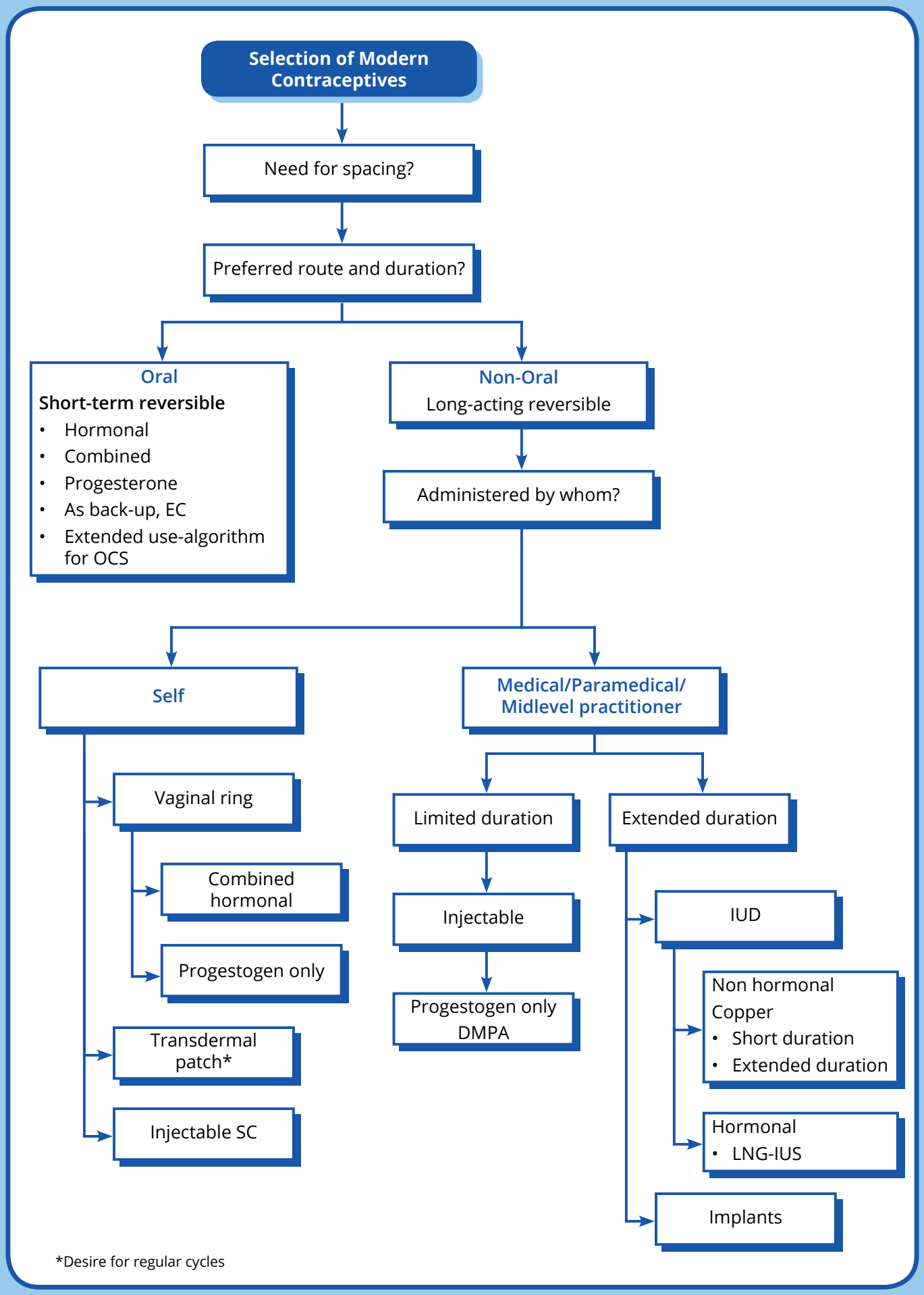
Moderators : Dr. Ritu Joshi, Dr. Reena Wani
Panel Members : Dr. Shyamal Sett, Dr. Archana Baser, Dr. Tarini Taneja, Dr. Komal Chavan, Dr. Monika Doshi

