Section

I

# MTP and PCPNDT Act

Chapter

1

# Medical Termination of Pregnancy (MTP) Act—Rules and Regulations



Mandakini Megh

The Medical Termination of Pregnancy (MTP) Act came into existence in India in 1971. As per this Act, MTP is the lawful abortion of a foetus and it empowers a woman to decide whether to continue her pregnancy or terminate it.

## History

In India, the British enacted the Indian Penal Code in 1860 which declared induced abortions as illegal, the only exception being when abortion was induced to save the life of the woman.[1] Although this clause in the penal code was changed in Great Britain in 1967, India did not change it until 1971.[1] Countless women died attempting illegal abortions as a result of the penal code. The Medical Termination of Pregnancy Act, 1971 (MTP Act)[2] was enacted in India to reduce the mortality and morbidity associated with unsafe abortions. The Act was amended in 2002[3] and further on October 29, 2014, the Ministry of Health and Family Welfare released a draft of the MTP (Amendment) Bill 2014.[4]

## MEDICAL TERMINATION OF PREGNANCY ACT[2–6]

The MTP Act enacted in 1971 and amended in 2002; the MTP Rules, 2003[5]; and the MTP Regulations, 2003 govern the provision of abortions of MTP in India. The MTP Act, and the Rules and Regulations framed thereunder provide an ambit under which legal abortion services can be provided up to 20 weeks of pregnancy.

The MTP Act provides details about the following aspects of abortion services:

- Conditions under which pregnancy may be terminated. [MTP Act: Section 3 (2)]
- Who can provide abortion services. [MTP Act: Section 2 (d) and Rule 4]

- Sites where abortion service can be provided. [MTP Act: Section 4]
- Documentation and records for abortion services. [Rule 5, Rule 9, Regulation 3, Regulation 4 (5), and Regulation 5]
- Punishments for violation of the MTP Act. [MTP Act: Section 5 (2), Section 5 (3) and Section 5 (4)]

## Conditions under which a Pregnancy may be Terminated

The MTP Act allows for termination of pregnancy in case of:

- Continuation of pregnancy would involve risk to the life of pregnant woman or may cause grave injury to her physical or mental health
- Substantial risk that the child, if born, would be seriously handicapped due to physical or mental abnormalities
- Pregnancy is caused by rape (presumed to constitute grave injury to mental health)
- Pregnancy is caused due to failure of contraceptive in married woman or her husband (presumed to constitute grave injury to mental health).

## Who can Provide Abortion Services

MTP can be legally provided only by a 'registered medical practitioner' (RMP)—a medical practitioner who possesses any recognised medical qualification as defined in Clause (h) of Section 2 of Indian Medical Council Act, 1956, whose name has been entered in a State Medical Register and who has one or more of the following experience or training in gynaecology and obstetrics (OBGY):

1. In the case of a medical practitioner, who was registered in a State Medical Register immediately before the commencement of the Act, with experience in the practice of OBGY for a period not less than three years.
2. In the case of a medical practitioner, who was registered in a State Medical Register after the commencement of the Act and
   a. Has completed six months of house surgery in OBGY; or
   b. Has experience in any hospital for a period of not less than one year in the practice of OBGY; or
   c. Holds a postgraduate degree or diploma in OBGY; or
   d. Has assisted an RMP in the performance of 25 cases of MTP of which at least five have been performed independently, in a hospital established or maintained by the Government, or a training institute approved for this purpose by the Government. This training will enable the RMP to do only first trimester terminations (up to 12 weeks of gestation).

## When can Pregnancy be Terminated

Pregnancy can be terminated by 1 RMP up to 12 weeks of pregnancy and up to 20 weeks with the consent of 2 RMPs.

## Sites where Abortion Service can be Provided

No termination of pregnancy shall be made in accordance with this Act at any place other than

i. Hospital established or maintained by the Government or

ii. A place approved by the Government or the District Level Committee (DLC) headed by the Chief Medical Officer (CMO) or District Health Officer (DHO).

No place shall be approved under Clause (ii)

- unless the Government is satisfied that termination of pregnancies may be done therein under safe and hygienic conditions; and.
- unless the following facilities are provided therein, namely
  - In case of first trimester (12 weeks of pregnancy): A gynaecology examination/labour table, resuscitation and sterilization equipment drugs and parental fluid, back-up facilities for treatment of shock and facilities for transportation; and
  - In case of second trimester (up to 20 weeks of pregnancy):
    a. Operation table and instruments for performing abdominal or gynaecological surgery
    b. Anaesthetic equipment, resuscitation equipment and sterilization equipment
    c. Drugs and parental fluids for emergency use, notified by Government of India from time to time

The certificate of approval by the DLC needs to be conspicuously displayed at the site to be easily visible to persons visiting the place.

MTP Act allows provision of medical methods of abortion (MMA) up to seven weeks of pregnancy at an unapproved site provided it has access/referral linkages to an MTP approved site. For the purpose of access, the RMP should display a certificate to this effect from the owner of the approved site.

In case of an emergency, any pregnancy may be terminated by an RMP to save the life of the woman at an unapproved place. Information about the same must be sent to the CMO the same day or latest the next working day.

The termination of pregnancy by a person who is not a RMP shall be an offence punishable with rigorous imprisonment for a term not be less than 2 years but which may extend to 7 years.

Whoever terminates any pregnancy in a place other than approved under the MTP Act shall be punishable with rigorous imprisonment for a term not less than 2 years but which may extend to 7 years.

Any person being owner of a place which is not approved under MTP Act shall be punishable with rigorous imprisonment for a term not be less than 2 years but which may extend to 7 years.

If a person wilfully contravenes or wilfully fails to comply with the requirements of any regulation made penalty of ₹1000.

## Documentation and Records for Abortion Services

***Form I***—*Opinion form* for each MTP done must be duly filled with reason for termination and signature with date **within three hours of MTP.** Opinion of the second RMP in case of

2nd trimester abortions must also be recorded either at the time of admission or within three hours of MTP. **The column for indicating the reason for MTP must never be left blank.**

***Form II***—*Reporting format*—A monthly statement of all MTPs done must be sent to CMO on this format. This should include both surgical and medical methods of abortions (MMA).

***Form III***—*Admission register*—All MTPs conducted at the facility must be recorded in the admission register maintained at the facility for each calendar year. The register must be maintained for a period of five years from the last entry. Entries shall be made serially and a fresh serial shall be started at the start of each calendar year and the serial number of the particular year shall be distinguished from the serial number of other years by mentioning the year against the serial number. Admission Register is a confidential document and is not open to inspection by any person except under the authority of law.

***Form C***—*Consent form*—Consent of only the woman is required if she is of and above the age of 18 years. Consent from husband/parent/guardian is not required for seeking an abortion from a woman who is of or above 18 years of age and who is not mentally ill.

Only in case of a minor and/or a mentally ill woman of any age, her guardian's consent is required. Guardian under the MTP Act means a person having the care of a minor or a mentally ill person. This person does not necessarily have to be the legal guardian.

Additional documentation of age proof is not required in addition to Form C.

**Form B**—*Certificate of approval* for a 'private' place issued by the DLC chaired by the CMO shall be conspicuously displayed such that it is easily visible to visitors. All Government facilities are by default approved to provide Comprehensive Abortion Care services and therefore do not need a certificate of approval.

## Medical Termination of Pregnancy (Amendment) Bill 2014[4]

On October 29, 2014 the Ministry of Health and Family Welfare (MOHFW) released a draft of the MTP (Amendment) Bill, which proposes to improve access to abortion and at the same time reduce women's dependency on healthcare providers during the process of seeking abortion.

- The bill proposes to replace the term "Registered medical practitioners" by the term "Registered healthcare providers" thus including vaids, hakims, Siddha practitioners, homeopaths as well as nurses and ANMs (auxiliary nurse midwives). The Bill thus proposes to train and allow non-allopathic and mid-level healthcare providers to perform abortions.
- It outlines the methods of abortion more clearly than the 1971 MTP Act, recognising medical termination of pregnancy as a separate and legal technique of abortion.
- First-trimester abortion will be considered a matter of woman's choice and a physician's opinion will no longer be required.
- A woman will require only one physician's opinion in the second trimester.
- The Amendment Bill also explicitly extends abortion care to unmarried women and aims at ensuring privacy for women seeking abortion.
- The gestational limit for abortion will be extended from 20 to 24 weeks and in addition, abortion will be provided for specific foetal anomalies after this period.

The amendment to the MTP Act is still pending.

## MTP Amendment Bill 2019[7]

The ministry is in the process of finalizing the Medical Termination of Pregnancy (MTP) Draft Amendment Bill, 2019 which will allow the much needed relaxations on abortion services for a defined set of women. One category includes victims of sexual violence (rape and incest). They will be allowed to terminate their pregnancy beyond the fetal age of 20 weeks within 24 weeks. Another category includes abortion of foetuses certified by doctors to be "incompatible with life".

The amendment to the MTP Act is still pending and many women have been forced to move the Supreme Court for permission to end their pregnancies that are beyond the legal limit of 20 weeks, after the delay in the MTP Act amendment.

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5. Ministry of Health and Family Welfare (Department of Family Welfare) Notification New Delhi. The 13th June 2003.
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## ANNEXURE

## Various Forms Under MTP Act 1971

### FORM A

[See sub-rule (2) of rule 5]

Form of application for the approval of a place under Clause (b) of Section 4.

Category of approved place:

A. Pregnancy can be terminated up to 12 weeks

B. Pregnancy can be terminated up to 20 weeks

1. Name of the place (in capital letters)
2. Address in full
3. Non-Governmental/Private/Nursing Home/Other Institutions
4. State, if the following facilities are available at the place—Medical Termination of Pregnancy (MTP) Act—Rules and Regulations

### CATEGORY A

i. Gynaecological examination/labour table.
ii. Resuscitation equipment
iii. Sterilization equipment
iv. Facilities for treatment of shock, including emergency drugs.
v. Facilities for transportation, if required.

### CATEGORY B

i. An operation table and instruments for performance abdominal or gynaecological surgery.
ii. Drugs and parental fluid in sufficient supply emergency cases
iii. Anaesthetic equipment, resuscitation equipment and sterilisation equipment.

Place:

Date: Signature of the owner of the place

### FORM B

[Refer sub-rule (6) of rule 5]

Certificate of approval

The place described below is hereby approved for the purpose of the Medical Termination of Pregnancy Act, 1971 (34 of 1971).

As read within up to ..... weeks

Name of the place

Address and other descriptions

Name of the owner

Place:

Date: To the Government of the .....

## FORM C

(See Rule 9)

I ..... daughter/wife of ..... aged about ..... years of ..... (here state the permanent address) at present residing at ..... do hereby give my consent to be termination of my pregnancy at ..... (State the name of place where the pregnancy is to be terminated).

