

## The Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) (Six Months Training) Rules, 2014

Ministry of Health and Family Welfare (Department of Health and Family Welfare) Notification No. G.S.R. 14(E), dated the 9th January, 2014\*.—In exercise of the powers conferred by clause (i) of sub-section (2) of Section 32 of the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 (57 of 1994), the Central Government hereby makes the following rules, namely :—

1. Short title and commencement.—(1) These Rules may be called the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) (Six Months Training) Rules, 2014.

(2) They shall come into force on the date of their publication in the official Gazette.

2. Definitions.—In these rules, unless the context otherwise requires,—

- (a) "Act" means the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 (57 of 1994);
- (b) "principal rules" means the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996;
- (c) "Six months training" means the training imparted under these rules;
- (d) "syllabus" means the syllabus given in Schedule I;
- (e) "Log book and assessment" means the Log book and assessment as specified in Schedule II;
- (f) words and expressions used herein and not defined in these rules but defined in the Act or in the principal rules, as the case may be, shall have the meanings, respectively, assigned to them in the Act or in the principal rules.

3. Nomenclature of the six months training in ultrasonography.—The six months training imparted under these rules shall be known as "the Fundamentals in Abdomino-Pelvic Ultra sonography : Level one for M.B.B.S. Doctors".

4. Period of the training.—The period of training for obtaining a certificate of training shall be 300 clock hours.

5. Components of the six months training curriculum.—(1) The major components of the training curriculum shall be—

\* Published in Gazette of India (Extraordinary), Part II, Section 3(i), dated 10-1-2014 Pages 26-49.

- (a) theory based knowledge to equip registered medical practitioners with the knowledge, professional skills, attitudes and clinical competencies;
- (b) skill based knowledge;
- (c) log book and Assessment.

(2) The comprehensive syllabus for the said six months training is as specified in Schedule I.

(3) The details related to log book and assessment are as specified in Schedule II.

**6. Eligibility for training.**—(1) Any registered medical practitioner shall be eligible for undertaking the said six months training.

(2) The existing registered medical practitioners, who are conducting ultrasound procedures in a Genetic Clinic or Ultrasound Clinic or Imaging Centre on the basis of one year experience or six months training are exempted from undertaking the said training provided they are able to qualify the competency based assessment as specified in Schedule II.

(3) If a medical practitioner fails to clear the said competency based examination after three attempts, he shall undertake the complete six months training, as provided under these rules, for the purpose of renewal of registration.]

**7. Accreditation of institutions for six months training and its recognition.**—(1) The following teaching institutions would be accredited as training centres to impart the six months training, namely:—

- (a) Centres of Excellence established under the Acts of Parliament;
- (b) Medical Council of India recognised institutions offering Post Graduate programmes in Obstetrics and Gynaecology or Radiology;
- (c) Institutions offering full time residency DNB programme in Obstetrics and Gynaecology or Radiology.]

(2) The names of the institutions recognised for this purpose shall be notified State wise by the State Health Medical Education Department:

Provided that the training institutes recognised for imparting the six months training shall maintain the standards of infrastructure, equipment and manpower including the faculty as per apex regulatory bodies like the Medical Council of India or the National Board of Examination.

**8. Selection of students.**—(1) The selection and intake of registered medical practitioners for admission to such trainings shall be on the basis of the following criteria:

- (a) Intake for admission to such trainings shall be up to 1:4 teacher to students ratio;
- (b) Selection shall be as per the merit list of the State Post Graduate Entrance Exam. or any other appropriate merit recognised by the Central Government/State Governments;
- (c) Preference upto 50 percent of the seats shall be given to the Government in service candidates;
- (d) Seats as mutually decided by the States/Union Territories shall be provided to the candidates from other States or Union Territories where there are no accredited institutes for imparting Six Months Training in Ultrasonography.]

9. **Changed criteria to be made prospective.**—These rules shall come into force with immediate effect in case of new registrations. However, all registered medical practitioners employed in a Genetic Clinic or Ultrasound Clinic or Imaging Centre on the basis of one year experience or six months training and failed to qualify the competency based exam as specified in Schedule II shall have to apply and clear six months training <sup>1</sup>[\* \* \*].

<sup>2</sup>[9. (1) The States/Union Territories shall complete the Competency based assessment for already registered medical practitioners within two years of this notification.]

10. **Fee structure for the training.**—(1) The training fee for conducting the six months training shall not exceed Rs. 20,000.

(2) For registered medical practitioners who are already registered for conducting ultra sonography in a Genetic Clinic or Ultrasound Clinic or Imaging Centre and require to clear a competency based evaluation, the fee shall not exceed Rs. 10,000.

(3) Fee structure or waiver thereof for in service registered medical practitioners shall be decided by the respective State Governments.

11. **Staff-Faculty.**—(1) The institute conducting the said six months training for registered medical practitioners shall appoint the Post graduate teachers in Radiology or Obstetrics or Gynaecology recognised by the respective regulatory bodies as full time faculty for the said training programme.

(2) The Deans or Head of the respective teaching institutions shall be responsible for monitoring the training programme in entirety.

12. **Monitoring requirements.**—Monitoring of the training institutions imparting the six months training shall be as per the existing norms laid down by the respective apex regulatory bodies.

13. **Competency based evaluation.**—The final competency based evaluation at the end of the six months training shall be held as per the mechanism specified in Schedule II.

14. **Validity of the training certificate.**—Certification of training obtained from any State shall be applicable for the purposes of registration under Act in all States.

<sup>2</sup>[14 (a). Certificate for qualifying Six Months Training in Ultrasonography and Competency based assessment shall be issued by Director Medical Education and countersigned by the concerned State Appropriate Authority.]