Preface

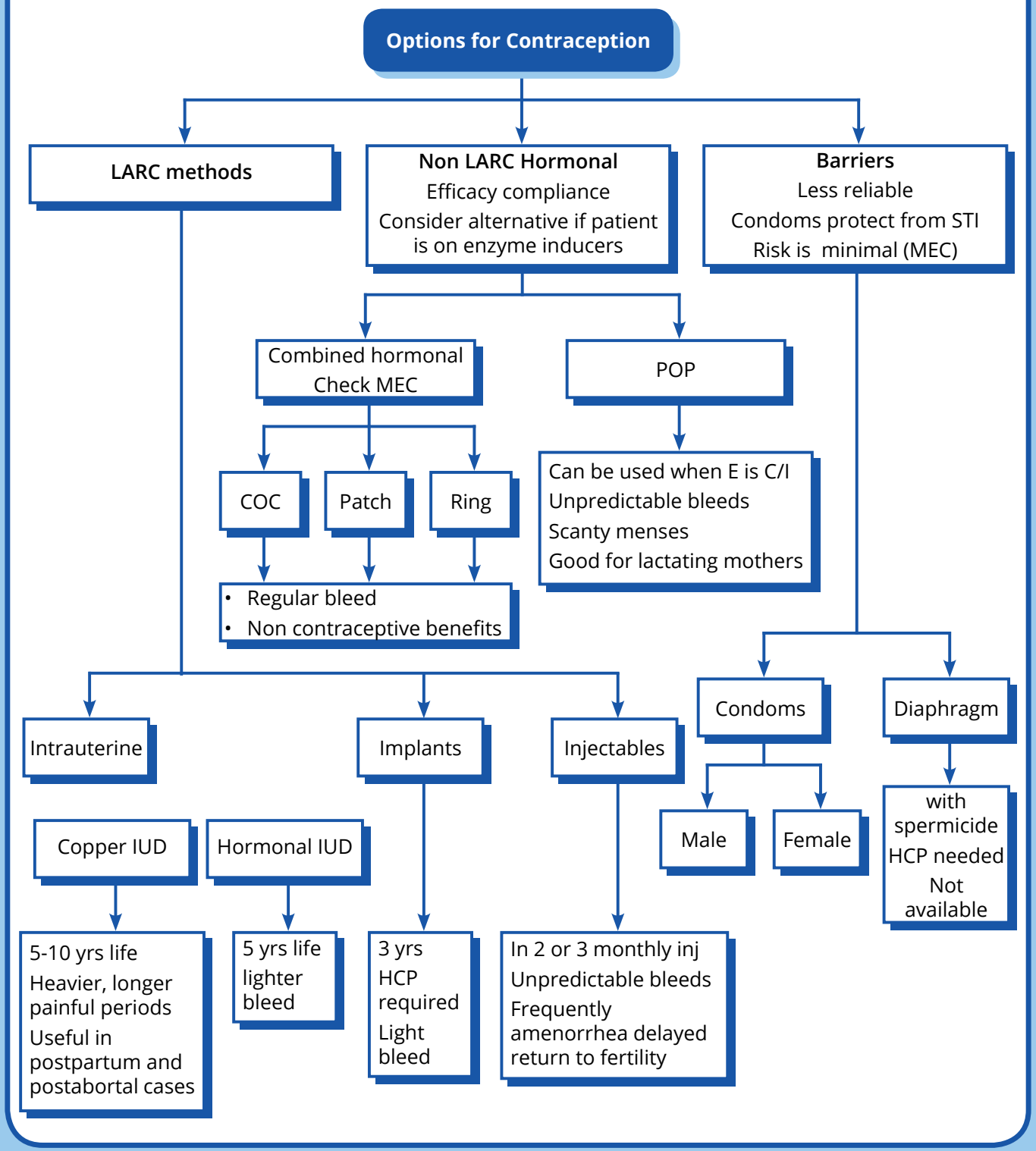
Unintended pregnancies have significant social and economic consequences. The effectiveness of different currently available methods in preventing pregnancy varies widely. It is generally accepted that long-acting reversible contraceptives (LARCs), including intrauterine devices (IUDs), and progestogen implants, are most effective apart from permanent sterilization methods such as vasectomy and tubal ligation. LARCs are safe and highly effective for women in reducing unintended pregnancy and abortion rates due to their long duration of action and requirements of minimal adherence.

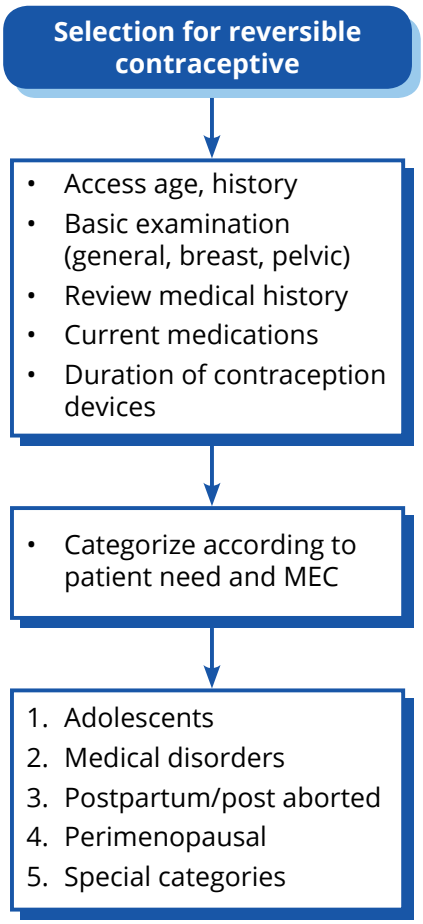
Ovulation occurs at a mean of 39 days post-partum in non-lactating women, which increases the risk of unintended and short-interval pregnancy. Around 70% of pregnancies are unintended during the first year post-delivery. Therefore, use of reversible contraceptive methods can provide several potential benefits and help in lowering the rate of unintended pregnancy and avoiding short-interval pregnancy.

Before selecting a post-partum reversible contraceptive method, women should be counseled prenatally, including counseling regarding the advantages, risks of IUD expulsion, as well as contraindications. Therefore, LARCs are recommended as effective means of contraception without its impact on future fertility. The algorithms provide a process for availability, methods, and selection of modern contraceptive options.


Selection of Modern Contraceptives
Need for spacing?
Preferred route and duration?
Oral
Short-term reversible
• Hormonal
• Combined
• Progesterone
• As back-up, EC
• Extended use-algorithm for OCS
Non-Oral
Long-acting reversible
Administered by whom?
Self
Vaginal ring
Combined hormonal
Progestogen only
Transdermal patch*
Injectable SC
Medical/Paramedical/ Midlevel practitioner
Limited duration
Injectable
Progestogen only DMPA
Extended duration
IUD
Non hormonal Copper
• Short duration
• Extended duration
Hormonal
• LNG-IUS
Implants
*Desire for regular cycles

Long-acting reversible contraception (LARC)				
Time of use / administration				
		IUD		
	Injectables	Copper	LNG	Implant
Interval	✓	✓	✓	✓
Post abortal	✓	✓	✓	✓
Post partum	---- >6 weeks	✓	✓* <48 hrs >4 weeks	✓*>6 weeks
Emergency	----	✓	----	----
* 6 weeks postpartum if lactating				





C/I: contraindicated; COCs: combined oral contraceptive; DMPA: depo-medroxyprogesterone acetate; EC: emergency contraception; HCP: health care provider; IUD: Intrauterine device; LNG- IUS: levonorgestrel intrauterine system; MEC: medical eligibility criteria; POP: progestin-only pills; SC: subcutaneous; STI: sexually transmitted infections.

