Training on PC PNDT

The Pre-conception & Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994

Group 2

CPQIH, Dispur

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Target groups

- Administration
- All doctors especially Radiologist/ Sonologist/ Medical Genetist / Gynecologists / Pediatricians
- All Staff especially in Radiology/ MRD/ Registration

Contents of training module

- Definition
- Registration certificate
- Signage, display
- Procedures/personnel involved
- Conditions for doing the tests
- Documentations (Form F, Form G, Form H, Register etc)
- Consent procedure
- Training frequency
- Training effectiveness
- Audits

Definition

- ✓An Act to provide for the regulation of the use of pre-natal diagnostic techniques for the purpose of detecting genetic or metabolic disorders or chromosomal abnormalities or certain congenital malformations or sex linked disorders and for the prevention of the misuse of such techniques for the purpose of pre-natal sex determination leading to female feticide.

PC PNDT

- ✓This act enacted in 1994 and brought into operation from 1996
- ✓The act has been amended in 2003.
- ✓It extends to the whole of India except to the state of Jammu and Kashmir.

Conditions for doing the tests

i. Age of the pregnant woman is above thirty-five years;
ii. History of two or more spontaneous abortions or fetal loss;
iii. History of exposure to potentially teratogenic agents such as drugs, radiation, infection or chemicals;
iv. Family history of mental retardation or physical deformities such as spasticity or any other genetic disease;
v. Any other condition as may be specified by the Central Supervisory Board;

Written consent

(1) No person shall conduct the pre-natal diagnostic procedures unless—

- ✓ he has explained all known side and after effects of such procedures to the pregnant woman concerned;
- ✓ he has obtained in the prescribed form her written consent to undergo such procedures in the language which she understands; and
- ✓ a copy of her written consent is given to the pregnant woman.

(2) No person conducting pre-natal diagnostic procedures shall communicate to the pregnant woman concerned or her relatives the sex of the fetus by words, signs or in any other manner.

Pre-natal Diagnostic Procedures

- All Gynecological or obstetrical or medical procedures like-
  - ✓Ultrasonography
  - ✓Fetoscopy
  - ✓Taking or removing samples of
    - Amniotic fluids
    - Chorionic villi
    - Blood
  - ✓Any tissue of a pregnant woman

Forms and documents needed

- Registration certificate of the Radiologists/Sonologists
- Registration certificate
- Register- for records of all Ultrasound and prenatal diagnostics tests done
- Form F- consent form in all cases
- Form G- consent form for invasive procedure
- Form H- form for recording of all details related to application, rejection, renewal, surprise visits etc

Registration

- All clinics/ centre/ nursing homes or mobile van where ultrasound is performed
- No separate registration for number of machines in the same clinic/centre

Certificate of Registration

ORIGINAL/DUPLICATE FOR DISPLAY

FORM B

[See Rules 6(2), 6(5) and 8(2)]

CERTIFICATE OF REGISTRATION
(To be issued in duplicate)

1. In exercise of the powers conferred under Section 19 (1) of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994), the Appropriate Authority ..... hereby grants registration to the Genetic Counselling Centre*/Genetic Laboratory*/Genetic Clinic*/Ultrasound Clinic*/Imaging Centre* named below for purposes of carrying out Genetic Counselling/Pre-natal Diagnostic Procedures*/Pre-natal Diagnostic Tests/ultrasonography under the aforesaid Act for a period of five years ending on .....

2. This registration is granted subject to the aforesaid Act and Rules thereunder and any contravention thereof shall result in suspension or cancellation of this Certificate of Registration before the expiry of the said period of five years apart from prosecution.

A. Name and address of the Genetic Counselling Centre*/ Genetic Laboratory*/ Genetic Clinic*/ Ultrasound Clinic*/ Imaging Centre*.