#### Schedule-I

### FUNDAMENTALS IN ABDOMINO PELVIC ULTRASONOGRAPHY

#### Level one 6 Months Course for M.B.B.S. Doctors

#### Ultrasonography Syllabus

This training will equip individuals with the knowledge, professional skills, attitudes and clinical competencies to use ultrasound imaging in an appropriate and safe manner.

1. Omitted by Notification No. G.S.R. 419(E) dated 26-6-2020, w.e.f. 29-6-2020.
2. Inserted by Notification No. G.S.R. 419(E) dated 26-6-2020, w.e.f. 29-6-2020.

Training will have broadly two components :

**1. Knowledge Based.**—The theoretical course will cover lectures on Physics of ultrasound, ultrasound machines and probes, How to use ultrasound, Pre-natal Diagnostic Techniques Act, laws of ultrasound, Medicolegal aspects, Methodology, patient preparations, Complete Obstetric Ultrasound uses including use in first, second and third trimesters, Diagnosis of threatened abortion, ectopic pregnancy, biometry, anomaly scanning, Intra-uterine Growth Retardation (IUGR), Placental evaluation, Amniotic fluid evaluation, color doppler uses and 3D & 4D ultrasound. Complete Gynaecological uses in evaluating female pelvis and evaluating infertility.

**2. Skill Based.**—(1) Ability to visualise in two dimensional image and a three dimensional structure.

(2) Hand-Eye co-ordination.

(3) Supervision is essential.

#### Summary Listing

**I. Knowledge based : Theory Course.**—The contents of the theoretical course should include at least the following, in addition to covering the subjects outlined in the syllabus above :

#### (A) Principles of Ultrasound Examination

- (i) Physics, instrumentation and safety
- (ii) Ultrasound systems and probes
- (iii) Instrumentation and control panel

#### (B) Conduct of ultrasound scanning

- (i) Consent
- (ii) Chaperone
- (iii) Confidentiality
- (iv) Infection control
- (v) Examination technique : probe movements and image orientation

#### (C) Normal pelvic anatomy

- (i) The Ultrasound Scan appearances of the normal uterus, ovary, endometrium and pelvis
- (ii) Endometrial and ovarian changes during menstrual cycles
- (iii) How to take measurements of dimensions of pelvic structures
- (iv) Measurement of endometrial thickness

#### (D) Early pregnancy

- (i) The Ultrasound Scan appearances in early pregnancy—Embryo, Placenta, Gestational Age, Twin pregnancy
- (ii) Recognition and diagnosis of complications of early pregnancy including
  - (a) extra-uterine pregnancy
  - (b) miscarriage
  - (c) retained products of conception.

**(E) Identification or Recognition of pelvic pathology**

- (i) Use of Ultrasound Scan in managing menorrhagia, intermenstrual bleeding, postmenopausal bleeding.
- (ii) Ultrasound Scan appearances in polycystic ovaries, uterine fibroids, adenomyosis and endometrial polyps
- (iii) Ultrasound Scan appearances of ovarian cysts-corpora luteum, simple and complex cysts and masses
- (iv) Complex ovarian masses or ovarian screening
  - (a) Endometrial pathology in postmenopausal women
  - (b) Gestational trophoblastic neoplasia
  - (c) Chronic pelvic pain
  - (d) The assessment of tubal patency in infertility and follicular tracking for assisted conception
  - (e) The assessment of prolapse, incontinence, and anal sphincter damage

**(F) Reproductive medicine**

- (i) Effect of contraceptive hormones and menopause on the endometrium.
- (ii) Use of Ultrasound Scan in identification of Intra-uterine Device or Intra-uterine System and Implanon position.

*Note.*—Attendance at a theoretical course is mandatory. The theoretical course need not include any hands-on component.

**II. Skill Based****(A) Basic Imaging Skills**

- (i) Machine set-up
- (ii) Counselling for scan
- (iii) Decide transabdominal vs. transvaginal route
- (iv) Choice of probe
- (v) Patient positioning
- (vi) Orientation
- (vii) Identify normal endometrium
- (viii) Identify normal myometrium
- (ix) Identify normal ovaries
- (x) Measure cervical length
- (xi) Recording images
- (xii) Note keeping and documentation

**(B) Early Pregnancy**

- (i) Confirm viability
- (ii) Date pregnancy
- (iii) Diagnose corpus luteum cyst
- (iv) Diagnose multiple pregnancy
- (v) Determine chorionicity / zygosity
- (vi) Identify retroplacental haematoma
- (vii) Diagnose anembryonic pregnancy
- (viii) Diagnose missed miscarriage

- (ix) Diagnose retained products of conception
- (x) Counselling for failed pregnancy
- (xi) Diagnose ectopic pregnancy
- (C) Menorrhagia**
  - (i) Identify submucous fibroid
  - (ii) Identify intramural fibroid
  - (iii) Identify subserous and pedunculated fibroid
  - (iv) Identify adenomyosis
- (D) Postmenopausal and intermenstrual bleeding**
  - (i) Measure endometrial thickness
  - (ii) Identify atrophic endometrium
  - (iii) Identify hyperplastic endometrium
  - (iv) Identify endometrial polyps
  - (v) Identify functional ovarian tumours
- (E) Pelvic Mass**
  - (i) Identify mass as uterine
  - (ii) Identify unilocular ovarian mass
  - (iii) Identify complex ovarian mass
  - (iv) Identify ascites
- (F) Reproductive Medicine**
  - (i) Identify cyclical changes in endometrium
  - (ii) Identify cyclical changes in ovary
  - (iii) Identify polycystic ovary
  - (iv) Locate Intra-uterine Device or Intra-uterine System position in uterus
- (G) Extra-Pelvic Scans**
  - (i) Identify normal placement of Implanon
  - (ii) Locate non-palpable Implanon
- (H) Contents-Section One**
  - (i) Instrumentations and basics
  - (ii) Physics for practical applications
  - (iii) Examination techniques
  - (iv) Trans-abdominal and Trans-vaginal Scan
- 1. The knowledge base.—(1) Principles of ultrasound examination :**
  - (i) Physics
  - (ii) Safety
  - (iii) Machine set-up and operation
  - (iv) Patient care
  - (v) Principles of report writing
  - (vi) Consent
- (2) The relevant principles of acoustics, attenuation, absorption, reflection, speed to sound;**
- (3) The effect on tissues of pulsed and continuous wave ultrasound beams : biological effects, thermal and non-thermal; safety.**