ECTOPIC PREGNANCY

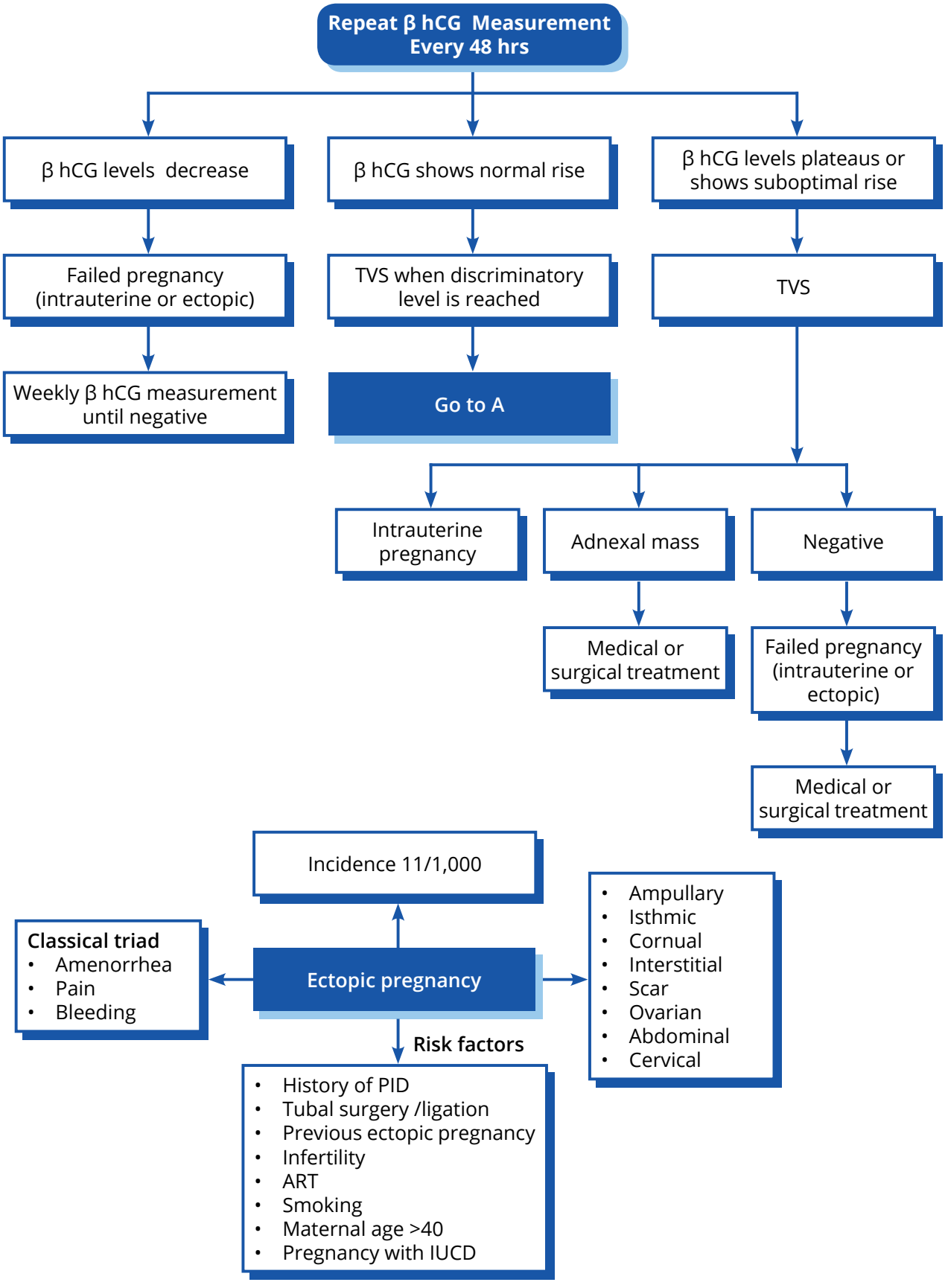
Moderators : Dr. Alka Kriplani, Dr. Chaitanya Ganapule
Panel Members : Dr. Bijoy Nayak, Dr. Atul Ganatra, Dr. Navina Singh