Place:

Date:

Signature

(To be filled in by guardian where the woman is a mentally ill person or minor).

I ..... son/daughter/wife of ..... aged about ..... years of ..... at present residing at (permanent address) ..... do hereby give my consent to the termination of my pregnancy of my ward ..... who is a minor/lunatic at ..... (place of termination of pregnancy).

Place:

Date: Signature

## FORM I

(See Regulation 3)

I ..... (Name and qualifications of the Registered Medical Practitioner in block letters) ..... (Full address of the Registered Medical Practitioner)

I ..... (Name and qualifications of the Registered Medical Practitioner in block letters) ..... (Full address of the Registered Medical Practitioner) hereby certify that *I/We/am/are of opinion, formed in good faith, that it is necessary to terminate the pregnancy of ..... (Full name of pregnant woman in block letters) resident of ..... (Full address of woman in block letters) for the reasons given below**.

I/We hereby give intimation that *I/We terminated the pregnancy of the woman referred to above who bears the serial No. ..... in the Admission Register of the Hospital/approved place.

Place:

Date:

Signatures of Registered Medical Practitioners

*Strike out whichever is not applicable.

** of the reasons specified items (i) to (v) write the one which is appropriate:

i. In order to save the life of the pregnant woman.

ii. In order to prevent grave injury to the physical or mental health of the pregnant woman.

iii. In view of the substantial risk that if the child was born it would suffer from such physical or mental abnormalities as to be seriously handicapped.

iv. As the pregnancy is alleged by pregnant woman to have been caused by rape.

v. As the pregnancy has occurred as a result of failure of any contraceptive device or methods used by married woman or her husband for the purpose of limiting the number of children.

***Note:*** Account may be taken of the pregnant woman's actual or reasonably foreseeable environment in determining whether the continuance of a pregnancy would involve a grave injury to her physical or mental health.

Place:

Date:

Signature of the Registered Medical Practitioner

## FORM II

[See Regulation 4 (5)]

1. Name of the State .....
2. Name of Hospital/approved place .....
3. Duration of pregnancy (give total no. only)
   a. Up to 12 weeks .....
   b. Between 12 and 20 weeks .....
4. Religions of women:
   a. Hindu
   b. Muslim
   c. Christian
   d. Others
   e. Total
5. Termination with acceptance of contraception:
   a. Sterilisation
   b. IUD
6. Reasons for termination (give total number under each sub-head):
   a. Danger to life of the pregnant woman.
   b. Grave injury to the physical health of the pregnant woman.
   c. Grave injury to the mental health of the pregnant woman.
   d. Pregnancy caused by rape.
   e. Substantial risk that if the child was born, it would suffer from such physical or mental abnormalities as to be seriously handicapped.
   f. Failure of any contraceptive device or method.

Signature of the Officer In-charge with date

## FORM III

(See Regulation 5)

ADMISSION REGISTER

(To be destroyed on the expiry of five years from the dated of the last entry in the Register)

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|
| S. no. | Date of admission | Name of patient | Wife/ daughter of | Age | Religion | Address |
| 8 | 9 | 10 | 11 | 12 | 13 | 14 |
| Duration of pregnancy | Reason on which pregnancy terminated | Date of termination of pregnancy | Date of discharge of patient | Result and remarks | Name of registered medical practitioner(s) by whom the opinion is formed | Name of registered medical practitioner(s) by whom pregnancy terminated |

Chapter

2



# MTP Act: Registration of Place and Maintenance of Records

❍ Gorakh G Mandrupkar

## Introduction

In India, we have a very liberal and proactive law for medical termination of pregnancy. Abortion is not considered as a basic right of an Indian woman but getting access to safe abortion under this law is definitely considered to be the basic right of every Indian woman.

Certain licenses for registration of place as well as certain norms for records and documentations are given by this law, which are mandatory.

## Place where Pregnancy may be Terminated

"No termination of pregnancy shall be made in accordance with this Act at any place other than

a. A hospital established or maintained by Government, or
b. A place for the time being approved for the purpose of this Act by Government or a District Level Committee constituted by that Government with the Chief Medical Officer or District Health Officer as the Chairperson of the said Committee: Provided that the District Level Committee shall consist of not less than three and not more than five members including the Chairperson, as the Government may specify from time to time."

## Approval of Place

For this, we have to refer the Rule 5 of this Act which states that:

1. No place shall be approved:
   a. Unless the Government is satisfied that termination of pregnancies may be done therein under safe and hygienic conditions; and

b. Unless the following facilities are provided therein

*In case of first trimester (up to 12 weeks of pregnancy)*

- A gynecology examination/labor table
- Resuscitation and sterilization equipment
- Drugs and parental fluid
- Back up facilities for treatment of shock
- Facilities for transportation

*In case of second trimester (from 12 to 20 weeks of pregnancy)*

- Along with the above all. . .
- Operation table
- Instruments for performing abdominal or gynecological surgery
- Anesthesia equipment
- Resuscitation equipment
- Sterilization equipment
- Drugs and parental fluids for emergency use, notified by Government of India from time to time.

## How to Apply?

Every application for the approval of a place shall be in Form A and shall be addressed to the chief medical officer of the district (district civil surgeon/MOHFW of corporation).

The place shall be inspected within 2 months of receiving the application and certificate of approval may be issued within the next 2 months, or in case any deficiency has been noted, within 2 months of the deficiency having been rectified by the applicant.

The chief medical officer of the district, after inspection of place, and if satisfied after such verification, enquiry or inspection, that termination of pregnancies may be done under safe and hygienic conditions, at the place, recommend the approval of such place to the committee.

The district level committee (DLC)* may after considering the application and the recommendations of the chief medical officer of the district approve such place and issue a certificate of approval in Form B.

The certificate of approval issued by the committee shall be conspicuously displayed at the place to be easily visible to persons visiting the place.

{* District level committee: Composition and tenure: One member of the district level committee shall be gynecologist/surgeon/anesthesiologist and other members from the local medical profession, non-governmental organizations, and panchayat raj institution of the district: Provided that one of the members of committee shall be a woman. Tenure of the committee shall be for two calendar years and the tenure of the non-government members shall not be more than two terms.}

## Who can Perform MTP?

As per the Rule 4 of this Act,

a. A registered medical practitioner[#], registered in a State Medical Register immediately before the commencement of the Act (i.e. before 1971), experienced in the practice of gynecology and obstetrics for a period of not less than three years.

b. A registered medical practitioner,
   i. Who has completed six months of house surgency in gynecology and obstetrics; or
   ii. Unless the following facilities are provided therein, if he had experience at any hospital for a period of not less than one year in the practice of obstetrics and gynecology; or
c. If he has assisted a registered medical practitioner in the performance of twenty-five cases of medical termination of pregnancy of which at least five have been performed independently, in a hospital established or maintained, or a training institute approved for this purpose by the Government.
d. In case of a medical practitioner who has been registered in a State Medical Register and who holds a postgraduate degree or diploma in gynecology and obstetrics, the experience or training gained during the course of such degree or diploma.

{Training under sub-rule c would enable to do only 1st Trimester (up to 12 weeks) terminations. For the terminations from 12–20 weeks, experience or training under sub-rules: a, b and d shall apply.}

(#"Registered medical practitioner" means a medical practitioner who possesses any recognized medical qualification as defined in Clause (h) of Section 2 of the Indian Medical Council Act, 1956, whose name has been entered in a State Medical Register and who has such experience or training in gynecology and obstetrics as may be prescribed by rules made under this Act.)

## Maintenance of Records

1. Form C: Consent form

   Before doing MTP (medical/surgical), consent should be obtained in the Form C from a woman undergoing MTP who is above 18 years with sound mental health.

   When she is minor (below age 18), consent must be obtained from legal guardian.

2. Form I (One): Form of certifying opinion or opinions

   Every registered medical practitioner who terminates any pregnancy shall, within three hours from the termination of the pregnancy, certify such termination in Form I.

   Up to 12 weeks of pregnancy opinion of one registered medical practitioner and from 12 to 20 weeks of gestation, opinion of two registered medical practitioners is taken.

## Custody of Forms: Regulation 04

1. Form C and Form I together shall be placed in an envelope which shall be sealed by the registered medical practitioner.
2. On every envelope there shall be noted the serial number assigned to the pregnant woman in the admission register (Form III) and the name and address of the registered medical practitioner or practitioners by whom the pregnancy was terminated and such envelope shall be marked "Secret".
3. Every envelope shall be sent immediately after the termination of the pregnancy to the head of the hospital or owner of the approved place where the pregnancy was terminated.
4. On receipt of the envelope, the head of the hospital or owner of the approved place shall arrange to keep the same in safe custody.

5. Every head of the hospital or owner of the approved place shall send to the district chief medical officer, in Form II a monthly statement of cases where medical termination of pregnancy has been done.
6. Where the pregnancy is not terminated in an approved place or hospital for life-saving indication, every envelope shall be sent by registered post to the chief medical officer of the district on the same day on which the pregnancy was terminated or on the next working day following the day on which the pregnancy was terminated.

### Maintenance of Admission Register (FORM III): Regulation 05

1. Every head of the hospital or owner of the approved place shall maintain a register in Form III for recording therein the details of the admissions of women for the termination of their pregnancies and keep such register for a period of five years from the end of the calendar year it relates to.
2. The entries in the Admission Register shall be made serially and a fresh serial shall be started at the commencement of each calendar year and the serial number of the particular year shall be distinguished from the serial number of other years by mentioning the year against the serial number, for example, Serial Number 5 of 2018 and Serial Number 5 of 2019 shall be mentioned as 5/2018 and 5/2019.
3. Admission Register shall be a secret document and the information contained therein as to the name and other particulars of the pregnant woman shall not be disclosed to any person.

### Admission Register not to be Open to Inspection: Regulation 06

"Admission Register shall be kept in the safe custody of the head of the hospital or owner of the approved place, or by any person authorized by such head or owner and shall not be open for inspection by any person except under the authority of law: First class magistrate/district civil surgeon/MOHFW of corporation/or designated officer by district chief medical officer.

Provided that the registered medical practitioner on the application of an employed woman whose pregnancy has been terminated, grant a certificate for the purpose of enabling her to obtain leave from her employer: Provided further that any such employer shall not disclose this information to any other person.

### Entries in Other Registers Maintained in Hospital or Approved Place: Regulation 07

In other hospital records like OPD case-sheet, operation theatre register, follow-up card or any other document or register other than the admission register, reference to the pregnant woman undergoing MTP shall be made therein by the serial number assigned to the woman in the admission register and not by her name.

### Destruction of Admission Register and Other Papers: Regulation 08

Every admission register shall be destroyed on the expiry of a period of five years from the date of the last entry in that register and other papers on the expiry of a period of three years from the date of the termination of the pregnancy concerned provided no medicolegal case is going on.

