

Important points in the PC-PNDT Act

Dear Sir,

We would like to highlight a few points from the PCPNDT act, which need explanation whereas others are confusing or controversial. The act was formulated in 1994 specifically for pre-natal diagnostic techniques (invasive procedures) and centers were termed as genetic clinics. When the Supreme Court of India in 2001 gave a verdict on a petition filed by an NGO that ultrasound clinics should be brought under the act, the Government just added the term ultrasound clinic everywhere along with genetic clinic. Most of the problems we face are a result of this addition.

The Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act 1994

Chapter I. 2. Definitions (d) genetic clinic: Explanation: For the purposes of this clause, a *Genetic Clinic* includes a vehicle, where ultrasound machine or imaging machine or scanner or other equipment capable of determining sex of the fetus or a portable equipment which has the potential for detection of sex during pregnancy or selection of sex before conception, is used.^[1,2]

Confusion: Vehicle, e.g. car carrying the machine (not used for doing ultrasound) is to be registered or not. Registration charges to be paid or not. If registered as genetic clinic, separate monthly report to be sent or not.

Current scenario: This clause is of no use as portable ultrasound is banned by the high court in Maharashtra and many other states by the appropriate authorities.

Chapter I. 2. Definitions (i) “pre-natal diagnostic procedures” means all gynecological or obstetrical or medical procedures such as ultrasonography, fetoscopy, taking or removing samples of amniotic fluid, chorionic villi, blood or any other tissue or fluid of a man, or of a woman for being sent to a Genetic Laboratory or Genetic Clinic for

conducting any type of analysis or pre-natal diagnostic tests for selection of sex before or after conception.^[1,2]

Explanation: Ultrasound is pre-natal diagnostic procedure as well as pre-natal diagnostic test.

Chapter I. 2. Definitions (p) “Sonologist or imaging specialist” means a person who possesses any one of the medical qualifications recognized under the Indian Medical Council Act, 1956 or who possesses a postgraduate qualification in ultrasonography or imaging Techniques or radiology.^[1,2]

Explanation: Radiologist and registered medical practitioner (MBBS) have been equated. There should be AND in place of OR.

Chapter III,4 (v) Provided that the person conducting ultrasonography on a pregnant woman shall keep complete record thereof in the clinic in such manner, as may be prescribed, and any deficiency or inaccuracy found therein shall amount to contravention of provisions of section 5 or section 6 unless contrary is proved by the person conducting such ultrasonography.^[1,2]

Explanation: Onus of proving not-guilty is on radiologist/sonologist and NOT on the authorities. This is similar to dowry or rape case where accused has to prove that he is not guilty. In other criminal cases the prosecution has to prove that the accused is guilty.

Chapter 5. 1. No person referred to in clause (2) of section 3 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 obtained under clause (b) is given to the pregnant woman.^[1,2]

Explanation: Ultrasound being pre natal diagnostic procedure we need to take patient declaration **in local language and give a copy to patient**. In fact authorities in Maharashtra are insisting on it.

CHAPTER VII. 23. Offences and penalties.- (1) Any medical geneticist, gynecologist, registered medical practitioner or any person who owns a Genetic Counseling Centre, a Genetic Laboratory or a Genetic Clinic or is employed

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in such a Centre, Laboratory or Clinic and renders his professional or technical services to or at such a Centre, Laboratory or Clinic, whether on an honorary basis or otherwise, and who contravenes any of the provisions of this Act or rules made thereunder shall be punishable with imprisonment for a term which may extend to three years and with fine which may extend to ten thousand rupees and on any subsequent conviction, with imprisonment which may extend to five years and with fine which may extend to fifty thousand rupees.^[1,2]

Explanation: Even if a radiologist is attached on HONORARY/ NAMESAKE basis to a ultrasound clinic, he is equally responsible for any contraventions of provisions of PCPNDT law done in the center and thus is equally liable for punishment like imprisonment and fine.

CHAPTER VIII. 31 Protection of action taken in good faith: No suit, prosecution or other legal proceeding shall lie against the Central or the State Government or the Appropriate Authority or any officer authorized by the Central or State Government or by the Authority for anything which is in good faith, done or intended to be done in pursuance of the provisions of this Act.^[1,2]

Explanation: The AA has full immunity if he states that he has taken any action in good faith.