- (4) Basic operating principles of medical instruments
- (5) Types of transducers :
- 2. **Skill sets.**—(1) Use of ultrasound controls :
  - (i) Signal processing—gray scale—time gain compensation, acoustic output relationship;
  - (ii) Artefacts, interpretation and avoidance—reverberation—side lobes—edge effects—registration—shadowing—enhancement;
  - (iii) Measuring systems—linear, circumference, area and volume—Doppler ultrasound—flow;
  - (iv) Imaging recording, storage and analysis;
  - (v) Interpretation of acoustic output information and its clinical relevance;
  - (vi) Patient information and preparation reporting
- (II) **Contents—Section Two**
  - (i) Ultrasound anatomy of the abdomen, pelvis and fetus
  - (ii) Embryology or pathophysiology in short as applied to abd-pelvis
- 1. **The knowledge base**
  - (i) Knowledge of normal ultrasound appearances of the endometrium, myometrium and ovaries throughout a menstrual cycle.
  - (ii) Understanding of techniques to measure the uterus, endometrium.
  - (iii) Knowledge of normal ultrasound appearances of the ovaries and adnexa.
    - (a) **Gynaecological abnormalities : uterine**
      - (i) Knowledge of the ultrasound appearances of fibroids and adenomyosis.
      - (ii) Knowledge of endometrial pathology.
      - (iii) Intra-uterine Contraceptive Device localisation.
    - (b) **Gynaecological abnormalities : ovarian lesions**
      - (i) Knowledge of the differential diagnosis of ovarian and para-ovarian lesions.
      - (ii) Knowledge of typical ultrasound findings of common ovarian appearances such as polycystic ovaries.
      - (iii) Knowledge of ultrasound features of ovarian cancer and the features of advanced disease
    - (c) **Extraovarian lesions**
      - (i) Knowledge of the principles of conducting ultrasound examination in chronic pelvic pain.
      - (ii) Knowledge of typical morphological features of endometriosis, and pelvic adhesions.

- (d) Ultrasonography Anatomy of Abdomen
  - (i) Knowledge Base—Normal appearance
  - (ii) Abnormalities commonly found
  - (iii) Reporting of Mass lesions
  - (iv) Measurements—specific locations and Proper Techniques

## 2. Skill sets

- (i) Ability to consistently identify and examine the uterus, ovaries, adnexa and pouch of Douglas.
- (ii) Ability to assess cyclical endometrial changes and endometrial responses to the combined pill and other hormonal preparations
- (iii) Ability to assess the uterine size and to accurately measure endometrial thickness.
- (iv) Ability to assess ovarian volume and functional changes in the ovaries and adnexa during menstrual cycle : follicular appearances, variation in the morphology of corpora lutea, functional cysts, fluid in pouch of Douglas.
- (v) Ability to diagnose uterine fibroids, measure their size and assess their relation to the endometrial cavity. Correlate ultrasound findings to clinical symptoms.
- (vi) Ability to assess fibroids and adenomyosis and differentiate where possible.
- (vii) Ability to interpret the measurement of endometrial thickness in the clinical context.
- (viii) Ability to differentiate between focal and global endometrial thickness.
- (ix) To be able to identify Intra-uterine Contraceptive Device and its location within the uterus.
- (x) Ability to perform ultrasound examination combined with palpation in order to accurately identify the origin of pelvic lesion and interpret this in the clinical context.
- (xi) Ability to assess the size of adnexal lesions including mean diameter and volume.
- (xii) Ability to approach the assessment of adnexal lesions in a systematic way. Familiarity with standardised terms and definitions to describe sonographic features of adnexal lesions.
- (xiii) Ability to diagnose simple functional and haemorrhagic cysts, polycystic ovaries, dermoids and endometriomas based on subjective assessment alone.
- (xiv) Ability to recognise abnormal pelvic fluid/ascites.
- (xv) Ability to take a good clinical history in order to facilitate differential diagnosis of pelvic pain.

- (xvi) Be able to assess tenderness and mobility of pelvic organs including the pouch of Douglas on transvaginal ultrasound scan.
- (xvii) Ability to recognise ovarian endometriomas, hydrosalpinges, the consequences of pelvic adhesions and peritoneal pseudocysts on ultrasound scan.