In that case save as otherwise directed by the Chief Secretary to the union territory administration or for in relation to any proceeding pending before him, as directed by a District Judge or a Magistrate of the first class.

## Frequently Asked Questions

1. Does a specific doctor only can perform MTP in said premises?
   No.
   Form B gives approval to place and not to specific practitioner or anesthesiologist though their names are written mistakenly on certificate. Any registered medical practitioner defined under this Act can perform MTP at any such approved hospital provided he/she follows the rules of maintenance of record keeping (MTP Act regulation 04).
2. Can any medical officer check admission register during inspection of hospital?
   Only district civil surgeon/MOHFW of corporation/or designated officer for inspection by these officers with written order can ask for admission register for inspection.
   (MTP Act regulation 06)
3. Can a doctor/head of institute handover record to police for investigations?
   No, not directly.
   Investigating authorities have to write to district civil surgeon/MOHFW of corporation about the said record. With written permission from these authorities, copy of necessary record should be handed over to police.
4. Is there any linkage between PCPNDT and MTP law?
   No. Not at all.
   PCPNDT law is for prevention of sex selection and regulation of technologies and techniques related to it.
   MTP law is for legalizing and promoting safe abortion services.
   The implementing authorities of both the laws are same, so many a times wrongly both of these laws are mixed together.

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Chapter

3

# MTP Act—Need for Change



❍ Nikhil Datar ❍ Nithya R Iyer

Abortion is not a pure medical or a legal issue. It has many facets ranging from ethics to morality to religion. In the ancient days abortion was considered as a sin and an action against God. However, circumstances have always made women practice some form of birth control and/or abortion for centuries. The concept of abortion has generated intense moral, ethical, political and legal debates since long. Abortion is not merely a techno-medical issue but "the fulcrum of a much broader ideological struggle in which the very meanings of the family, the state, motherhood and young women's sexuality are contested".

In India, attitudes and practices have changed significantly with education and empowerment of women. Abortion in India has been legal since 1971.The Act was amended in 2002. The MTP Act is in need of one more amendment in the interest of women's rights.

## BACKGROUND OF THE MTP ACT IN INDIA

### Before 1971

The Indian Penal Code 1860 (IPC), which is the basic criminal law of the country, keeping in view with the religious, moral, social and ethical background of the Indian community, has made "induced abortion" a criminal offence under Sections 312 to 316 of IPC 1860.[1]

The IPC states that "whoever voluntarily causes a woman with a child to miscarry shall—if such a miscarriage be not caused in good faith for the purpose of saving life of the woman, be punished with imprisonment of either description for a term which may extend to 3 years or with a fine or with both and if the woman be 'quick' with child shall be punished either with a term which may be extended up to 7 years and shall be liable to fine."[1]

Thus, 'induced abortion' is an offence under two circumstances.

1. When the woman is 'with child' (as soon as gestation begins), or
2. When she is 'quick with child' (as soon as quickening is felt by mother)

Countless women died attempting illegal abortions as a result of the penal code, and it was a combination of this and the growing population that made the country reconsider its initial stance.[1] In 1964, the Central Family Planning Board of the Government of India met and formed a committee designed to examine the subject of abortion from medical, legal, social, and moral standpoints.[1] The Abortion Study Committee, led by the Health Minister of the State of Maharashtra, Mr Shantilal Shah, spent two years studying the issue, and submitted a report with its suggestions in December 1966.[1] This report considered the penal code to be too restrictive and recommended that the law related to abortions be relaxed.

### 1971 and Beyond

The Medical Termination of Pregnancy (MTP) Act, was enacted by the Indian Parliament in the year 1971 with the intention to reduce avoidable wastage of women's life.[2] The MTP Act came into effect from 1 April 1972 and was amended in the years 1975 and 2002.

When it was introduced, it was a great achievement for women's health. Nearly 30 years later, the law and associated rules and regulations are considered "overtly medicalised" and "bureaucratic", and as such, not oriented toward women's right to access safe and legal abortion services.

## CURRENT SCENARIO

In last 40 years, medical science has evolved significantly. With the advent of ultrasound it is possible to diagnose abnormalities in the fetus in the womb and give an accurate prognosis to the woman. The methods of inducing abortions have evolved significantly making late terminations relatively far safer. However, the law has not kept pace with these medical advances.

The author challenged the provisions of the MTP Act by filling a case "Dr Nikhil Datar and others Vs Government of India" on behalf of one of his patients who carried a 24 weeks severely abnormal fetus and wished to terminate her pregnancy. This was the first case in the history of Indian judiciary on this issue.

Till now, the author has helped nearly 100 women who wished to terminate their pregnancies which were advanced beyond 20 weeks because of severe fetal abnormality or when they were as a result of rape. The author has helped them pro bono to seek judicial intervention at various High Courts and the Supreme Court of India. The courts, after analysing the issues on case to case basis, have allowed almost all these women to undergo termination of pregnancy even though the gestation was advanced beyond 20 weeks. **It must be noted that the MTP Act is not yet amended. Till then, the only remedy available is to approach the High Court.**

## PITFALLS IN THE INDIAN MTP ACT

1. A woman's right to abortion is not 'unconditional'. In other words, a woman cannot demand for an abortion without any reasons. According to the MTP Act, Section 3(2)(b): Pregnancy can be terminated only if:
   - There is a substantial risk that if the child were born, it would suffer from such physical or mental abnormalities as to be seriously handicapped.

- The continuance of the pregnancy would involve a risk to the life of the pregnant woman or of grave injury to her physical or mental health.

Thus, MTP Act, 1971 does not give unconditional right to a woman to terminate her own pregnancy. The complete decision depends on the medical practitioner, who in "good faith" can approve termination of pregnancy.

A provider dependant law, however liberal it may be, can become 'restrictive' under different socio-political and religious compulsions, without the alteration of even a single word.

Thus, the IPC and the MTP Act infringes the right to privacy, right to health and right to dignity which is guaranteed by Article 21 (right to life and right to personal liberty).[3]

2. India is not against abortions, it does not believe in the "pro-life" ideology. MTP. Act, 1971 in its Sections 3, 2(2) states that "MTP can be performed where there is 'substantial risk' that if the child were born, it would suffer from such physical or mental abnormalities as to be seriously handicapped". But this is allowed only till 20 weeks. However, no explanation for the arbitrary limit of 20 weeks period is found in the Shantilal Shah Committee report (1966) as well as in parliamentary discussions.

   In India, there is no official pronouncement of age of viability. The clarity on concept of when to call a termination of pregnancy an 'abortion' and when to call it a 'delivery' is not there.

   It is important to note that there is no specific quantification available as how to measure the 'substantiality' of a particular handicap. In the Shantilal Shah Committee Report, Dr HL Shivpuri had stated that "The word 'substantial risk' is very vague ... it is open to different interpretations by courts of law and may lead to endless trouble for doctor concerned. Efforts should have been made to better define the risks". But unfortunately this controversial term still stands undefined. The doctors can only give the statistical prognosis regarding any handicap but not individualistic prognosis.

   With the advent of newer technologies, an accurate prenatal diagnosis can be given to the patient. Many abnormalities can be detected before 20 weeks but cardiac, gastrointestinal anomalies may not get detected below 20 weeks. Typically, results of amniocentesis get available after 20 weeks. In rural India, we are fighting for access to healthcare. Women may not be able to seek medical services before 20 weeks. In such a situation, will it be fair to diagnose an anomaly, give a grave prognosis and still compel a woman to continue the pregnancy against her wish?

   FIGO Committee for The Study of Ethical Aspects of Human Reproduction and Women's Health[4] agreed that a woman carrying a severely malformed fetus had the ethical right to have her pregnancy terminated. The qualification 'severe' is used in this context to indicate malformations that are either potentially lethal or whose nature is such that even with medical treatment, they are likely, in the view of the parents and their medical advisors, to result in unacceptable mental and/or physical disability." Also late termination has medically became very safe and it is being used when there is a risk to mother's life or in cases of fetal death in the womb.

3. The Nuffield Council on Bioethics[5] is funded jointly by the Medical Research Council, the Nuffield Foundation and the Welcome Trust and it consists of health economist, disability

commissioner, anthropologist, reputed doctors from fields of obstetrics, neonatology, lawyers, ethicist, rights activists.

While discussing the critical care decisions in fetal and neonatal medicine, the council came up with the following conclusions:

- "We regard the moment of birth, which is straightforward to identify, and usually represents a significant threshold in potential viability, as the significant moral and legal point of transition for judgements about preserving life—working party.
- When the baby's life results in a level of irremediable suffering, there is no ethical obligation to act in order to preserve that life—working party.
- It would be wrong to force a woman to behave rightly by submitting to medical or surgical interventions to benefit a foetus against her will."

4. Unlike other countries where the law is titled as "Abortion Act", it is titled as "Medical termination of pregnancy Act" in India. Probably, in 1971, the parliament was not keen on using the word "abortion" directly to avoid socio-political implications. Under the Act, the term "Termination of pregnancy" is not defined. Plain reading of the term implies that any procedure that terminates the pregnant status of the woman is termination of pregnancy. It means that irrespective of the fetal status, alive or dead, any procedure that separates the products of conception from the uterus is MTP. Thus, missed miscarriage or even induction of labour done for severe growth restriction could also be construed to fall under this definition. On the other hand, the term abortion has a specific and clear meaning. The word is defined as "any procedure that causes or hastens the process of fetal death." This clarity will also help to solve the ethical question while dealing with late terminations beyond 20 weeks. At this point of time, there is no clarity on how to deal with the live fetus after late termination. In most of the countries like UK, which allow late terminations, it is a norm to do intrauterine feticide and ensure that dead fetus is born when late abortion is done. In India, we are completely unclear on this issue.
5. As per the MTP Act, the rules are laid down by the Central Government and it empowers the state and district governments to make regulations. This adds layers of bureaucratic procedures, leading to unnecessary administrative barriers. Thus, the general spirit of state regulations appears to be 'controlling' than 'facilitating' abortion services.
6. The MTP Act covers those pregnancies which occur out of failure of contraception, but this clause is applicable only to married couples. Hence, illegal abortions are the only resource for the most vulnerable women in need—the unmarried, the adolescent girls, separated and single women.
7. The regulatory processes as mentioned in the MTP Act and regulations should have equitable and transparent policies to be applied to both private and public sectors. There is an assumption that public health institutions, by the virtue of being in the public sector, have a regulatory process built within them.
8. Amended MTP Rule mandates the district committee to inspect the facility seeking registration within two months of receiving the application. However, it does not specify measures or redressal mechanism if the certification procedures are not completed within the stipulated time frame.