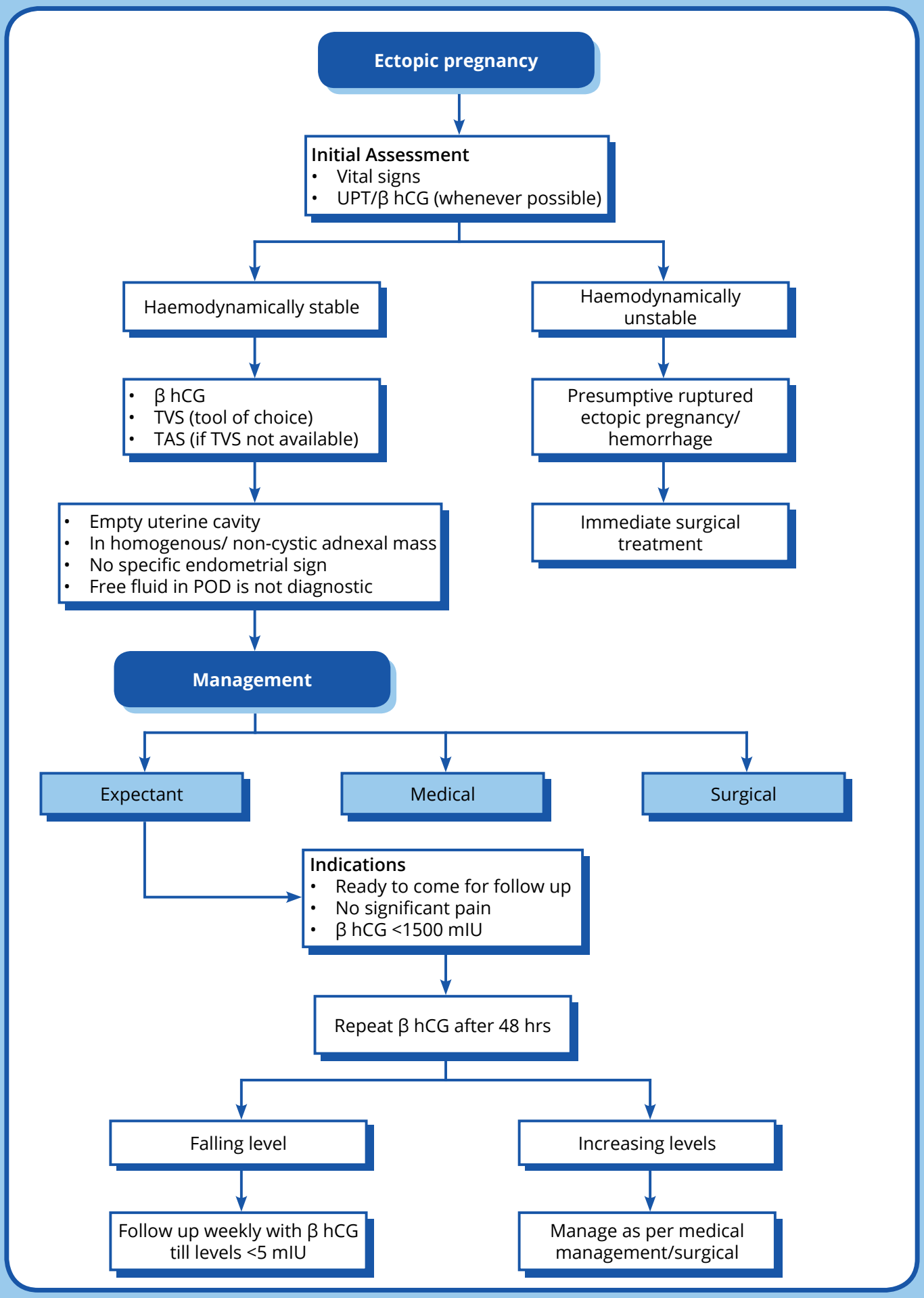
Preface

Ectopic pregnancy is a high-risk condition wherein a fertilized ovum gets implanted outside the uterine cavity. This condition poses a significant threat to women of reproductive age and is a leading cause of maternal death during the first trimester. It is reported to affect around 1% to 2% of all pregnancies. Risk factors for ectopic pregnancy include surgery or infection that causes tubal damage, as well as maternal smoking and in vitro fertilisation. However, the majority of women with an ectopic pregnancy have no identifiable risk factor. Advances in diagnosis and treatment of ectopic pregnancy have reduced the mortality rates by 50%.

First-trimester bleeding and abdominal pain may be indicative of common symptoms of an unruptured ectopic pregnancy. It is essential to consider ectopic pregnancy when a pregnant woman presents with these symptoms. The details involving clinical history on pregnancy dating, the onset and intensity of symptoms, and a review of risk factors can help in determining the best diagnostic course, as well as the speed of processing the workup. Noting the severity of symptoms is important; especially for those with more severe bleeding, and hemodynamic instability. Surgical treatment may be warranted in such cases. The following flowcharts may help in guiding the diagnostic and treatment approaches for patients with ectopic pregnancy.

PUL


Repeat β hCG Measurement Every 48 hrs
β hCG levels decrease
β hCG shows normal rise
β hCG levels plateaus or shows suboptimal rise
Failed pregnancy (intrauterine or ectopic)
TVS when discriminatory level is reached
TVS
Weekly β hCG measurement until negative
Go to A
Intrauterine pregnancy
Adnexal mass
Negative
Medical or surgical treatment
Failed pregnancy (intrauterine or ectopic)
Medical or surgical treatment
Incidence 11/1,000
Classical triad
• Amenorrhea
• Pain
• Bleeding
Ectopic pregnancy
• Ampullary
• Isthmic
• Cornual
• Interstitial
• Scar
• Ovarian
• Abdominal
• Cervical
Risk factors
• History of PID
• Tubal surgery /ligation
• Previous ectopic pregnancy
• Infertility
• ART
• Smoking
• Maternal age >40
• Pregnancy with IUCD


Ectopic pregnancy
Initial Assessment
• Vital signs
• UPT/β hCG (whenever possible)
Haemodynamically stable
Haemodynamically unstable
• β hCG
• TVS (tool of choice)
• TAS (if TVS not available)
Presumptive ruptured ectopic pregnancy/ hemorrhage
• Empty uterine cavity
• In homogenous/ non-cystic adnexal mass
• No specific endometrial sign
• Free fluid in POD is not diagnostic
Immediate surgical treatment
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