(a) (1) *Gynaecological ultrasound*

- (i) Accurate measurement of the
- (ii) endometrium in the accepted sagittal plane
- (iii) Assessment of the adnexal regions : accurate identification of the normal ovaries, normal fallopian tube, normal pelvic fluid
- (iv) Accurate measurement of normal and abnormal adnexal structures; mean diameter and volume
- (v) Recognise and evaluate common endometrial and myometrial abnormalities
- (vi) Recognise and evaluate common ovarian abnormalities
- (vii) Recognise and evaluate complex ovarian masses and refer on appropriately
- (viii) Communicating normal results to patients
- (ix) Communicating appropriate abnormal results to patients
- (x) Producing written summary and interpretation of results
- (xi) Issue structured written report
- (xii) Arranging appropriate follow up or intervention

(2) *Skill Set*

- (i) Ability to consistently identify and examine Abdominal structures
- (ii) Identify Normal
- (iii) Identify Common Pathological Lesions
- (iv) How and When to seek further opinion

(b) *Liver and Spleen or Biliary System or Gall Bladder or Pancreas*

Patient preparation and Scanning Techniques

—Sonographic Anatomy

- (i) **Liver**—Diffuse liver disease, Fatty Liver, Grades, Acute hepatitis, cirrhosis and portal hypertension, Focal Mass lesions—Cystic Lesions or Solid Lesions
- (ii) **Spleen**—Splenomegaly or Focal splenic mass—Solid mass, cysts, subphrenic abscess
- (iii) **Gall Bladder**—Cholelithiasis or GB filled with calculi or Atypical calculus or Pitfalls

- (iv) **Pancreas**—Inflammatory Acute pancreatitis  
(pancreatic and extrapancreatic manifestation)
  - (a) Pseudocystor Chronic Pancreatitis or Neoplasms (solid and cystic looking)
- (c) **Prostate**
  - (i) Sonographic anatomy (prostate, seminal vesicles)
  - (ii) Technique (transabdominal approach)
  - (iii) To identify central zone and peripheral zone or Measurement of prostate volume
  - (iv) Pathology
    - (a) Benign hypertrophy Prostatitis
    - (b) Prostatic abscess Cancer of prostate
- (d) **Urinary System**  
Kidneys & ureters...scanning technique
- (e) **Kidneys**
  - (i) Sonographic anatomy
  - (ii) Echogenicity, corticomedullary demarcation, renal sinus, Hypertrophied
  - (iii) Column of Bertin
  - (iv) URETERS Congenital anomalies (agenesis, ectopia duplex collecting system and ureterocele)
  - (v) Hydronephrosis or Renal calculus or Infection or Tumours or Mimics of calculus
  - (vi) Nephrocalcinosis or Pyelonephritis, pyonephrosis renal and perinephric abscess, chr. Pyelonephritis or Tuberculosis or Renal cell carcinoma, spectrum of sonographic appearance or Angiolipoma
  - (vii) Benign Cystic lesions (simple cortical cyst, complex cortical cyst, parapelvic cyst)
  - (viii) Polycystic kidney disease
- (f) **Bladder**
  - (i) Bladder calculus, bladder volume measurement.
  - (ii) Bladder wall (technique of thickness measurement)
  - (iii) Bladder mass, cystitis
- (j) **Contents—Section Three : Basics of obstetric scanning and interpretation in all trimesters—3 Modules**
  - I. **Module 1 Early pregnancy : Trans-abdominal ultrasound examination of early pregnancy**

- (ii) Ability to measure gestational sac size and crown-rump length.
- (iii) Ability to identify early cardiac activity using B-mode.
- (iv) Identify fetal number
- (v) Ultrasound diagnosis of early embryonic demise
- (vi) Ultrasound assessment of a woman with suspected ectopic pregnancy
- (vii) Ability to establish the diagnosis of multiple pregnancy with confidence and to assess chorionicity and amnionicity.
- (viii) Ability to diagnose early embryonic demise based on assessment of gestational sac size and/or crown-rump length. Identify, assess and measure retained products of conception in women with incomplete miscarriages.
- (ix) Ability to correlate clinical, morphological and biochemical findings.
- (x) Ability to evaluate adnexa in a systematic and effective way and to interpret the findings in a clinical context. Identify the site and the number of corporalutea.
- (xi) Identify tubal and non-tubal ectopic pregnancy and examine for the presence of a yolk sac or an embryo. Assess the amount and quality of fluid in the pouch of Douglas.
- (xii) Seek help with confirmation of diagnosis and further management.
- (xiii) Recognise limits of competency.
- (xiv) Know limits of own ability and when to refer for further opinion. Accurate documentation of measurements.
- (xv) Producing written summary and interpretation of results.
- (xvi) Communicating normal results to parents.
- (xvii) Communicating abnormal results to parents.
- (xviii) Arranging appropriate referral, follow up or intervention.

II. *Module 2—Basic : Ultrasound assessment of fetal size, liquor and the placenta*

(a) *The aims of the module :*

To gain basic competences that are potentially useful in day-to-day obstetric practice, including lie, presentation, placental site and liquor assessment. Basic biometry techniques will be taught but competence to the level of 'independent practice' is not required.

(b) *The knowledge base*

1. *Biometry*

- (i) Awareness of the various lies and presentations
- (ii) Fetal growth or Physiology
- (iii) Pathology
  - (A) Maternal
  - (B) Placental
  - (C) Fetal
- (iv) Fetal biometry or Anatomical landmarks or Reference charts or Interpretation (including variability)
- (v) Calculation and value of :
  - (A) Ratios
  - (B) Estimated fetal weight

2. *Amniotic fluid*

- (i) Amniotic fluid volume or Physiology or Change with gestation or Pathology
- (ii) Ultrasound measurement
- (iii) Subjective vs. objective
- (iv) Max vertical pocket or Amniotic Fluid Index
- (v) Reference charts
- (vi) Interpretation (including variability)
- (vii) Oligohydramnios
- (viii) Definition and associations
- (ix) Polyhydramnios
- (x) Definition and associations