9. Section 4 of the MTP Regulations states that detailed record and reporting procedures are to be followed while maintaining confidentiality of the abortion seeker. As per the regulations, the name of the patient undergoing the MTP should not be mentioned anywhere else except the admission register and consent form. It is expected to seal both the forms in an envelope. Since the name is to be kept secret, how does one address the woman? How does one confirm her identity according to the WHO's safe surgery checklist? How does one give discharge card or bill? How does one fill up online reporting form without name being mentioned? These practical questions need to be addressed clearly.
10. Under the "Drug and Cosmetics Act" it is expected to maintain a separate register of scheduled drugs. Since mifepristone and misoprostol come under this category, a separate register is needed to be maintained along with the details of the usage. This is again contradictory to the above mentioned provisions of the MTP Act.
11. **The PCPNDT Act and the MTP Act:** Though the aim of both these acts are very distinct, there have been attempts to link the two laws with the intention of preventing sex-selective abortion. But it is necessary to understand that the two laws are not contradictory or conflicting but can easily coexist.
12. Code of Medical Ethics specifies that before performing an operation, the physician should obtain in writing the consent from the husband or wife, parent or guardian in the case of minor, or the patient, himself as the case may be. In an operation which may result in sterility the consent of both husband and wife is needed. No act of *in vitro* fertilization or artificial insemination shall be undertaken without the informed consent of the female patient and her spouse as well as the donor. Such consent shall be obtained in writing only after the patient is provided, at her own level of comprehension, with sufficient information about the purpose, methods, risks, inconveniences, disappointments of the procedure and possible risks and hazards. But in case a woman wants to abort such a conception, as per the MTP Act, she can get an MTP performed without the consent of her husband. Thus, in this manner the MTP Act also conflicts the Code of Medical Ethics.
13. **MTP Act and POCSO Act:** According to POCSO Act, only a woman above the age of 18 years can consent for act of sex. It means that any sexual act done by a minor is considered as "without consent" and amounts to rape. When a girl below the age of 18 seeks medical help for termination of pregnancy, the doctor mandatorily needs to inform the police. This puts the privacy of the woman, which is given paramount importance under the MTP Act, at stake. Since most of the young girls would rather not want to inform the police, they are again not left with a choice but to undergo illegal terminations in the hands of the quacks, risking their lives.

## CONCLUSION

The MTP Act needs major amendments in three sectors.

- Rights of abortion of a woman must be respected and recognized.
- Especially for substantial foetal anomalies, termination must be allowed irrespective of gestational age.
- The conflicting legal positions under other laws such as IPC, code of medical ethics need to be resolved at once.

The author had challenged the provisions of the MTP Act in the High Court of Bombay in 2008 for one of his patients. He is still pursuing the special leave petition at the Supreme Court of India. In the recent past, the National Commission for women have recommended amendments to the law.[6]

The report of the committee of Mr Naresh Dayal and NK Ganguly is not yet acted upon by the Government.[7] The gynaecologists from the country are also the second victims of this lopsided law. They need to wake up and start collecting meticulous data particularly on severe anomalies reported beyond 20 weeks of pregnancy. This will go a long way in establishing that this is a public health hazard. Unless this is not demonstrated, the law will not change for the better.

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Chapter

4

# PCPNDT Act and Rules



Mandakini Megh Meenakshi Rao

## INTRODUCTION

"It is no exaggeration to call this gendercide. Women are missing in their millions—aborted, killed, neglected to death."

—The Economist, Leaders, Gendercide, March 6th, 2010.

The practice of sex selective abortion (or social sex selection) has been a critical influencer of skewed sex ratios. It has, therefore, been sought to be legally regulated or termed illegal in some countries of the world, and India is one of them. There is a little doubt that strong socio-cultural and religious biases and a preference for sons in some communities have shaped societal attitudes in favour of the son.[1]

As members of a profession which has a privileged status and has bestowed on us a position of honour, it is our ethical responsibility to ensure that no one from our profession indulges in unethical and unlawful practices. The Pre-natal Diagnostic Techniques Act, 1994 and its subsequent amendment in 2003 as the Pre-conception and Prenatal Diagnostic Techniques (Prohibition of Sex Selection) Act (PCPNDT Act) were not brought into force because common people were resorting to sex selection, but because the medical fraternity made it possible and easy for them to do so.

The child sex ratio is calculated as the number of girls per 1000 boys in the 0–6 years age group. In India, the ratio has shown a sharp decline from 976 girls to 1000 boys in 1961 to 927 as per the 2001 census.[2] The declining child sex ratio has its roots in the practice of sex selection. In certain parts of the country, there are less than 800 girls for every 1000 boys. The child sex ratio is a powerful indicator of the social health of any society.

The adverse child sex ratio can severely impact the delicate equilibrium of nature and destroy our moral and social fabric. Contrary to what many believe, lesser number of girls in a society

will not enhance their status. Instead, this could lead to increased violence against women, rape, abduction, trafficking and onset of practices such as polyandry (many men marrying one woman).

The law has its own place but has been hampered by difficulties in implementation and societal apathy. Efforts are being made to effectively implement the law.

Sex selection is not only about technology. At the heart of the matter is the low status of women in society and the deep-rooted prejudices they face through their life. Consequently, what we see is discrimination and neglect of the girl child, which could be in terms of inadequate nutrition, denial or limited access to education and health, child labour and domestic violence. At its worst, it translates into one of the most repugnant form of violence against women: Sex selection.

## The Commonly used Techniques for Sex Selection

### *Pre-conception Techniques*

- Pre-implantation genetic diagnosis
- Sperm sorting and sperm separation

### *Prenatal Diagnostic Techniques (PNDT)*

Developed in the 1970s, PND through techniques such as ultrasound scanning and amniocentesis followed by sex selective abortion, remains the most common method of sex selection practiced around the world for the last three decades.

- Amniocentesis
- Chorion villus biopsy
- Sonography
- NIPT

### *Other Methods*

- Diet
- Ayurvedic therapies

## Background

Amniocentesis was first introduced in India in 1975 by the All India Institute of Medical Sciences (AIIMS), New Delhi, for detecting congenital deformities in a fetus. By the mid-1980s, it was being largely misused to determine the sex of the unborn child and to carry out sex selective abortions—with the girl child as the obvious target in Maharashtra, Punjab and Haryana. The practice soon spread to the rest of the country.

In 1988, the state of Maharashtra became the first in the country to ban prenatal sex determination through the enactment of the *Maharashtra Regulation of Prenatal Diagnostics Techniques Act*. At the national level the *Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act* (PNDT Act) was enacted on September 20, 1994.

The 1994, Act provided for the "regulation of the use of prenatal diagnostic techniques for the purpose of detecting genetic or metabolic disorders, chromosomal abnormalities or certain

congenital malformations or sex-linked disorders and for the prevention of misuse of such techniques for the purpose of pre-natal sex determination leading to female feticide and for matters connected therewith or incidental thereto." Except under certain specific conditions, no individual or genetic counselling center or genetic laboratory or genetic clinic shall conduct or allow the conduct in its facility of, prenatal diagnostic techniques including ultrasonography for the purpose of determining the sex of the fetus; and "no person conducting prenatal 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."

The Act provides for the constitution of a *Central Supervisory Board (CSB)* whose function is mainly advisory, to review and monitor implementation of the Act and for the appointment of *Appropriate Authorities (*AAs) in States and Union territories to enforce the law and penalize defaulters and *Advisory Committees* (ACs) to aid and advise the AAs.

## Provisions under the Act

### *Important Sections of the Act*

**Section 5** deals with the prohibition of communicating the sex of the fetus. Misuse of PCPNDT even by a qualified person, solely for sex-determination and in conditions not falling under the exceptions under the Act.

**Section 6** deals with prohibition of determination of sex. Sex selection which would include any technique, procedure, test, administration, prescription or provision of anything, before or after conception, for the purpose of ensuring or increasing the probability of birth of male child. This would include even Ayurvedic pills or any alternative therapy claiming to be effective for this purpose.

**Section 18** deals with registration of genetic counseling centers (GCC), genetic laboratories (GL) or genetic clinics (GC).

**Section 22** deals with prohibition of advertisement relating to pre-conception and prenatal determination of sex and punishment for contravention. Issue, publication or circulation of any advertisement of facilities or any means of selecting or determining sex of the fetus before or after conception. The advertisement may be in any form: Notice, circular, label, wrapper or any other document, advertisement through internet (any search engine) or any other media in electronic or print form, and also includes any visible representation made by means of any hoarding, wall-painting, signal, light, sound, and smoke or gas.

**Section 29** deals with maintenance of records by genetic counseling centers, genetic laboratories or genetic clinics. Every genetic counseling centre, genetic laboratory, genetic clinic, ultrasound clinic and imaging centre is required to maintain a register showing the names and addresses of the men or women given genetic counseling, subjected to prenatal diagnostic procedures or tests, the names of their spouses or fathers and the date on which they first reported for such counseling, procedure or test.

**Rule 3B** deals with sale of ultrasound machines/imaging machines. No organization including a commercial organization or a person, including manufacturer, importer, dealer or supplier of ultrasound machines/imaging machines or any other equipment, capable of detecting sex

of fetus, shall sell, distribute, supply, rent, allow or authorize the use of any such machine or equipment in any manner, whether on payment or otherwise to any GCC, GL, genetic clinic, ultrasound clinic or imaging centre or a person not registered under the Act.

## Amendments

The Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 has since been amended with effect from 14.2.2003 following a public interest litigation (PIL) filed in 2000 and the findings revealed by the census 2001.

### *Amendments to the Act Mainly Cover to*

1. Bring the technique of pre-conception sex selection within the ambit of this Act so as to prevent the use of such technologies which significantly contribute to the declining sex ratio.
2. Bring the use of ultrasound machines within the purview of this Act more explicitly so as to curb their misuse for detection and disclosure of sex of the fetus lest it should lead to female feticide.
3. Further empower the CSB for monitoring the implementation of the Act.
4. Introduce state level supervisory board for monitoring and reviewing the implementation of the Act in states/UTs.
5. Constitute a multi-member state appropriate authority (AA) for better implementation and monitoring of the Act in the states.
6. Make punishments prescribed under the Act more stringent so as to serve as deterrent for minimizing violations of the Act.
7. Empower the AAs with the powers of Civil Court for search, seizure and sealing the machines, equipment and records of the violators of law including sealing of premises and commissioning of witnesses.
8. Making mandatory the maintenance of proper records in respect of the use of ultrasound machines and other equipment capable of detection of sex of fetus and also in respect of tests and procedures leading to pre-conception selection of sex.
9. Regulate the sale of ultrasound machines only to the bodies registered under the Act.
10. Prescribes punishments for contravention of its provisions—imprisonment up to three years and a fine up to 10000.

Based on the amendments made to the Act, the Rules framed thereunder have also been amended under the amended rules.