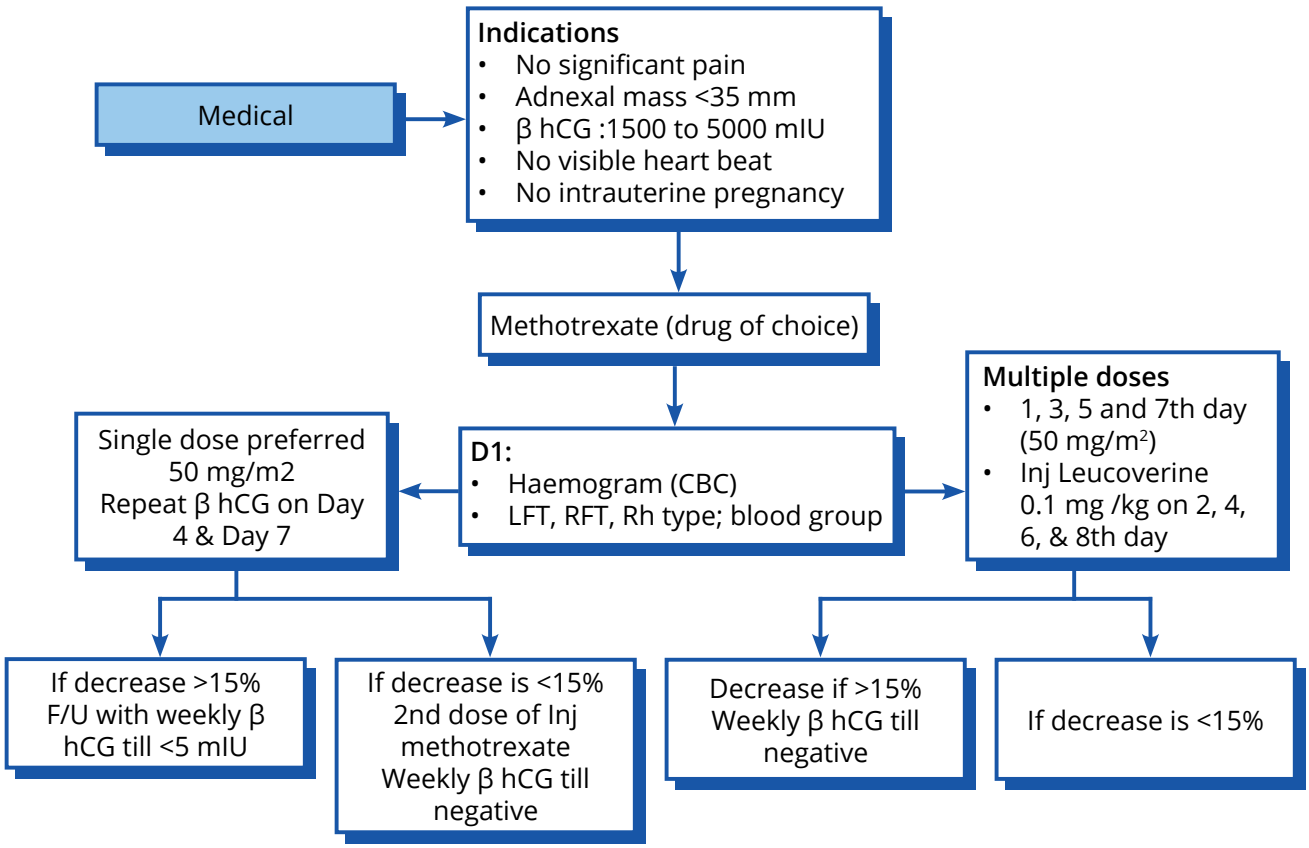
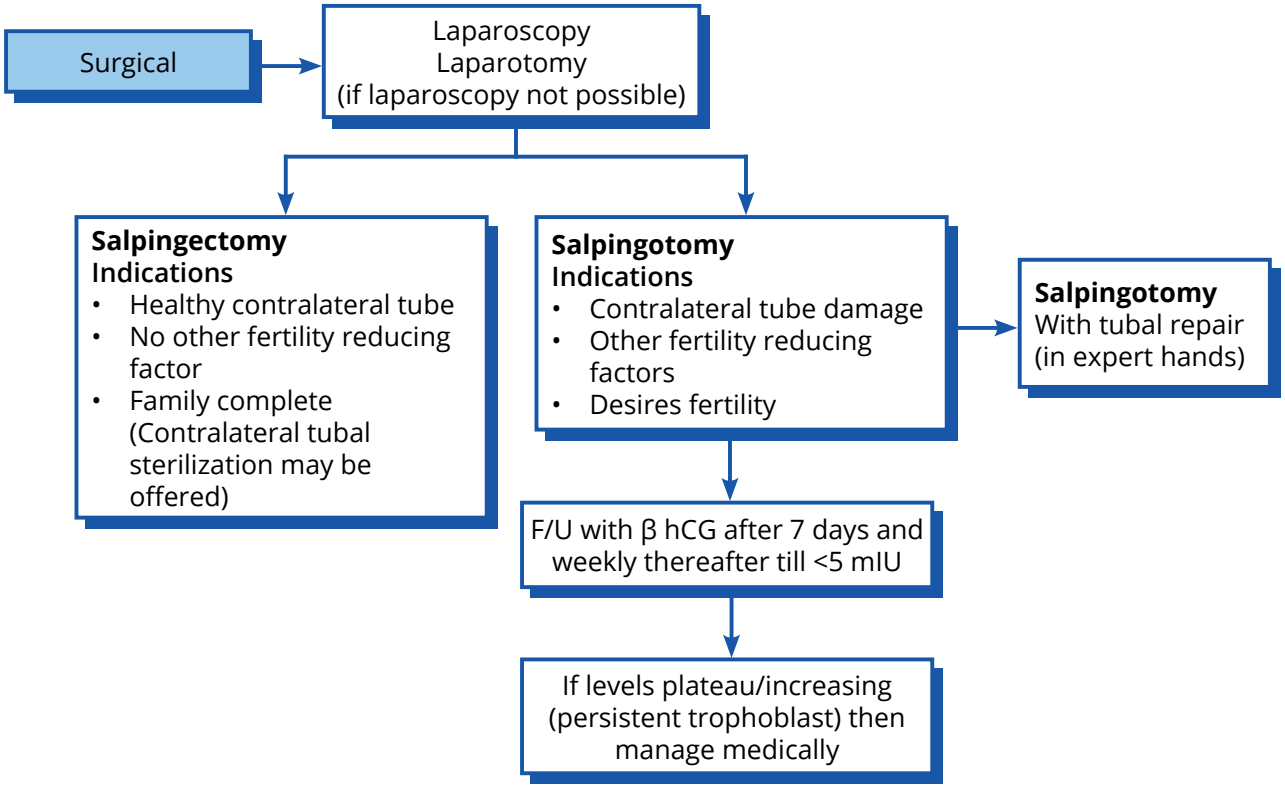


Table 1. Multiple-dose MTX treatment protocol

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: suverilance 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= leucoverin.



Cervical pregnancy

- Medical management is the choice with systemic methotrexate
- Surgical management only if life threatening bleeding

Scar pregnancy

- Medical management is the choice with systemic methotrexate
- Surgical management only if life threatening bleeding

CBC: complete blood count; HCG: human chronic gonadotropin; PUL: pregnancy of unknown location; RFTs: Renal functions tests, LFTs: liver function tests, POD: pouch of Douglas; PID: pelvic inflammatory disease; TAS: transabdominal scan; TVS: transvaginal scan; IUCD: intrauterine contraceptive device; UPT: uterine pregnancy test.