3. *Placenta*

- (i) Ultrasound assessment of site
- (ii) Indication for Transabdominal and transvaginal ultrasound
- (iii) Placenta praevia
- (iv) Classification
- (v) Management

## (c) Skill Sets

- (i) Accurate measurement of Bi-parietal Diameter, Head Circumference, Abdominal Circumference, Femur Length
- (ii) Accurate documentation of measurements and observations, including chart plotting
- (iii) Assessment of liquor volume
- (iv) Be able to perform and interpret assessment of Amniotic Fluid Volume, maximum vertical pool depth and Amniotic Fluid Index using ultrasound
- (v) Measurement of Amniotic Fluid Index
- (vi) Assessment of liquor volume
- (vii) Measurement of Maximal Vertical Pool Depth
- (viii) Assessment of placental position using the trans-abdominal route
- (ix) Arranging appropriate follow up or referral
- (x) Producing written summary and interpretation of results
- (xi) Communicating normal results to parents
- (xii) Maintain awareness of limitations of own competence

## III. Module 3 : Intermediate : Ultrasound of normal fetal anatomy

## (a) The aims of the module :

The overall aim of this module is to ensure that the trainee understands the indications for a fetal anatomy scan, is able to perform the scan safely and competently and to report the findings of the scan.

## (b) Learning outcomes

The trainee should be able to :

- (i) take a proper clinical history.
- (ii) carry out ultrasound examination in the appropriate environment with respect to the patients privacy, cultural and religious needs.
- (iii) understand the normal morphological ultrasound appearances of the fetus and its environment.
- (iv) diagnose normal fetal anatomy.
- (v) be aware of the normal anatomical variants.
- (vi) understand the limits of their competence and the need to seek advice where appropriate.
- (vii) Communicate the results to the parents.
- (viii) write a structured report.
- (ix) learn when to refer patients where appropriate.

- (c) *The knowledge base*
- (i) Know anatomical landmarks for performing standard fetal measurements Bi-parietal Diameter, Head Circumference, Abdominal Circumference, Femur Length.
  - (ii) Recognise normal appearance of fetal structures and appreciate different appearance at different gestations.
  - (iii) Know the detection rates of common anomalies.
  - (iv) Provide parents with necessary information in a form they understand.
  - (v) Communicate scan findings and information given to parents to other health professionals.
- (d) *Skill sets*
- (i) Identify fetal position within uterus
  - (ii) Be able to move probe with purpose to identify
  - (iii) fetal structures
  - (iv) Be able to consistently and systematically identify the features described in an "optimal" anomaly scan.  
Be able to perform standard fetal measurements Bi-parietal Diameter, Head Circumference, Abdominal Circumference, Femur Length including and also transcerebellar diameter, ventricular atrial diameter and Antero-posterior diameter of the renal pelvis
  - (v) Identify placental site
  - (vi) Recognise limits of competency
  - (vii) Recall patients appropriately for further scans if structures not seen clearly
  - (viii) Accurate measurements of Bi-parietal Diameter, Head Circumference, Abdominal Circumference, Femur Length, Transverse Cerebral Diameter and lateral atrial diameter of the cerebral ventricles
  - (ix) Confirm normal anatomy of head and face
  - (x) Confirm normal anatomy of spine
  - (xi) Confirm normal anatomy of heart and chest
  - (xii) Confirm normal anatomy of abdomen
  - (xiii) Confirm normal anatomy of limbs
  - (xiv) Perform full anomaly scan
  - (xv) Recognise common structural anomalies
  - (xvi) Locate and assess placenta
  - (xvii) Assess liquor volume
  - (xviii) Provide parents with information about
  - (xix) Normal scan findings

- (xx) Abilities and limitations of ultrasound
- (xxi) To be aware of the limitations of this technique and know when to refer
- (xxii) To be able to discuss with parents the possibility of an abnormality and the need for a further opinion

(K) Contents—Section Four

1. *Introduction to the problem of declining child sex ratio and provisions of the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act.*

Continuous decline in child sex ratio since 1961 Census is a matter of concern for the country. Beginning from 976 in 1961 Census, it declined to 927 in 2001. As per Census 2011 the Child Sex Ratio (0-6 years) has dipped further to 919 against 927 girls per thousand boys recorded in 2001 Census. Child sex ratio has declined in 18 States and 3 UTs and except for the States of Himachal Pradesh (909), Punjab (846), Chandigarh (880), Haryana (834), Mizoram (970), Tamil Nadu (943), Karnataka (948), Delhi (871), Goa (942), Kerala (964), Gujarat (890), Arunachal Pradesh (972), and Andaman and Nicobar Islands (968) showing marginal improvement, rest of the 21 States/UTs have shown decline.

**"The Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act."**

"An Act to provide for the prohibition of sex selection, before or after conception, and for regulation of pre-natal diagnostic techniques for the purposes of detecting abnormalities or metabolic disorders or chromosomal abnormalities or certain congenital malformations or sex-linked disorders and for the prevention of their misuse for sex determination leading to female foeticide and for matters connected therewith or incidental thereto."

2. *Implementation of the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 :*

The Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act was enacted on September 20, 1994 and the Act was further amended in 2003. The Act provides for the prohibition of sex selection, before or after conception, and for regulation of pre-natal diagnostic techniques for the purposes of detecting genetic abnormalities or metabolic disorders or chromosomal abnormalities or certain congenital malformations or sex linked disorders and for the prevention of their misuse for sex determination leading to female foeticide and for matters connected therewith or incidental thereto.