1. **A provision for appeal has been made:** Any person having grievance against the sub-district level AA can make an appeal to the district level AA within 30 days of the order of subdistrict, similarly for grievance against the district level AA, an appeal can be made to the state/UT level AA within 30 days of the order of the district level AA. Appeal can be made to the central government against the order of the central appropriate authority and to state government against the state appropriate authority

2. **23 indications, prescribed by ICMR**, have been included in the PNDT Rules for which ultrasound scanning can be conducted during pregnancy for the well-being of the pregnant woman and her fetus.
3. Forms have been simplified. **Consent** is required only in case of **invasive techniques.**
4. For non-invasive techniques like ultrasonography , the medical professional is required to make a declaration on each report of ultrasonography/image scanning, certifying that he/she has neither detected nor disclosed the sex of the fetus to anybody. Before undergoing such test, the pregnant woman has to declare that she does not want to know the sex of the fetus.[3]

## MINISTRY OF HEALTH AND FAMILY WELFARE NOTIFICATION

### New Delhi, the 31st January, 2014

*Amendment Rules, 2014*

1. In the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996, for Form F, the following Form shall be substituted: [See Proviso to Section 4(3), Rule 9(4) and Rule 10(1A)]

## FORM FOR MAINTENANCE OF RECORD IN CASE OF PRENATAL DIAGNOSTIC TEST/ PROCEDURE BY GENETIC CLINIC/ULTRASOUND CLINIC/IMAGING CENTRE

**Section A:** To be filled in for all Diagnostic Procedures/Tests

1. Name and complete address of Genetic Clinic/Ultrasound Clinic/Imaging Centre: _____
2. Registration No. (Under PCPNDT Act, 1994) _____
3. Patient's name _____ Age _____
4. Total number of living children: _____
   a. Number of living sons with age of each living son (in years or months): _____
   b. Number of living daughters with age of each living daughter (in years or months): _____
5. Husband's/Wife's/Father's/Mother's Name: _____
6. Full postal address of the patient with contact number, if any: _____ _____ _____
7. a. Referred by (full name and address of Doctor(s)/Genetic Counseling Centre): _____ _____

   (Referral slips to be preserved carefully with Form F)

   b. Self-referral by Gynaecologist/Radiologist/Registered Medical Practitioner conducting the diagnostic procedures: _____

(Referral note with indications and case papers of the patient to be preserved with Form F)
(Self-referral does not mean a client coming to a clinic and requesting for the test or the relative/s requesting for the test of a pregnant woman)

8. Last menstrual period or weeks of pregnancy: _____

**Section B:** To be filled in for performing non-invasive diagnostic procedures/tests only

9. Name of the doctor performing the procedure/s: _____
10. Indication/s for diagnosis procedure: _____

(specify with reference to the request made in the referral slip or in a self-referral note)
Ultrasonography prenatal diagnosis during pregnancy should only be performed when indicated. The following is the representative list of indications for ultrasound during pregnancy. (Put a "Tick" against the appropriate indication/s for ultrasound).

i. To diagnose intrauterine and/or ectopic pregnancy and confirm viability.
ii. Estimation of gestational age (dating).
iii. Detection of number of fetuses and their chorionicity.
iv. Suspected pregnancy with IUCD *in situ* or suspected pregnancy following contraceptive failure/MTP failure.
v. Vaginal bleeding/leaking.
vi. Follow-up of cases of abortion.
vii. Assessment of cervical canal and diameter of internal os.
viii. Discrepancy between uterine size and period of amenorrhea.
ix. Any suspected adenexal or uterine pathology/abnormality.
x. Detection of chromosomal abnormalities, fetal structural defects and other abnormalities and their follow-up.
xi. To evaluate fetal presentation and position.
xii. Assessment of liquor amnii.
xiii. Preterm labor/preterm premature rupture of membranes.
xiv. Evaluation of placental position, thickness, grading and abnormalities (placenta praevia, retroplacental hemorrhage, abnormal adherence, etc.).
xv. Evaluation of umbilical cord—presentation, insertion, nuchal encirclement, number of vessels and presence of true knot.
xvi. Evaluation of previous caesarean section scars.
xvii. Evaluation of fetal growth parameters, fetal weight and fetal well-being.
xviii. Color flow mapping and duplex Doppler studies.
xix. Ultrasound-guided procedures such as medical termination of pregnancy, external cephalic version, etc. and their follow-up.
xx. Adjunct to diagnostic and therapeutic invasive interventions such as chorionic villus sampling (CVS), amniocenteses, fetal blood sampling, fetal skin biopsy, amnio-infusion, intrauterine infusion, placement of shunts, etc.
xxi. Observation of intrapartum events.
xxii. Medical/surgical conditions complicating pregnancy.
xxiii. Research/scientific studies in recognized institutions.

11. Procedures carried out (non-invasive) (put a "Tick" on the appropriate procedure)
    i. Ultrasound (important note: Ultrasound is not indicated/advised/performed to determine the sex of fetus except for diagnosis of sex-linked diseases such as Duchenne muscular dystrophy, hemophilia A, B, etc.)
    ii. Any other (specify): _____
12. Date on which declaration of the pregnant woman/person was obtained: _____
13. Date on which procedures carried out: _____
14. Result of the non-invasive procedure carried out (report in brief of the test including ultrasound carried out): _____ _____ _____ _____ _____
15. The result of prenatal diagnostic procedures was conveyed to _____ on_____
16. Any indication for MTP as per the abnormality detected in the diagnostic procedures/ tests: _____

**Date:**
Place:

Name, Signature and Registration Number with Seal of the Gynaecologist/ Radiologist/Registered Medical Practitioner Place: Performing diagnostic procedure/s

**Section C:** To be filled for performing invasive procedures/tests only

17. Name of the doctor/s performing the procedure/s: _____
18. History of genetic/medical disease in the family (specify): _____
    Basis of diagnosis ("Tick" on appropriate basis of diagnosis):
    a. Clinical
    b. Bio-chemical
    c. Cytogenetic
    d. Others (e.g. radiological, ultrasonography, etc. specify)
19. Indication/s for the diagnosis procedure ("Tick" on appropriate indication/s):
    A. Previous child/children with:
        i. Chromosomal disorders
        ii. Metabolic disorders
        iii. Congenital anomaly
        iv. Mental disability
        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): _____
20. Date on which consent of the pregnant woman/person was obtained in Form G prescribed in PCPNDT Act, 1994: _____

21. Invasive procedures carried out ("Tick" on appropriate indication/s)
    i. Amniocentesis
    ii. Chorionic villi aspiration
    iii. Fetal biopsy
    iv. Cordocentesis
    v. Any other (specify)
22. Any complication/s of invasive procedure (specify): _____
    _____
23. Additional tests recommended (please mention if applicable)
    i. Chromosomal studies
    ii. Biochemical studies
    iii. Molecular studies
    iv. Pre-implantation gender diagnosis
    v. Any other (specify)
24. Result of the procedures/tests carried out (report in brief of the invasive tests/procedures carried out): _____
25. Date on which procedures carried out: _____
26. The result of prenatal diagnostic procedures was conveyed to _____ on _____
27. Any indication for MTP as per the abnormality detected in the diagnostic procedures/tests: _____

**Date:**
Place

Name, Signature and Registration Number with Seal of the Gynaecologist/Radiologist/Registered Medical Practitioner performing Diagnostic Procedure/s

**Section D:** Declaration

## DECLARATION OF THE PERSON UNDERGOING PRENATAL DIAGNOSTIC TEST/PROCEDURE

I, Mrs/Mr _____ declare that by undergoing _____ Prenatal Diagnostic Test/Procedure. I do not want to know the sex of my foetus.

**Date:** Signature/thumb impression of the person undergoing the Prenatal Diagnostic Test/Procedure

In case of thumb impression:
Identified by (Name) _____ Age: _____ Sex: _____
Relation (if any): _____ Address and Contact No.: _____
_____
Signature of a person attesting thumb impression: _____
Date: _____

## DECLARATION OF DOCTOR/PERSON CONDUCTING PRENATAL DIAGNOSTIC PROCEDURE/TEST

I, _____ (name of the person conducting ultrasonography/image scanning) declare that while conducting ultrasonography/image scanning on Ms/Mr _____ _____ (name of the pregnant woman or the person undergoing pre-natal diagnostic procedure/test), I have neither detected nor disclosed the sex of her fetus to anybody in any manner.

Signature: _____

Date: _____

Name in Capitals, Registration Number with Seal of the Gynaecologist/ Radiologist/Registered Medical Practitioner conducting diagnostic procedure

### Registration and Qualification Requirements for Places and Professionals

**Genetic counseling centre (GCC):** An institute, hospital, nursing home, or any other place by whatever name called which provides genetic counseling to patients. A genetic counseling centre should be under a medical geneticist or a gynecologist/pediatrician having 6 months experience or 4 weeks training in genetic counseling.

**Genetic clinic (GC):** Any clinic, institute, hospital, nursing home, or any other place by whatever name called which is used for conducting pre-natal diagnostic procedures. Genetic clinic will also include each and every mobile genetic clinic. For a genetic clinic, the gynecologist should have adequate experience in prenatal diagnostic procedures, i.e. should have performed at least 20 procedures in chorionic villi aspirations per vagina or per abdomen, chorionic villi biopsy, amniocentesis, cordocentesis, fetoscopy, fetal skin or organ biopsy or fetal blood sampling, etc. under supervision of an experienced gynecologist in these fields. A registered medical practitioner (who possesses any recognized medical qualification as defined in the Indian Medical Council Act, 1956 and whose name has been entered in a State Medical Register) practicing in a genetic clinic should have a postgraduate degree or diploma or six months training duly imparted in the manner prescribed in the "PCPNDT (Prohibition of sex selection), (six months training Rules) 2014" or one year experience in sonography or image scanning or a medical geneticist.

**Genetic laboratory (GL):** Any laboratory and includes a place where facilities are provided for conducting analysis or tests of samples received from genetic clinic for pre-natal diagnostic test.

### Qualification and Training in Ultrasonography for MBBS Doctors (www.med-edu.in)

1. "Principle rules" means the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996.
2. "Six months training" means the training imparted under these 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 abdominopelvic ultrasonography: Level one for MBBS 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:
      a. Theory based knowledge to equip registered medical practitioners with the knowledge, professional skills, attitudes and clinical competencies;
      b. Skill-based knowledge; and
      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: Any registered medical practitioner shall be eligible for undertaking the said six months training. Registered medical practitioners who are already registered for conducting ultrasonography in a genetic clinic or ultrasound clinic or imaging centre on the basis of one year experience or six months training are required to clear a competency based evaluation for the purpose of renewal of registration.
7. Fee structure for the training:
   a. The training fee for conducting the six months training shall not exceed ₹20,000/-
   b. 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 ₹10,000/-.
   c. Fee structure or waiver thereof for in service registered medical practitioners shall be decided by the respective centers.
8. Competency based evaluation shall be held as per Schedule II after six months training is completed.
9. 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.