ACUTE UTERINE BLEEDING

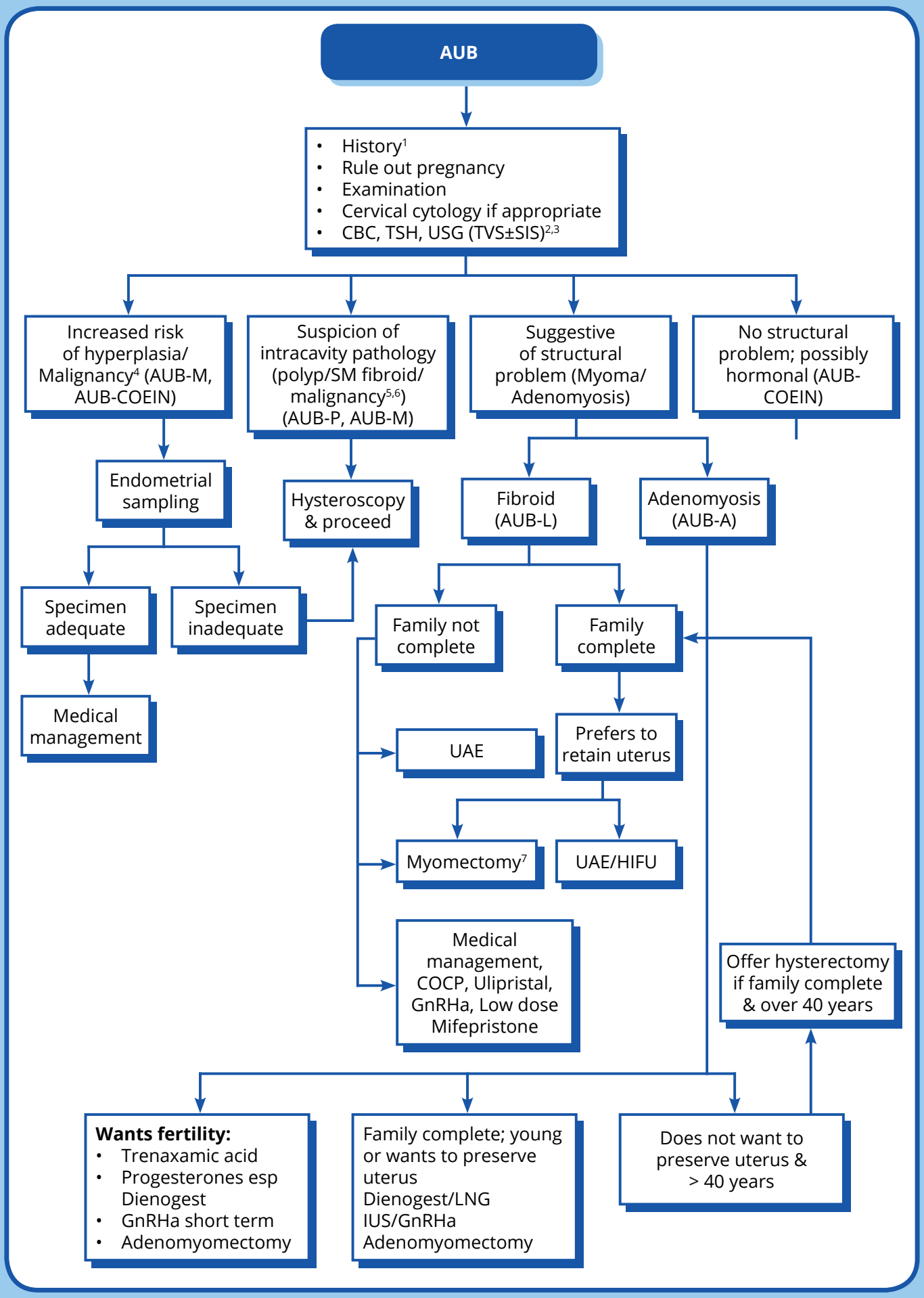
Moderators: Dr. Prakash Trivedi, Dr. Bhaskar Pal
Participants: Dr. Rajesh Modi, Dr. Rekha Kurian, Dr. Geetendra Sharma, Dr. Archana Verma, Dr. Rajendra Nagarkatti