The Act is implemented through the following implementing bodies :

- (i) Central Supervisory Board
- (ii) State Supervisory Boards and Union Territory Supervisory Boards

- (iii) Appropriate Authority for the whole or a part of the State or Union Territory
- (iv) State Advisory Committee and Union Territory Advisory Committee
- (v) Advisory Committees for designated areas (part of the State) attached to each Appropriate Authority.
- (vi) Appropriate Authorities at the District and Sub-District levels

### 13. Registration :

Appropriate Authority of the district is responsible for registration of ultrasound diagnostic facilities.

#### 4. Application fee :

(1) Rs. 25,000.00 for Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic or Imaging Centre.

(2) Rs. 35,000.00 for an institute, hospital, nursing home, or any place providing jointly the service of Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic or Imaging Centre or any combination thereof.

#### 5. Mandatory Displays at ultrasound centre :

(1) Pre-conception and Pre-natal Diagnostic Techniques (PC and PNDT) Certificate : It is mandatory for every clinic or facility or hospital etc. registered under the Pre-conception and Pre-natal Diagnostic Techniques Act to display the certificate of registration at a conspicuous place at such Centre, Laboratory or Clinic.

(2) Signage board or banner in English and local language indicating that foetal sex is not disclosed at the concerned facility.

(3) Copy of the Pre-conception and Pre-natal Diagnostic Techniques Act must be available in every ultrasound centre.

#### 6. Renewal of registration :

(1) Every certificate of registration is valid for a period of 5 years

(2) Renewal of registration to be done 30 days before the date of expiry of the certificate of registration.

#### 7. Mandatory maintenance of records : Register showing in serial order :

(1) Names and addresses of men or women subject to pre-natal diagnostic procedure or test.

(2) Names of their spouses or fathers.

(3) Date on which they first reported for such counselling, procedure or test.

(4) A monthly report should be submitted to the Appropriate Authority regularly, before the 5th of every month. A copy of same monthly reports with the signature of the Appropriate Authority acknowledging receipt must be preserved.

## 8. Preservation of the following duly completed forms

- (i) Form F
- (ii) Referral Slips of Doctors
- (iii) Forms of consent
- (iv) Sonographic plates or slides

## 9. Record storage :

All above records should be preserved for 2 years.

## 10. Powers of Appropriate Authority :

- (1) Appropriate Authority can enter freely into any clinic or facility for search and seizure.
- (2) Examine and inspect the registers, records including consent forms, referral slips, Forms, sonographic plates or slides and equipment like ultrasonography machines.
- (3) To ensure presence of at least two independent witnesses of the same locality or different locality during the search.

11. For further Do's and Don'ts about following the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act and rules a Handbook of Pre-conception and Pre-natal Diagnostic Techniques Act rules with Amendments published by Ministry of Health, Government of India has made available online on [www.pndt.nic.in](http://www.pndt.nic.in)

## Schedule-II

## LOGBOOK AND ASSESSMENT

## 1. The Logbook

The Logbook records the training activity, tutorials and self-directed learning undertaken and competencies achieved.

Maintenance and regular review of the logbooks during interim assessments will allow the Principal Trainer and Trainee to monitor progress and identify deficiencies over the course of training. The Trainer will sign the appropriate sections of the Logbook documents with regard to attendance, skill and competence. It is imperative that all participants appreciate that the Trainee's progress has to meet standards that satisfy the Trainers. At the end of the training programme, the Principal Trainer has to certify that the competencies and skills attained by the Trainee are to his/her satisfaction.

## (1) Training Plan Level 1 exercise to be performed under direct supervision :

At this initial assessment, a training plan should be agreed between the Principal Trainer and the Trainee, using the competency, skills and attitudes lists to set the learning objectives. (This should include, identifying a theory course to be attended within 6 months of induction assessment, if not already undertaken.) The initial learning objectives and the activity plan to meet these should be tailored to the individual learning needs of the Trainee. Subsequent learning objectives should be

set at interim assessments until the Trainee has attained all the competencies, skills and attitudes on the lists.

It is the Trainee's responsibility to undertake this planned learning. The Principal Trainer should guide this, but need not undertake all training themselves.

In addition to the recording of competence, the logbook also contains sections for the recording of ultrasound images and basic clinical details of clients seen by the trainee. The ultrasound images should be of high quality and demonstrate aspects of the ultrasound scan which are pertinent to the clinical case and should have been obtained by the trainee. The trainee should review suitable images with the Trainer, prior to attaching them to the logbook.

This logbook is intended to record experience of ultrasound imaging in clinics where clients are referred for ultrasound imaging as part of the management of their abdomino-pelvic and gynaecological conditions (early pregnancy clinics, pre-abortion assessment clinics, etc.) either in hospital or community setting.

It also:

- (a) Provides a summary of the syllabus in the form of a list of necessary competencies.
- (b) Records the outcomes of the learning objectives agreed between you and your Trainers.
- (c) Provides a record of your achievements as you attain competence in the required areas.
- (d) Records the certified assessment of your competence when applying for the Certificate.
- (e) Provide a permanent record of interesting cases to act as a reference for future practice.

(2) *Minimum Number of Scans for Level-I Training (Total 200 cases)*

**Obstetric Scans**

Viable Pregnancies	10
Non-Viable Pregnancies	10
Normal Biometry	10
Growth Restrictions	10
Abnormal Pregnancy	10 (ectopic or multiple etc.)
Gynaec	10
IUCD's	5
Fibroids	10
Ovarian Cysts	10
Gynaec Disorders	10
<b>Non-Obstetric Scans</b>	
Normal abdominal Scan	20
Gall Stone Disease	10

Extra hepatic Biliary Channel	5
Hepatic Solid Masses	5
Hepatic Cystic Lesions	5
Pancreas	5
Urinary	25
Normal Scan	10
Cystic lesions of Kidney including Hydronephrosis	5
Solid lesions of Kidneys	5
Ureteric and Bladder Stones	5
Prostate	5
<b>Observations—</b>	
Transvaginal Scan	10
Color Doppler Studies Obstetric	10

## 2. Assessment

As well as the initial assessment, the Principal Trainer must perform at least one interim assessment to check the Trainee's progress and the summative (final) assessment of competence. The Principal Trainer has to certify that the competencies and skills attained by the Trainee are to his/her satisfaction.