B. Pre-natal diagnostic procedures* approved for (Genetic Clinic).
Non-Invasive
(i) Ultrasound
Invasive
(ii) Amniocentesis
(iii) Chorionic villi biopsy
(iv) Foetoscopy
(v) Foetal skin or organ biopsy
(vi) Cordocentesis
(vii) Any other (specify)

C. Pre-natal diagnostic tests* approved (for Genetic Laboratory)
(i) Chromosomal studies
(ii) Biochemical studies
(iii) Molecular studies

D. Any other purpose (please specify)

3. Model and make of equipments being used (any change is to be intimated to the Appropriate Authority under rule 13).

4. Registration No. allotted

5. Period of validity of earlier Certificate of Registration. (For renewed Certificate of Registration only) From ..... To .....

Signature, name and designation of

Form F

FORM F

[See Proviso to Section 4(3), Rule 9(4) and Rule 10(1A)]

FORM FOR MAINTENANCE OF RECORD IN RESPECT OF PREGNANT WOMAN BY GENETIC CLINIC/ULTRASOUND CLINIC/IMAGING CENTRE

1. Name and address of the Genetic Clinic/Ultrasound Clinic/Imaging Centre.
2. Registration No.
3. Patient's name and her age
4. Number of children with sex of each child
5. Husband's/Father's name
6. Full address with Tel. No., if any
7. Referred by (full name and address of Doctor(s)/Genetic Counselling Centre (Referral note to be preserved carefully with case papers)/self referral
8. Last menstrual period/weeks of pregnancy
9. History of genetic/medical disease in the family (specify)
   Basis of diagnosis:
   (a) Clinical
   (b) Bio-chemical
   (c) Cytogenetic
   (d) Other (e.g.radiological, ultrasonography etc. specify)
10. Indication for pre-natal diagnosis

    A. Previous child/children with:
    - (i) Chromosomal disorders
    - (ii) Metabolic disorders
    - (iii) Congenital anomaly
    - (iv) Mental retardation
    - (v) Haemoglobinopathy
    - (vi) Sex linked disorders
    - (vii) Single gene disorder
    - (viii) Any other (specify)

    B. Advanced maternal age (35 years)
    C. Mother/father/sibling has genetic disease (specify)
    D. Other (specify)

11. Procedures carried out (with name and registration No. of Gynaecologist/Radiologist/Registered Medical Practitioner) who performed it.

    Non-Invasive

    (i) Ultrasound (specify purpose for which ultrasound is to done during pregnancy) [List of indications for ultrasonography of pregnant women are given in the note below]

    Invasive
    - (ii) Amniocentesis
    - (iii) Chorionic Villi aspiration
    - (iv) Foetal biopsy
    - (v) Cordocentesis
    - (vi) Any other (specify)

12. Any complication of procedure – please specify
13. Laboratory tests recommended[6][3]
    - (i) Chromosomal studies
    - (ii) Biochemical studies
    - (iii) Molecular studies
    - (iv) Preimplantation genetic diagnosis
14. 14. Result of
    (a) pre-natal diagnostic procedure (give details)
    (b) Ultrasonography Normal/Abnormal
    (specify abnormality detected, if any).
15. Date(s) on which procedures carried out.
16. Date on which consent obtained. (In case of invasive)
17. The result of pre-natal diagnostic procedure were conveyed to .....on .....
18. Was MTP advised/conducted?
19. Date on which MTP carried out.

Date:
Place

Name, Signature and Registration number of the Gynaecologist/Radiologist/Director of the Clinic

DECLARATION OF PREGNANT WOMAN

I, Ms. _____ (name of the pregnant woman) declare that by undergoing ultrasonography /image scanning etc. I do not want to know the sex of my foetus.

Signature/Thump impression of pregnant woman

3 Strike out whichever is not applicable or not necessary

DECLARATON OF DOCTOR/PERSON CONDUCTING ULTRASONOGRAPHY/IMAGE SCANNING

I, _____ (name of the person conducting ultrasonography/image scanning) declare that while conducting ultrasonography/image scanning on Ms. _____ (name of the pregnant woman), I have neither detected nor disclosed the sex of her foetus to any body in any manner.

Name and signature of the person conducting ultrasonography/image scanning/ Director or owner of genetic clinic/ultrasound clinic/imaging centre.

_____

Form G

FORM G

[See Rule 10]

FORM OF CONSENT

(For invasive techniques)

I, ... wife/daughter of ..... Age ..... years residing at ..... hereby state that I have been explained fully the probable side effects and after effects of the pre-natal diagnostic procedures.