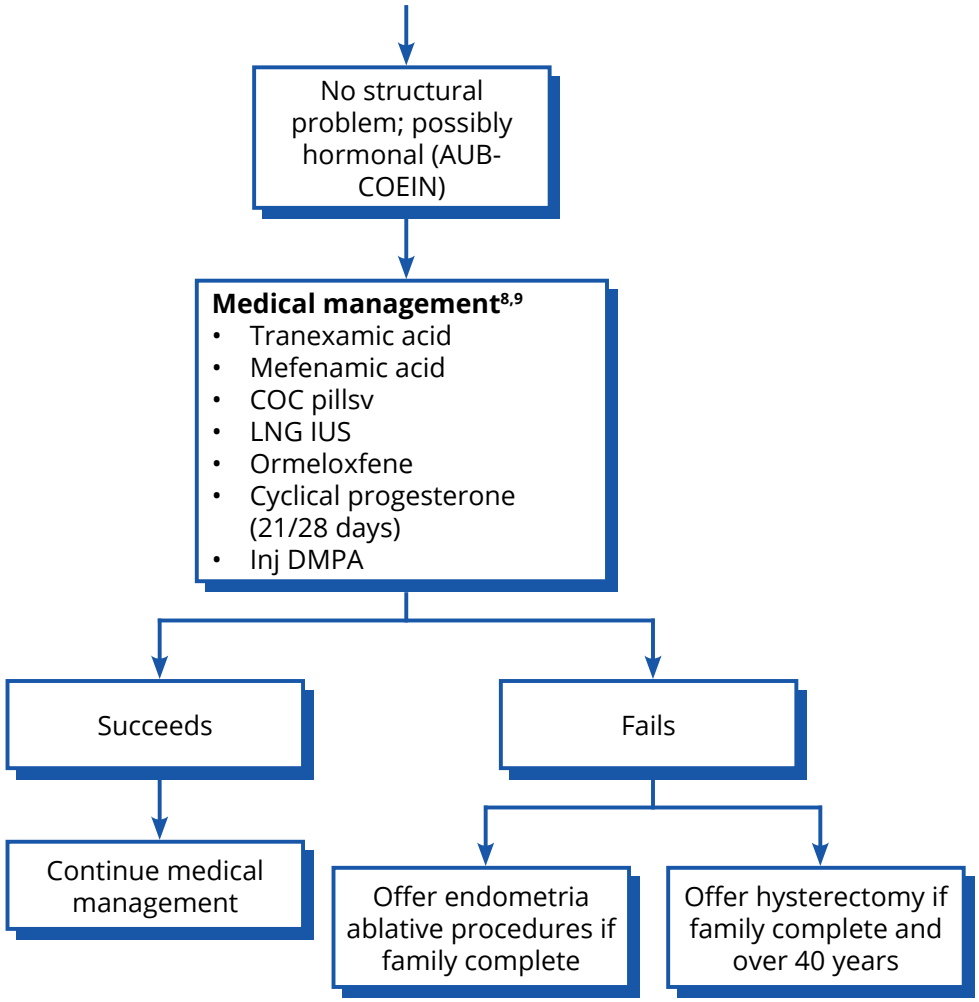
Preface

Acute uterine bleeding (AUB) which is unrelated to pregnancy has been described as "bleeding that is sufficient in volume as to, in the opinion of the treating clinician, require urgent or emergent intervention". Many women of reproductive age experience acute bleeding when not pregnant, but this aspect has not received much attention. Also, uterine hemorrhage occurs secondary to pregnancy.

AUB is a relatively common clinical condition in women and can be source of distress and a challenge for clinicians; and many of these women are managed with inpatient surgical procedures. Medical treatment with single or combined gonadal steroidal drugs given parenterally or orally show promise, but further researcher is need to better define the appropriate drugs, dose, and administrative scheduling.

In case of women with AUB medical management should be the first-choice. Surgical approaches should be considered unless bleeding is suspected to related to retained products of conception or from intrauterine lesions such as aborting submucous leiomyomas.


AUB
History[1]
Rule out pregnancy
Examination
Cervical cytology if appropriate
CBC, TSH, USG (TVS±SIS)[2,3]
Increased risk of hyperplasia/ Malignancy[4] (AUB-M, AUB-COEIN)
Suspicion of intracavity pathology (polyp/SM fibroid/ malignancy[5,6]) (AUB-P, AUB-M)
Suggestive of structural problem (Myoma/ Adenomyosis)
No structural problem; possibly hormonal (AUB-COEIN)
Endometrial sampling
Hysteroscopy & proceed
Fibroid (AUB-L)
Adenomyosis (AUB-A)
Specimen adequate
Specimen inadequate
Family not complete
Family complete
Medical management
UAE
Prefers to retain uterus
Myomectomy[7]
UAE/HIFU
Medical management, COCP, Ulipristal, GnRHa, Low dose Mifepristone
Offer hysterectomy if family complete & over 40 years
Wants fertility:
Trenaxamic acid
Progesterones esp Dienogest
GnRHa short term
Adenomyomectomy
Family complete; young or wants to preserve uterus
Dienogest/LNG IUS/GnRHa
Adenomyomectomy
Does not want to preserve uterus & > 40 years



[1]History
Age, H/o amennorhoea, history suggestive of bleeding disorder, hormone intake (Progesterone/COCP/Danazol/Tamoxifen), h/o drug intake (antithrombotics etc), risk factors eg DM, Hypertension, Obesity, Thyroid disorders.

[2]When to investigate?
AUB persisting for 3 months
Any AUB causing anaemia
Any postmenopausal bleeding

[3]Other specific tests
SIS only if doubtful intracavity pathology
Tests for coagulation (suggestive history, puberty menorrhagia)
MRI for pre-op evaluation of fibroids if indicated
Pre-operative investigations

[4]Increased risk of hyperplasia/malignancy
Women 40 years, Intermenstrual bleeding, DM, Obesity, Hypertension, Prolonged unopposed exposure to estrogen

[5]Postmenopausal bleeding
Any postmenopausal bleeding needs an ultrasound assessment on Endometrial thickness (ET) preferably by TVS. Hysteroscopy with curettage is indicated if ET 4mm.

[6]Endometrial carcinoma
Treatment is total hysterectomy with bilateral salpingo-oophorectomy with bilateral pelvic lymphadenectomy

[7]Pre-treatment of Myoma prior to surgery
Only indicated for hysteroscopic myomectomy for submucus fibroids 4cm or severe anaemia while waiting for surgery
GnRHa or Ulipristal acetate used
Reduces fibroid volume
May obscure tissue planes

[8]Management of acute bleeding
Tranexamic acid (may need parental) & high dose hormones (Progesterones/COCP,Estrogen)

[9]Coagulopathy
May need replacement of coagulation factors
Treatment with hormones & trenaxamic acid (no NSAID)

CBC: complete blood count; COCP: Combined oral contraceptive pills; DMPA: depot medroxyprogesterone acetate; GnRHa: Gonadotropin releasing hormone agonist; HIFU: High-Intensity Focused Ultrasound; LNG_IUS: Levonorgestrel intra-uterine system; TSH: Thyroid-stimulating hormone; UAE: Uterine artery embolization; USG: ultrasonography.

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† Schindler AE. Progestational effects of dydrogesterone *in vitro, in vivo* and on the human endometrium. *Maturitas.* 2009;65(1):S3-S11.

Reference: 1. Schindler AE, *et al.* Classification and pharmacology of progestins. *Maturitas.* 2003;46(1):S7-S16.

*Modified as per Indian regulation. **2.** http://lolipharma.net/en/products/supplements/inofoliccombi.html

Further information available on request from: Abbott India Limited, 3-4, Corporate Park, Sion-Trombay Road, Chembur, Mumbai 400071, India. www.abbott.co.in

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THANK YOU FOR **YOUR TRUST** THAT MADE US

The World's No.1 Progestogen‡*

IF IT'S ORALLY EFFECTIVE, IT'S†

duphaston®

Dydrogesterone Tablets IP 10mg

† Schindler AE. Progestational effects of dydrogesterone *in vitro*, *in vivo* and on the human endometrium. *Maturitas*. 2009;65(1):S3-S11.
* Data on file. ‡ Internal calculations based on Quintiles IMS database, IMS Health Analytics Link MAT03 2017.