It is the responsibility of the independent examiner to be nominated by Director, Medical Education Department of the concerned State to certify final competence, in order to exit the training programme.

### (1) Guidelines for Assessors

- (a) Assessors may be Ultrasonographers, Obstetricians or Gynaecologists or doctors experienced in ultrasonography.
- (b) Assessor should explain to the person being assessed, that the purpose of this exercise is to assess technical competence.
- (c) The trainee should perform the procedure based on his/her usual practice. The trainee and trainer should fill in the forms separately and use them to inform discussion following observation of the trainee. The assessment is designed to assess technical skills. It enables discussion on technique and will allow discussion on why the trainee acted as she/he did.
- (d) It is planned that each trainee should be assessed by Objective Structured Assessment of Technical Skills at least twice in a training programme; by different assessors, one of whom should be the Independent Examiner, as part of the summative assessment.
- (e) Trainees must already have achieved competence (direct supervision), in the procedure being evaluated.

For each procedure, the following must be completed :

- (a) Itemised Checklist Score  
(b) Objective Structured Assessment of Technical Skills assessment sheet

It is not necessary to obtain written consent from patients, but it would be prudent to say that the Trainee is partaking in an assessment with full supervision. Patients may choose not to be part of the assessment process.

3 copies of the forms should be kept;

- (a) One for the trainee's portfolio  
(b) One for the Principal Trainer  
(c) One to go back to the Faculty with all forms when the certificate is applied for.

(2) Objective Structured Assessment of Technical Skills (OSATS)

(A) BASIC SKILLS Skill	Level 1	Level 2	Trainer to sign and date when competence achieved
	Super-vised	Indepen- dent	
Machine set-up			
Counselling for scan			
Decide transabdominal vs. Transvaginal route			
Choice of probe			
Patient positioning			
Orientation			
Identify normal Endometrium			
Identify normal Myometrium			
Identify normal ovaries			
Measure cervical length			
Recording images			
Note keeping			
Special Remarks			
(B) EARLY PREGNANCY Skill	Level 1	Level 2	Trainer to sign and date when competence achieved
	Supervised	Independent	
Confirm viability			

The Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) (Six Months Training) Rules, 2014

(B) EARLY PREGNANCY Skill	Level 1	Level 2	Trainer to sign and date when competence achieved
	Supervised	Independent	
Date pregnancy			
Diagnose corpus luteum cyst			
Diagnose multiple pregnancy			
Identify retroplacental haematoma			
Diagnose anembryonic pregnancy			
Diagnose missed miscarriage			
Diagnose retained products of conception			
Counselling for failed pregnancy			
Diagnose ectopic pregnancy			

Special Remarks

(C) MENORRHAGIA Skill	Level 1	Level 2	Trainer to sign and date when competence achieved
	Supervised	Independent	
Identify submucous fibroid			
Identify intramural fibroid			
Identify subserous and pedunculated fibroid			
Identify adenomyosis			

Special Remarks

(D) POSTMENOPSA AND INTERMENSTRUAL BLEEDING Skill	Level 1	Level 2	Trainer to sign and date when competence achieved
	Supervised	Independent	
Measure endometrial thickness			

(D) POSTMENOPSA AND INTERMENSTRUAL BLEEDING Skill	Level 1	Level 2	Trainer to sign and date when competence achieved
	Supervised	Independent	
Identify atrophic endometrium			
Identify hyperplastic endometrium			
Identify endometrial polyps			
Identify functional ovarian tumours			

## Special Remarks

(E) PELVIC MASS Skill	Level 1	Level 2	Trainer to sign and date when competence achieved
	Supervised	Independent	
Identify mass as uterine			
Identify unilocular ovarian mass			
Identify complex ovarian mass			
Identify ascites			

## Special Remarks

(F) REPRODUCTIVE MEDICINE Skill	Level 1	Level 2	Trainer to sign and date when competence achieved
	Supervised	Independent	
Identify cyclical changes in endometrium			
Identify cyclical changes in ovary			
Identify polycystic ovary			
Locate Intra-uterine Device or Intra-uterine System position in uterus			

(F) REPRODUCTIVE MEDICINE Skill	Level 1	Level 2	Trainer to sign and date when competence achieved
	Supervised	Independent	
<b>EXTRA PELVIC SCANS</b>			
Identify normal placement of Implanon			
Locate non-palpable Implanon			

Special Remarks

(G) GENERAL ABDOMEN Skill	Level 1	Level 2	Trainer to sign and date when competence achieved
	Supervised	Independent	
<b>LIVER AND SPLEEN or BILIARY SYSTEM</b>			
Patient preparation and Scanning Techniques- Sonographic Anatomy			
Diffuse liver disease			
Fatty Liver, Grades			
Acute hepatitis, cirrhosis and portal hypertension			
Focal Mass lesions-Cystic Lesions or Solid Lesions			
Spleen-Splenomegaly or Focal splenic mass-Solid mass, cysts, subphrenic abscess			