I wish to undergo the pre-implantation/pre-natal diagnostic technique/test/procedures in my own interest to find out the possibility of any abnormality (i.e. disease/deformity/disorder) in the child I am carrying.

I undertake not to terminate the pregnancy if the pre-natal procedure/technique/test conducted show the absence of disease/deformity/disorder.

I understand that the sex of the foetus will not be disclosed to me.

I understand that breach of this undertaking will make me liable to penalty as prescribed in the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994) and rules framed thereunder.

Date
Place

Signature of the pregnant woman.

I have explained the contents of the above to the patient and her companion (Name ..... Address ..... Relationship .....) in a language she/ they understand.

Name, Signature and/Registration number of
Gynaecologist/Medical Geneticist/Radiologist/Paediatrician/
Director of the Clinic/Centre/Laboratory

Date

Name, Address and Registration number of
Genetic Clinic/Institute

SEAL

Maintenance and preservation of records

- A Register containing the name of the patient and spouse, address, referring doctor name and date of the scanning etc to be maintained.
- Signage board in English and in the local language must be displayed, indicating the fetal sex is not disclosed in the clinic.
- A copy of the registration certificate shall be displayed.

Bilingual display of this information is mandatory

Contd..

- Preserve Form F and Form G for all cases.
- All records to be maintained for 2 years.
- In case of medicolegal cases, till the final disposal of legal proceedings.
- All centres need to send a report of all the tests and procedures performed by them to the concerned appropriate authority by 5^{th} of every month.

Form H

FORM H

[See Rule 9(5)]

FORM FOR MAINTENANCE OF PERMANENT RECORD OF APPLICATIONS FOR GRANT/REJECTION OF REGISTRATION UNDER THE PRE-NATAL DIAGNOSTIC TECHNIQUES (REGULATION AND PREVENTION OF MISUSE) ACT, 1994.

1. Sl. No.

2. File number of Appropriate Authority.

3. Date of receipt of application for grant of registration.

4. Name, Address, Phone/Fax etc. of Applicant:

5. Name and address(es) of Genetic Counselling Centre*/Genetic Laboratory*/Genetic Clinic* /Ultrasound Clinic*/Imaging Centre*.

6. Date of consideration by Advisory Committee and recommendation of Advisory Committee, in summary.

7. Outcome of application (state granted/rejected and date of issue of orders - record date of issue of order in Form B or Form C).

8. Registration number allotted and date of expiry of registration.

9. Renewals (date of renewal and renewed upto).

10. File number in which renewals dealt.

11. Additional information, if any.

Name, Designation and Signature of
Appropriate Authority

Guidance for Appropriate Authority

(a) Form H is a permanent record to be maintained as a register, in the custody of the Appropriate Authority.

(b) * Means strike out whichever is not applicable.

(c) On renewal, the Registration Number of the Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic/Ultrasound Clinic/Imaging Centre will not change. A fresh registration Number will be allotted in the event of change of ownership or management.

(e) Registration number shall not be allotted twice.

(f) Each Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic/ Ultrasound Clinic/Imaging Centre may be allotted a folio consisting of two pages of the Register for recording Form H.

(g) The space provided for 'additional information' may be used for recording suspension, cancellations, rejection of application for renewal, change of ownership/management, outcome of any legal proceedings, etc.

(h) Every folio (i.e. 2 pages) of the Register shall be authenticated by signature of the Appropriate Authority with date, and every subsequent entry shall also be similarly authenticated.".

Training frequency and audits

- Training to be given to all at induction as well as department training
- Reorientation training at least every 6 monthly
- Training also needed if amendment occurs
- Audits of PC PNDT compliance should be a part of monthly MRD audits.

Offences and penalties

- Offenses by persons:
  - First offence- 3 years imprisonment and fine Rs 10,000/-
  - Subsequent offences: 5 years imprisonment and fine up to 50,000/-
- The state medical council may suspend the person for 5 years for first offence and permanently for any subsequent offence.
- Patient or attendant: 3 months imprisonment and Rs 1000/- fine or both

Thank you