Abbreviated Prescribing Information. Dydrogesterone Tablets IP. Duphaston® Composition: Each white film-coated tablet contains: Dydrogesterone IP 10 mg. Excipients q.s. Colour: Titanium dioxide IP. **Indications:** Progesterone deficiencies, Treatment of progesterone deficiencies such as: • Treatment of dysmenorrhoea • Treatment of endometriosis • Treatment of secondary amenorrhoea • Treatment of irregular cycles • Treatment of dysfunctional uterine bleeding • Treatment of pre-menstrual syndrome • Treatment of threatened and habitual abortion • Treatment of infertility due to luteal insufficiency. Hormone replacement therapy - To counteract the effects of unopposed oestrogen on the endometrium in hormone replacement therapy for women with disorders due to natural or surgical induced menopause with an intact uterus. **Dosage and Administration:** Dosages, treatment schedule and duration of treatment may be adapted to the severity of the dysfunction and the clinical response. Dysmenorrhoea: 10 or 20 mg dydrogesterone per day from day 5 to day 25 of the menstrual cycle. Endometriosis: 10 to 30 mg dydrogesterone per day from day 5 to day 25 of the cycle or continuously. Dysfunctional uterine bleeding: When treatment is started to arrest a bleeding episode, 20 or 30 mg dydrogesterone per day is to be given for up to 10 days. For continuous treatment, 10 or 20 mg dydrogesterone per day should be given during the Second half of the menstrual cycle. The starting day and the number of treatment days will depend on the individual cycle length. Withdrawal bleeding occurs if the endometrium has been adequately primed with either endogenous or exogenous estrogen. Secondary amenorrhoea: 10 or 20 mg dydrogesterone per day, to be given daily for 14 days during the second half of the theoretical menstrual cycle to produce an optimum secretory transformation of an endometrium that has been adequately primed with either endogenous or exogenous estrogen. Pre-menstrual syndrome: 10 mg dydrogesterone twice daily starting with the second half of the menstrual cycle until the first day of the next cycle. The starting day and the number of treatment days will depend on the individual cycle length. Irregular cycles: 10 or 20 mg dydrogesterone per day starting with the second half of the menstrual cycle until the first day of the next cycle. The starting day and the number of treatment days will depend on the individual cycle length. Threatened abortion: An initial dose of up to 40 mg dydrogesterone may be given followed by 20 or 30mg per day until symptoms remit. Habitual abortion: 10 mg dydrogesterone twice daily until the twentieth week of pregnancy. Infertility due to luteal insufficiency: 10 or 20 mg dydrogesterone daily starting with the Second half of the menstrual cycle until the first day of the next cycle. Treatment should be maintained for at least three consecutive cycles. Hormone replacement therapy: Continuous sequential therapy: An estrogen is dosed continuously and one tablet of 10 mg dydrogesterone is added for the last 14 days of every 28 day cycle, in a sequential manner. Cyclic therapy: When an estrogen is dosed cyclically with a treatment-free interval, usually 21 days on and 7 days off. One tablet of 10 mg dydrogesterone is added for the last 12-14 days of estrogen therapy depending on the clinical response, the dosage can subsequently be adjusted to 20 mg dydrogesterone per day There is no relevant use of dydrogesterone before menarche. The safety and efficacy of dydrogesterone in adolescents aged 12-18 years has not been established. Currently available data are described in section 4.8 and 5.1, but no recommendation on a posology can be made. **Contraindications:** Known hypersensitivity to the active substance or to any of the excipients. Known or suspected progestogen dependent neoplasms. Undiagnosed vaginal bleeding. Contraindications for the use of estrogens when used in combination with dydrogesterone. **Warnings and Precautions:** Before initiating dydrogesterone treatment for abnormal bleeding, the etiology for the bleeding should be clarified. Breakthrough bleeding and spotting may occur during the first months of treatment. If breakthrough bleeding or spotting appears after some time on therapy, or continues after treatment has been discontinued, the reason should be investigated, which may include endometrial biopsy to exclude endometrial malignancy. **Pregnancy and Lactation:** Pregnancy: It is estimated that more than 10 million pregnancies have been exposed to dydrogesterone. So far there were no indications of a harmful effect of dydrogesterone use during pregnancy. Some progestogens have been reported in the literature to be associated with an increased risk of hypospadias. However due to confounding factors during pregnancy, no definitive conclusion can be drawn regarding the contribution of progestogens to hypospadias. Clinical studies, where a limited number of women were treated with dydrogesterone early in pregnancy, have not shown any increase in risk. No other epidemiological data are hitherto available. Effects in non-clinical embryo-fetal and post-natal development studies were in line with the pharmacological profile. Untoward effects occurred only at exposures which exceeded the maximum human exposure considerably, indicating little relevance to clinical use. Dydrogesterone can be used during pregnancy if clearly indicated. Breastfeeding: No data exist on excretion of dydrogesterone in mother's milk. Experience with other progestogens indicates that progestogens and the metabolites pass to mother's milk in small quantities. Whether there is a risk to the child is not known. Therefore, dydrogesterone should not be used during the lactation period. Fertility: There is no evidence that dydrogesterone decreases fertility at therapeutic dose. **Adverse Reactions:** The most commonly reported adverse drug reactions of patients treated with dydrogesterone in clinical trials of indications without estrogen treatment are migraines/headache, nausea, menstrual disorders and breast pain/tenderness. Undesirable effects that are associated with an estrogen-progestogen treatment : Breast cancer, endometrial hyperplasia, endometrial carcinoma, ovarian cancer • Venous thromboembolism • Myocardial infarction, coronary artery disease, ischemic stroke. Issued on: 3/4/14. Source: Prepared based on full prescribing information (version 03) dated 13/03/2015.

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