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3. Minimum Requirements 3. (1) Any person having adequate space and being or employing:

- a. Gynecologist having experience of performing at least 20 procedures in chorionic villi aspirations per vagina or per abdomen, chorionic villi biopsy, amniocentesis, cordocentesis foetoscopy, foetal skin or organ biopsy or foetal blood sampling etc. under supervision of an experienced gynecologist in these fields, or
- b. a Sonologist, Imaging Specialist, Radiologist or Registered Medical Practitioner having Post Graduate degree or diploma or six months training or one year experience in sonography or image scanning, or
- c. A medical geneticist may set up a genetic clinic/ ultrasound clinic/imaging centre.^[1,2]

Explanation: Radiologist is at par with Registered Medical Practitioner having six months training or one year experience in sonography or image scanning,

Controversy: The term sonologist has two separate definitions one as per chapter I.2.p. And other as per above rule 3.3.1 b.

9. Maintenance and preservation of records. - (1) Every Genetic Counseling Centre, Genetic Laboratory, Genetic

Clinic, Ultrasound Clinic and Imaging Centre shall maintain a register showing, in serial order, the names and addresses of the men or women given genetic counseling, subjected to pre-natal diagnostic procedures or pre-natal diagnostic tests, the names of their spouses or fathers and the date on which they first reported for such counseling, procedure or test.^[1,2]

Controversy: Does an ultrasound clinic have to keep such a register that was initially meant to be maintained by a genetic clinic or laboratory?

10. 1A. Any person conducting ultrasonography/image scanning on a pregnant woman shall give a declaration on each report on ultrasonography/image scanning that he/she has neither detected nor disclosed the sex of fetus of the pregnant woman to anybody. The pregnant woman shall before undergoing ultrasonography/image scanning declare that she does not want to know the sex of her fetus.^[1,2]

Confusion: Are our and patients' declaration required on each report of ultrasound?

There is confusion as per chapter 3.5.1. Ultrasound being diagnostic procedure declaration has to be taken in language patient understands and copy to be given to patient. Thirdly form F also has declaration of patient as well as doctor. **How many declarations are needed to be given and in what language is not clear!**

13. Intimation of changes in employees, place or equipment.

– Every Genetic Counseling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre shall intimate every change of employee, place, address and equipment installed, to the Appropriate Authority within a period of thirty days of such change.^[1,2]

Confusion: Change in equipment and radiologist we do report, however change in other employees, like say an attendant or nurse, do we need to report?

17. Public Information – (2) at least one copy of act and these rules shall be available on the premises of every Genetic Counseling Centers, Genetic Laboratories, Genetic Clinics, Ultrasound Clinics, Imaging Centers and shall be made available to the clientele on demand.

Confusion: Various authorities insist on this particular matter differently as to the location of where the copy should be kept, e.g.- reception, chamber, ultrasound room.

18. Code of conduct. Code of Conduct to be observed by persons working at Genetic Counseling Centers, Genetic Laboratories, Genetic Clinics, Ultrasound Clinics, Imaging Centers etc. - All persons including the owner, employee or any other person associated with Genetic Counseling

Centers, Genetic Laboratories, Genetic Clinics, Ultrasound Clinics, Imaging Centers registered under the Act/ these Rules shall display his/her name and designation prominently on the dress worn by him/her.^[1,2]

Explanation: Every staff member of an ultrasound clinic has to wear name batch.

Additional points we must understand clearly:

A. RELEASE OF SEALED MACHINE IS NOT THE END- In maximum cases ultrasound machines have been seized by the AA for trivial paperwork deficiency. The offence being cognizable, non-bailable and non-compoundable, they put up a criminal case. Even if court releases the machine in a period of 2-3 months, the criminal case continues and radiologist is liable for imprisonment for a term which may extend to three years and with fine which may extend to ten thousand rupees and on any subsequent conviction, with imprisonment which may extend to five years and with fine which may extend to fifty thousand rupees. **IN ADDITION** – The name of the sonologist is reported to the State Medical Council concerned for **suspension**

of the registration if the charges are framed by the court **till the case is disposed-off** and on conviction for removal of his name from the register of the Council for a period of five years for the first offence and permanently for the subsequent offence.

B. Local advisory board has geneticist, pediatrician, and gynecologist and does not have a radiologist as the act was not meant for radiologist/sonologist when it came into existence. So we do not have a say in local advisory board.

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