   (Prohibition of Sex Selection) Act and Rules, a Handbook of Pre-conception and Prenatal Diagnostic Techniques Act and Rules with Amendments published by Ministry of Health, Government of India has made available (please refer the website for details www.pndt.nic.in)

## Requirements of Record-keeping by GCC, GC and GL

Under Section 9 of the PCPNDT Rules, 1996, every GCC, GL, GC shall send a complete report in respect of all pre-conception or pregnancy related procedures/techniques/tests conducted by them in respect of each month by 5th day of the following month to the concerned appropriate authority and keep the record of Form F with them for two years. It is pertinent to mention that every sonologist is required to fill Form F before conducting an ultrasound on a pregnant mother. The form has 19 questions including the reason for conducting the sonography, along with patient details.

### As per the Act, the following records are to be maintained by any GCC, GC or GL, under the Act

- Form D, i.e. the form regarding maintenance of records by GCC Form E, i.e. the form for maintenance of records by GL
- Form F, i.e. the form for maintenance of record in respect of the pregnant woman by GL/ultrasound clinic/imaging centre, including declaration of the pregnant woman and doctors
- Form G, i.e. the form of consent for invasive techniques

### Checklist for Registration of a Genetic Clinic, Counseling Centre, USG Centre, Imaging Centre

1. Application—Form A (two copies)
2. Affidavit containing undertakings from owners that they shall not conduct any test or procedure for selection of sex before or after conception and they will not disclose the sex of the fetus to anybody. They shall prominently display a notice saying they do not conduct such tests[4]
3. Particulars about fee paid ₹25000 for any one type of service, ₹35000 for a combination thereof (by demand draft in favor of AA)[5]
4. Site plan of place
5. If a society/trust: Registration certificate from Competent Authority and a copy of Rules and Regulations/Board Resolution.
6. Quotation/proforma invoice for sonography machine from authorized dealer/manufacturer (if relevant) with company PNDT Certificate.
7. Certified photostat copy/copies of educational qualifications and MMC registration of the person operating the machine (wherever applicable)
8. Certified photostat copy/copies of training/experience certificate of the person operating the machine (wherever applicable)
9. In case of a nursing home, registration under the Nursing Home Act
10. Any other additional documents/papers as considered necessary by appropriate authorities[6]

### What should the Scan Centers do under the Act?

#### *Display*

Registration certificate, PNDT board and pamphlets

#### *Records*

Mandatory records for GCC, GL, USG clinic and imaging center

1. Register showing in serial order
   - Name and Addresses of men or women given genetic counseling and/or subjected to prenatal diagnostic procedure or test.
   - Names of their spouses or fathers; and
   - Date on which they first reported for such counseling.
2. GCC—maintenance of record as per Form D.

3. GL—maintenance of records as per Form E.
4. GC—maintenance of record as per Form F

### *Form D/E/F under the Rules*

The scan centre shall send consolidated report statutorily by 5th for the previous month to the AA or any officer so authorized.

## Other Kinds of Records

- Case records
- Forms of consent
- Laboratory results
- Microscopic pictures
- Sonographic plates or slides
- Recommendations and letters.

**The referrals notes of the doctor recommending scan and a declaration from the pregnant mother regarding her non-interest in knowing the sex of the fetus is a must for every case.**

## For how long do the records have to be maintained?

All records should be maintained for at least two years[7] after any prenatal diagnostic technique has been performed on a pregnant woman. However, if there is any legal proceeding pending in the Court of Law, then these records should not be destroyed till the proceedings have been disposed off.[8] In case the records are maintained on a computer or any other electronic equipment, a printed copy of the record is to be taken and preserved after authentication by the person responsible for such a record.[9] Records at all reasonable times are to be made available for inspection to the AA or a person authorized by the AA.[10]

## Punishments for the Offences

An offence under this law is

**Cognizable:** A police officer may arrest the offender without warrant,

**Non-bailable:** Getting bail is not the right of the accused. The courts have discretion to grant bail.

**Non-compoundable:** Parties to the case cannot settle the case out of court and decide not to prosecute (Sec 27).

The punishments for offences involving sex selection or sex determination and non-maintenance of records (violation of Sections 5 and 6 of Act) are:

- Imprisonment of up to 3 years (5 years in case of subsequent offence) and fine of ₹10,000 ('fifty thousand in case of subsequent offence). However, this does not apply to any woman who was compelled by anyone to undergo such diagnostic techniques or such selection.
- Name of the registered medical practitioner shall be reported by the appropriate authority to the State Medical Council concerned for taking necessary action including suspension of the registration if the charges are framed by the Court and till the case is disposed of, 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.

- If any person seeks aid for sex selection or for conducting prenatal diagnostic technique on any pregnant other than those specified in Subsection (2) of Section 4, he shall be punishable with imprisonment up to three years and with fine up to fifty thousand rupees for the first offence and for any subsequent offence with imprisonment up to five years and with fine up to one lakh rupees.

*For registration related offences, the appropriate authority (AA) may:*

- Suspend or cancel the registration, as per the magnitude of the violation.
- During the period of suspension of registration, the equipment will be sealed and signed and kept with the owner.
- After cancellation of the registration, the equipment has to be sealed and seized.

For non-registration, 5 times the registration fee may be charged as penalty and an undertaking shall have to be furnished as per the PNDT Rules.

For violation of Section 22 of PNDT Act 1994[12] (any advertisement related offences) the prescribed punishment is imprisonment which may extend to 3 years; and fine which may extend to ₹10,000. For other offences, the prescribed punishment is: Imprisonment which may extend to 3 months or with fine which may extend to ₹1,000 for first offence and additional fine up to ₹500 per day may be levied for the period of contravention for subsequent offence.

If a company violates the PCPNDT Act, then the person in charge of the organization is liable for punishment.

## CONCLUSION

Along with the enforcement of law, what is needed is a mindset change. Each one of us counts. Each one of us has a role to play—as parents, siblings, family members and friends. And as professionals, whether teachers, doctors, lawyers, judges, administrators, law enforcement personnel, elected representatives, journalists, writers, artists . . .

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Chapter

5



# PCPNDT Act: Practitioner's Perspective

❍ Atul Ganatra

The Prenatal Diagnostic Techniques Act of 1994 and its subsequent amendment in 2003 as the Pre-conception and Prenatal Diagnostic Techniques (prohibition of sex selection) Act (PCPNDT Act) was brought into force to stop female feticide.

As members of the gynaecological fraternity and as responsible citizens and members of society, it is our duty to not indulge in unethical and unlawful practices. We, as gynaecologists, have to prove a point here, not only to the society but also to the authorities that USG is used not only a diagnostic tool but also as a life-saving investigation in many cases.

It has been observed that many of our colleagues are not well-versed with the PCPNDT Act, which can get them into unnecessary trouble with the authorities. We do not intend to print the whole Act but just to present the basic requirements in a simplified manner. In the first part of this series, we have made a list of do's and don'ts, which will make it easier for our members to follow the legal PCPNDT Act.

- Understanding the social aspect
- Understanding the PCPNDT Act
- Record keeping is must
- No harm in a few formalities like Form F and monthly report.
- All of us have to obey the law of land
- Pledge to eradicate the menace of female feticide from our society
- Try to get the actual culprits behind the bars

## Do's

- Registration of the clinic is mandatory. Only one registration per clinic is required (even if there is more than one machine). Details of all machines and all gynaecologists (along with copies of their certificates) should be submitted.

- Portability of sonography machine not allowed.
- Copy of the registration certificate must be displayed—one near the USG machine and another in the waiting room.
- Signage, in English and in the local language, must be displayed, indicating that fetal sex is not disclosed in the clinic.
- Ensure that the number of machines and the gynaecologists attached to the clinic have been mentioned in the registration certificate or on a separate sheet by the appropriate authorities (AA).
- Form F must be filled in completely and without any delay as soon as the patient's USG is done. The signed consent of the patient as well as the gynaecologist's signature are a must. Form G is only for invasive procedures.
- A monthly report should be submitted to the AA regularly, before the 5th of every month. A copy of the same, with the signature of the AA acknowledging receipt, must be preserved
- All copies of Form F and monthly reports should be preserved for 2 years. The referral letters from doctors should also be preserved.
- PCPNDT Act booklet must be available in the waiting room.
- The AA must be informed, in writing, about changes in any machine or radiologist. A copy of the same, with the signature of the AA, should be preserved.
- If a locum radiologist is appointed, the AA must be informed in advance (with the details of the locum radiologist's registration and Medical Council registration certificate).
- Be cooperative if and when the AA visits your clinic to examine the records.

### Don'ts

- Do not disclose the sex of the child to anyone—under any pressure or in any circumstances.
- Do not start a USG clinic without PCPNDT registration.
- Do not visit any clinic or hospital for USG unless it is registered for PCPNDT, even if it is for non-obstetric reasons (exception can be made when it is for a very urgent/life-threatening case, but this has to be proved by documentation).
- Registration certificates are non-transferable. Do not give your degree certificate to anyone or any place unless you are visiting it regularly.
- Do not give an experience certificate to anyone.
- Do not get scared by anyone if you are following all the rules as per the PCPNDT law.
- Do not allow anyone to check your records unless the person is accompanied by the AA or legally authorized by AA.
- Do not hesitate to ask for an ID before allowing any person to search your records.
- NGOs on their own can neither instruct you nor can they check your records.

## GREY AREAS

Copy of Form F to be given to patients: Who can answer—two versions.

- Preserving of films.
- Preserving of reports.

## AREAS OF CONCERN

- Lack of proper knowledge on the part of appropriate authority (AA).
- Non-uniform implementation of the Act as per the understanding of AAs.
- Making of laws by AAs—Maharashtra, Gujarat.
- No time/intention mainly in case of registrations
- New/renewals—advance notice never given by AAs as per CSB minutes.
- Adamant AAs.
- No proper co-ordination between Center/State/District.
- Nobody cares/listens at Government level.

## REGISTRATION

### What is Registered?

- Centre/USG machine/Sonologist/Place, etc.
- The answer is that it is the place (clinic or center or hospital or nursing home) where ultrasound is performed.
- No separate registration is required for a number of machines at the same place.

### Procedure of Registration

- Application in duplicate (Form 'A') to the CMO of District or any other Medical Officer constituted as an appropriate authority.
- Every application should be accompanied by an affidavit containing an undertaking that the Clinic/Centre shall not conduct a test or procedure for selection or detection of sex of the fetus.
- Undertaking that you will prominently display a notice for the same.
- ₹ 25,000, for ultrasound clinic/imaging centre; ₹ 35,000/- for any combination of genetic lab/clinic

### Procedure of Certification

- Application will be scrutinized by appropriate authority regarding fulfillment of requirements under the Act.
- Enquiry by the AA includes an inspection of the premises after giving due notice to applicant
- After AA is satisfied, the application will be placed before the Advisory Committee which then shall scrutinize the application and advise the AA.
- AA after considering the advice will grant certificate of registration in duplicate.
- It is mandatory to display the certificate of registration
- Certificate is non-transferable

### Rejection of Application for Registration

- If after enquiry and after giving an opportunity of hearing to the applicant and after taking advise from the Advisory Committee, the Appropriate Authority has come to a conclusion

that the applicant has not complied with the requirements of the Act, then the said application will be rejected.