Special Remarks

(H) GENERAL ABDOMEN Skill	Level 1	Level 2	Trainer to sign and date when competence achieved
	Supervised	Independent	
<b>URINARY SYSTEM</b>			
Kidneys & ureters... scanning technique			

(H) GENERAL ABDOMEN Skill	Level 1	Level 2	Trainer to sign and date when competence achieved
	Supervised	Independent	
Sonographic anatomy			
Echogenicity, corticomedullary demarcation, renal sinus, Hypertrophied			
Column of Bertin			
URETERS Congenital anomalies (agenesis, ectopia, duplex collecting system and urethrocele)			
Hydronephrosis or Renal calculus or Infection or Tumours or Mimics of calculus			
Nephrocalcinosis or Pyelonephritis, pyonephrosis, renal and perinephric abscess, chr. Pyelonephritis or Tuberculosis or Renal cell carcinoma, spectrum of sonographic appearance or Angiolipoma			
Benign Cystic lesions (simple cortical cyst, complex cortical cyst, parapelvic cyst)			
Polycystic kidney disease			

## Special Remarks

(I) GENERAL ABDOMEN Skill	Level 1	Level 2	Trainer to sign and date when competence achieved
	Supervised	Independent	
BLADDER			
Bladder calculus, bladder volume measurement			

(I) GENERAL ABDOMEN Skill	Level 1	Level 2	Trainer to sign and date when competence achieved
	Supervised	Independent	
Bladder wall (technique of thickness measurement)			
Bladder mass, cystitis			

## Special Remarks

(J) GENERAL ABDOMEN Skill	Level 1	Level 2	Trainer to sign and date when competence achieved
	Supervised	Independent	
GALL BLADDER or PANCREAS			
Gall Bladder— Cholelithiasis			
GB filled with calculi or Atypical calculus or Pitfalls			
Pancreas—Inflammatory Acute pancreatitis pancreatic and extra pancreatic manifestation			
Pseudocystor Chronic Pancreatitis or Neoplasms (solid and cystic looking)			

## Special Remarks

(K) GENERAL ABDOMEN Skill	Level 1	Level 2	Preceptor to sign and date when competence achieved
	Supervised	Independent	
PROSTATE			
Sonographic anatomy (prostate, seminal vesicles)			
Technique (transabdominal approach)			
To identify central zone and peripheral zone or Measurement of prostate volume			

(K) GENERAL ABDOMEN Skill	Level 1	Level 2	Preceptor to sign and date when competence achieved
	Supervised	Independent	
Pathology—Benign hypertrophy Prostatitis Prostatic abscess—Cancer of prostate			
Special Remarks			

### GUIDELINES FOR ASSESSMENT FOR FINAL EXAMINATION

Minimum pass marks—For practicals 60 and Theory 50

#### I. THEORY ASSESSMENT

- (a) 100 marks—two hours
- (b) 50 multiple choice questions of one mark each = 50 marks
- (c) 10 short answers with five marks each = 50 marks
- (d) Short Question will have a defined space for the candidate to fit answer

#### I[II. (a) PRACTICAL ASSESSMENT FINAL EXAMINATION

- (a) 20 marks for log book
- (b) 50 marks for demonstrations
- (c) 30 marks viva

#### II. (b) PRACTICAL ASSESSMENT COMPETENCY BASED ASSESSMENT

- (a) 60 marks for demonstrations
- (b) 40 marks viva

Note : The examiner can choose any FIVE for Final Examination and SIX for Competency Based Assessment of these TEN for demo and allot 10 marks each]

#### Step 1: Preparation

- 1.1 Equipment preparation
- 1.2 Patient preparation
- 1.3 Operator preparation
- 1.4 Expose the lower abdomen and apply the gel
- 1.5 Select the transducer

#### Step 2: Commence the growth and high-risk pregnancy scanning protocol

- 2.1 Patient position
- 2.2 Scan plane

1. Substituted by Notification No. G.S.R. 419(E) dated 26-6-2020, w.e.f. 29-6-2020.

- 2.2 Transabdominal scan plane
- Endovaginal scan plane
- 2.3 Standard second and third trimester protocol image requirements
  - 1. Fetal lie, life, number, presentation and situs
  - 2. Maternal uterus and adnexae
  - 3. Amniotic fluid and placental location
  - 4. Fetal biometry
  - 5. Fetal anatomy
- Step 3 :Overview of second and third trimester routine ultrasound examination
- Step 4: Perform targeted scan relevant to clinical condition of fetus and/or mother
  - 4.1 Scan for multiple pregnancy
- Step 5: Scan for intrauterine growth restriction
  - 5.1 Fetal biometry, growth, and weight
- Step 6: Scan for amniotic fluid and membranes
  - 6.1 Calculate the amniotic fluid volume
- Step 7: Scan for placenta and umbilical cord abnormalities
  - 7.1 Placenta
  - 7.2 Umbilical cord
- Step 8: Scan for fetal biophysical profile
- Step 9: Scan for fetal complications of maternal disease
  - 9.1 Fetal hydrops
  - 9.2 Maternal diabetes
  - 9.3 Maternal hypertension and pre-eclampsia
  - 9.4 Other maternal diseases
- Step 10 Demonstrate—to assess general abdominal scan—maternal liver/gall bladder/kidneys
- <sup>1</sup>[III. VIVA—30 marks on three case situations for Final Examination and 40 marks on four case situations for Competency Based Assessment]  
Clinicosonographic co-relation  
Video clip and case studies

#### IV. CASE STUDY

Case Number :	Date :
Preliminary data	
Ultrasonography Findings	
Impressions	
Key Learnings	

1. Substituted by Notification No. G.S.R. 419(E) dated 26-6-2020, w.e.f. 29-6-2020.