- The reasons for the rejection shall be given in writing and as specified in Form C appended to the Rules under PNDT Act.
- The rejection of registration shall be communicated to the applicant within 90 days from the date of the receipt of the registration.

## Cancellation or Suspension of Registration

- Appropriate authority can at any time either on its own or on a complaint by anyone can issue a show cause notice to the genetic counselling centre, genetic laboratory or genetic clinic, ultrasound clinic or imaging centre as to why its registration should not be cancelled or suspended for breach of any of the provisions of the PNDT Act or the Rules. The reasons for every such notice should be mentioned in the notice itself.
- Thereafter the clinic, laboratory or center must be given an opportunity to defend itself against the charges. After giving the center, laboratory or clinic a reasonable opportunity of being heard and after taking into account the advice given by the Advisory Committee, the appropriate authority may either suspend the registration of such a place or cancel the registration depending upon the gravity of the charge.
- Action can be taken by the Appropriate Authority irrespective of any criminal action that will be taken against such a place.
- In certain exceptional cases like in the case of public interest, the appropriate authority may suspend or cancel registration without issuing a show cause notice. However, the reasons for waiving show cause notice have to be given in written.

## Provision of Appeal

- Any *genetic counselling center*, *genetic laboratory* or *genetic clinic* may appeal against an order of cancellation or suspension of registration within 30 days of the order of cancellation or suspension. The appeal may be made to:
  1. The appropriate authority at the district level if the order is passed by the appropriate authority at sub-district level.
  2. The appropriate authority at the State/UT level if the order is passed by the appropriate authority at district level.
- Each appeal shall be disposed of by the district appropriate authority or by the state/UT appropriate authority, as the case may be, within 60 days of its receipt. The appeal shall be made to the central government if the order is passed by the central appropriate authority.
- The appeal shall be made to the state government if the order is passed by the state appropriate authority.

## Renewal of Registration

- Every certificate of registration shall be valid for a period of five years since its issuance.
- Thirty days before the date of expiry of the certificate of registration, a fresh application for a certificate of registration should be made.

- The application for renewal must be made in duplicate in the prescribed Form A (same as the one prescribed for obtaining the first registration certificate) to the appropriate authority.
- The appropriate authority shall acknowledge the receipt of the application in the acknowledgement slip provided at the bottom of Form A on the very same day if personally delivered, otherwise on the next day by post.
- Along with the application for renewal of certificate, registration fees of half of what was initially payable will be paid depending upon whether it is for a *genetic counselling center*, *genetic laboratory* or *genetic clinic*, ultrasound clinic or imaging center or for a joint facility.
- After the receipt of the application, the appropriate authority will hold an enquiry including an inspection of the premises after giving due notice into whether the applicant has fulfilled all the requirements necessary under the Act. The appropriate authority will also give the applicant a hearing.
- After conducting the enquiry and hearing, if the appropriate authority finds everything satisfactory, then it will place the application before the Advisory Committee for its scrutiny.
- Thereafter having regard to the advice of the Advisory Committee, the appropriate authority will renew the certificate of registration in the prescribed Form B (same as the one prescribed for the first registration certificate) for a further period of 5 years starting from the date of expiry of the old certificate.
- On the receipt of the renewed certificate of registration in duplicate, the two copies of the earlier certificates will have to be surrendered immediately to the appropriate authority.
- One copy of the renewed certificate has to be displayed in a conspicuous place of the center, laboratory or clinic.
- If the appropriate authority fails to renew the certificate of registration within 90 days of its receiving the application for renewal, it will amount to automatic renewal or deemed renewal.

## Rejection of Application of Renewal

- After conducting an enquiry into the application for renewal, after hearing the applicant and after taking the advice of the Advisory Committee, if the appropriate authority finds that the applicant has not complied with the requirements of the Act, then, the appropriate authority can reject the application for renewal.
- Every order of rejection will contain reasons for rejection and it will be communicated in the prescribed Form C49 (same as the one prescribed for the initial rejection).
- Once the applicant receives the communication of rejection, the applicant must immediately surrender both the copies of the earlier certificate of registration.
- In case the appropriate authority fails to communicate its rejection to the applicant within 90 days of receiving the application for renewal, then it amounts to automatic renewal or deemed renewal.

## FORM A

[See Rule 4(1) and 8(1)]

(To be submitted in duplicate with supporting documents as enclosures)

Form application for registration for renewal of registration of a genetic counselling centre/genetic laboratory/genetic clinic/ultrasound clinic/imaging centre

## ACKNOWLEDGEMENT

[See Rule 4(2) and 8(1)]

The application in Form A in duplicate for grant*/renewal* of registration of Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic/Ultrasound Clinic/Imaging Centre by ..... (Name and address of applicant) has been received by the appropriate authority ..... on (date).

*The list of enclosures attached to the application in Form A has been verified with the enclosure submitted and found to be correct or

*On verification it is found that the following documents mentioned in the list of enclosures are not actually enclosed.

## ORIGINAL/DUPLICATE FOR DISPLAY

## FORM B

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

Certificate of Registration (To be issued in duplicate)

## FORM C

[See Rule 6(3), 6(5) and 8(3)]

Form for Rejection of Application for Grant/Renewal of Registration

## FORM D

[See Rule 9(2)]

Form for Maintanance of Records by the Genetic Counselling Centre

## FORM E

[See Rule 9(3)]

Form for Maintenance of Records by Genetic Laboratory

## FORM H

[See Rule 9(5)]

Form for maintenance of permanent record of applications for grant/rejection of registration under the Prenatal Diagnostic Techniques (regulation and prevention of misuse) Act, 1994.

## FORM F (refer to Chapter 4)

See Provision to Section 4(3), Rule 9(4) and Rule 10(1A)

Form for Maintenance of Record in Respect of the Pregnant Woman
By
Genetic Clinic/Ultrasound Clinic/Imaging Centre

## 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 prenatal diagnostic procedures wish to undergo the pre-implantation/prenatal 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 prenatal procedure/technique/test conducted show the absence of disease/deformity/disorder.

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

I understand that breach of this undertaking will make me liable to penalty as prescribed in the prenatal Diagnostic Technique (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994) and Rules framed Thereunder.

Date: _____

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

Date: ..... Medical Geneticist Radiologist/Paediatrician/Director of the Clinic/ Centre/Laboratory

**Name of the Ultrasound Clinic/Imaging Centre** **Reg.No:**

**Complete report in respect of pre-conception or pregnancy related procedures/techniques/tests**

| *S.No* | *Date* | *Name of patient Husband/father* | *Age* | *Reg.No* | *Address* | *Ref. by* | *Length of preg.* | *Indication* | *No. of children with sex* | *Nature of proc.* | *Parti-culars of doctor* | *Report* | *Was MTP adv.* |
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***Source:*** www.ncpcr.gov.in PCPNDT Act 1994

Chapter

6



# An Update on POCSO Act and Challenges in Relation to MTP Act

❍ Ashok Shukla

The Protection of Children from Sexual Offences Act, 2012, is an enactment to provide for protection of children (any person below eighteen years of age) from the offences of sexual assault, sexual harassment and pornography with due regard for safeguarding the interest and well-being of the child at every stage of the judicial process. It also incorporates child-friendly procedures for reporting, recording of evidence, investigation and trial of offences and provision for establishment of Special Courts for speedy trial of such offences to help the survivor speedy justice.

World Health Organization estimates that globally some 40 million children aged 0–14 years suffer from some form of abuse and neglect requiring health and social care.

The Act defines a child as any person below eighteen years of age, and regards the best interests and welfare of the child as matter of paramount importance at every stage, to ensure the healthy physical, emotional, intellectual and social development of the child. The Act is gender neutral. In POCSO Act, the term sexual assault is used instead of rape. If grave harm is caused to the victim or if the offence is committed by a person in authority, the offence is termed "aggravated" offence.

## How to Assess Age of a Child Victim/Survivor?

- Age of victim has to be determined in the same manner as is being done in respect of a person who is accused of an offence;
- Age has to be determined in terms of Section 94 of Juvenile Justice Act;
- The Court has first to look for the available certificates;

- The Court has to rely on first preference certificate irrespective of availability of other certificate;
- The Court cannot doubt the first preference certificate on the ground that other certificates are showing some different age;
- Medical opinion can be sought for only if all priority certificates are found to be not available;
- Medical opinion does not provide the exact age;
- Sufficient margin (say two years) on either side has to be given in respect of medical opinion;
- Range of age in medical opinion upon margin being given will leave room for doubts;
- Benefit of doubt has to go in favour of the accused and therefore, the upper age of medical opinion has to be accepted by the court in respect of age of victim.

## Salient Features of POCSO 2012

| *Section* | *Provision* |
|---|---|
| **S.3** | **Penetrative Sexual Assault:** Insertion, penetration, manipulation with the penis, any body part, or any object into the vagina, mouth, urethra or anus of a child. |
| **S.5** | **Aggravated Penetrative Sexual Assault:** 'Person in authority' and/or if additional harm and injury is committed. |
| **S.7** | **Sexual Assault:** Touching a child with sexual intent (non-penetrative) (touching vagina, penis, anus, breast or any body part of a child). |
| **S.9** | **Aggravated Sexual Assault:** 'Person in authority' and/or if additional harm and injury is committed. |
| **S.11** | **Sexual Harassment:** Word, sound, gesture, exhibiting any body part, showing pornography with sexual intent. Making a child exhibit any body part, stalking the child, threatening the use of pornographic media |
| **S.13 and S.15** | **Pornography:** Use of a child for pornographic purposes. Storing pornographic media of a child for commercial use. |
| **S.19–21** | **Mandatory Reporting:**<br>S.19 (1) any person who has knowledge of sexual offence committed or likely to be committed on a child<br>S.20 management and staff of media, hotels, lodges, hospitals, clubs, studios and photographic facilities<br>S.21 Failure to report or record is punishable<br>S.21 (3) However, a child who fails to report not punished. |

All offences under the POCSO Act are considered as grave offences. Hence they are non-bailable and cognisable and the trial is to be conducted by the Court of Sessions.

## Punishment for Offences for Using Child for Pornographic Purposes

| *Offence* | *POCSO Act, 2012* | *2019 Bill* |
|---|---|---|
| Use of child for pornographic purposes | Maximum: 5 years | Minimum: 5 years |
| Use of child for pornographic purposes resulting in penetrative sexual assault | Minimum: 10 years<br>Maximum: Life imprisonment | Minimum: 10 years (in case of child below 16 years: 20 years)<br>Maximum: Life imprisonment |
| Use of child for pornographic purposes resulting in aggravated penetrative sexual assault | Life imprisonment | Minimum: 20 years<br>Maximum: Life imprisonment, or death. |
| Use of child for pornographic purposes resulting in sexual assault | Minimum: Six years<br>Maximum: Eight years | Minimum: Three years<br>Maximum: Five years |
| Use of child for pornographic purposes resulting in aggravated sexual assault | Minimum: Eight years<br>Maximum: 10 years | Minimum: Five years<br>Maximum: Seven years |

The Protection of Children from Sexual Offences (Amendment) Bill, 2019 was introduced in Rajya Sabha by the Minister of Women and Child Development, Ms. Smriti Zubin Irani, on July 18, 2019. The Bill amends the Protection of Children from Sexual Offences Act, 2012. It was passed in Lok Sabha on 1st August 2019.

The amendments were aimed at establishing clarity regarding the aspects of child abuse and punishment thereof, hence amendments in Sections 2, 4, 5, 6, 9, 14, 15, 34, 42 and 45 of the POCSO Act 2012 were made.

Sections 4, 5 and 6 was amended to provide option of stringent punishment, including death penalty, for committing sexual assault and aggravated penetrative sexual assault crime on a child to protect the children from sexual abuse.

Sections 14 and 15 of the POCSO Act 2012 was to address the menace of child pornography. It was proposed to levy fine for not destroying or deleting or reporting the pornographic material involving a child with an intention to share or transmit it.

## Role of Attending Physician under POCSO Act

1. It is mandatory for attending physician to provide such information to the Special Juvenile Police Unit (SJPU) or to the local police as the case may be under Section 20 and failure to report shall be punished with imprisonment of either description which may extend to six months or with fine or with both under Section 21.
2. Medical examination of a child (Section 27): The medical examination of the child in respect of whom any offence has been committed shall be conducted in accordance with [Section 164A] of Code of Criminal Procedure, 1973 (2 of 1974) not waiting for FIR or complaint to be registered. In case the victim is a girl child, the medical examination shall be conducted by a woman doctor in presence of the parent of the child or any other person whom the

child reposes trust or confidence or in absence of any relative then examination should be conducted in presence of woman nominated by the head of the medical institution.

3. Emergency Medical Care Rule 5, POCSO Rules 2012: Emergency medical care shall be rendered in such a manner as to protect the privacy of the child, and in presence of the parent or guardian or any other person in whom the child has trust and confidence without demanding any legal or magisterial requisition or other documentation as a pre-requisite to rendering such care. The registered medical practitioner rendering emergency medical care shall provide treatment to all injuries, treatment for exposure to STD including prophylaxis, treatment for exposure to HIV including prophylaxis for HIV, possible pregnancy and emergency contraception as well as if need arises, then psychological consultation can be referred for.

## CHALLENGES OF POCSO ACT IN RELATION TO MTP ACT

The Medical Termination of Pregnancy (MTP) Act 1971—a law that was considered ahead of its times—legalized abortion in India up to 20 weeks of pregnancy, based on certain conditions and when provided by a registered medical practitioner at a registered medical facility.

The main intention of the Act was easy access for safe legal abortion.

The Medical Termination of Pregnancy Regulations, 1975 state that the admission register of MTP shall be a secret document and the information contained therein as to the name and other particulars of the pregnant woman shall not be disclosed to any person. The consent forms would be kept in separate envelope with marking as SECRET on the envelope.

The POCSO Act requires medical providers to report any case of underage pregnancy (below 18 years of age) as a case of sexual assault/abuse. In accordance with International Child Protection Standards, the Act provides for mandatory reporting of sexual offences and it casts legal duty upon any person who has knowledge or a suspicion that a child has been sexually abused. POCSO unfortunately criminalises consensual adolescent sexual activity. Minor girl under POCSO Act is considered unable to give consent for sexual intercourse hence irrespective of marital status mandatory reporting has to be done by medical provider to the local police authority. Madras High Court has suggested amendments to POCSO Act over consensual sex after 16 years of age.

MTP Act Section 8 guarantees protection for providers who act in good faith. In less than 18 years pregnant patient, it becomes the legal duty for the medical providers to follow all legal requirements under both MTP and the POCSO Act.

## ISSUES TO BE KEPT IN MIND DURING TERMINATION OF PREGNANY IN A CHILD (<18 YEARS)

1. Mandatory reporting to the local police or special juvenile police unit or child protection committee.
2. POCSO Act only mentions reporting and not investigating by the medical provider or lodging FIR. So the medical provider can go ahead with the treatment and does not require to wait for the authorities to take action and may proceed with the termination of the pregnancy in line with the provisions of the MTP Act after maintaining the detailed case records.

3. Consent for termination: As here the child being a minor, consent becomes invalid and hence guardian's consent would be required for MTP. The MTP Act defines Guardian as a person having the care of the minor person. This means any adult (above age of 18 years) who has the care of the minor girl could be *de facto* guardian and could consent to an abortion on her behalf.
4. Rape is a legal ground for terminating a pregnancy under Section 3 of the MTP Act and the limit in the Act is up to 20 weeks. It is important to provide medical care at the earliest and on the other side legal proceedings can continue.
5. Products of conception: MTP Act Section 8 guarantees protection for providers who act in good faith so providers who dispose of the products of conception due to inadequate facilities, etc. should be protected from prosecution. Since pregnancy in a minor girl is termed rape, therefore under Section 201, the products of conception might be the evidence of the offence.

## CONCLUSION

Some more amendments would be required in both MTP Act regarding the duration of pregnancy as many times pregnancy is detected late; and in POCSO Act where the age of consent for sexual activity is 18 years causing many young women above 16 years of age in consensual sexual relationship getting diverted to quacks for termination of pregnancy endangering their life and obstructing the easy access to safe abortion what she had before POCSO Act. But till the government considers these factors and make appropriate amendments, all medical service providers have to fulfil all the requirements and legal obligations of both MTP Act and POCSO Act.

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Chapter

7

# Medicolegal Challenges in PCPNDT Act: Case Examples



MC Patel

In the population censes of 1971, 1981 and 1991, serious gender imbalance between 0 and 6 years of male children to female children was noticed. To check gender imbalance, Pre-Natal Diagnostic Technique (Regulation and Prevention of misuse) Act was enacted in 1994. In spite of the PNDT Act 1994, there was no improvement in the figures in census of 2001. On the contrary, further gender imbalance was noticed making the issue more of social worry.

It was noticed that ratio of 0–6 years of male to female children in India was 1000:945 in 1991 and 1000:927 in 2001. Public interest litigation was filed by NGOs before the Supreme court for better implementation of the Act to check gender imbalance. So, further amendments were made in 2002 and 2003 and pre-conceptional sex selection was added and the Act is known as The Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection)—PCPNDT Act. From time to time, further amendments were added in sections and rules in 2011, 2012, 2013, 2014, etc, for better implementation of the Act.

## AIMS

- Prohibition of pre-natal determination and/or communication of the sex of the foetus.
- Prohibition of pre-conceptional sex selection.
- Prohibition of any advertisement by any person and/or organisation and/or institution regarding facilities of pre-natal sex determination and/or pre-conceptional sex selection.
- Any centre, managing antenatal patients, must be registered under this Act either as a genetic counselling centre, genetic laboratory, genetic clinic and/or ultrasound clinic/imaging centre.
- No centre can function without registration (Section 18)
- All these centres are regulated under PNDT Act.

## Punishment under PCPNDT Act

Any offence under this Act shall be ***cognizable, non-bailable and non-compoundable.***

## Challenge 1

As the offence is non-bailable, if appropriate authority has involved the police, police can make an arrest and only court can grant bail.

It has happened in many cases especially when team from Rajasthan has raided for search and seizure. In Gujarat, doctors from Modasa, Himmatnagar, Panchmahal, Banaskantha were arrested and the lower court rejected bail. The High Court of Rajasthan, Jodhpur bench granted bail and they were out of custody. Doctors remained in jail for approximately 5 days to 15 days. There are provisions for punishment for contravention of any provision of this Act under Sections 23 and 25.

## Section 23

Provision of punishment for person giving the aids:

- For first conviction: Imprisonment of up to 3 years and fine of up to ₹10,000.
- Any subsequent conviction: Imprisonment of up to 5 years and fine of up to ₹50,000.
- Name of registered medical practitioner (RMP) shall be reported by appropriate authority to State Medical Council for necessary action including suspension of registration, if charges are framed.

## Challenge 2

- Merely on framing the charge sheet, appropriate authorities can write to the Medical Council of the respective state to take necessary action including suspension of registration.
- There is provision that on conviction of a doctor, his name can be removed from Register of Council for 5 years in case of first offence; and permanently for the subsequent offence.

This is not fair as the offense is yet to be proved.

In one instance in Ganganagar, Rajasthan, the appropriate authority filed a case in court of First Class Magistrate against 18 doctors on a single ground that during inspection of their respective clinic, the doctors were found without aprons and name plates and charge sheet was framed. The appropriate authority wrote to Medical Council of Rajasthan to take necessary action including suspension of registration. In response, Medical Council registration of all eighteen doctors was suspended. Of course, the ruling was challenged in the High Court of Rajasthan, which ruled in favour of the doctors that merely on framing of charge sheet, such kind of action cannot be taken.

Provision for punishment for person seeking the aids:

For first conviction: Imprisonment up to 3 years and fine up to Rs. 50,000.

Any subsequent conviction: Imprisonment up to 5 years and fine up to Rs. 1 Lakh.

Husband and relatives of the pregnant woman undergoing prenatal diagnostic technique for the purpose of sex determination shall be presumed to have compelled the woman to

undergo the same unless the contrary is proved. Provision of the Act shall not apply to the woman who was compelled to undergo such technique.

The provision also applies to pre-conceptional sex selection.

### Challenge 3

Very few or almost negligible cases has been filed against patient or relatives seeking aids for prenatal sex determination and/or pre-conceptional sex selection.

In our society, there is a wrong belief that cases can only be filed against doctors doing sonography. If cases are filed against patients or relatives seeking sex determination or pre-conceptional sex selection, then there will be a fear in society and demand for sex determination or pre-conceptional sex selection will be reduced. After all, this is type of demand and supply. If there is no demand, there will be no supply.

### Section 25

Contravention of any provisions or any rules for which no penalty has been elsewhere provided in this Act:

- There will be punishment of imprisonment up to 3 months or fine up to Rs. 1000 or both.
- Continuing contravention, additional Rs. 500 for everyday during which such contravention continues after conviction for the first such contravention.

### Under Section 4(3) of the Act

Any deficiency or inaccuracy found in record shall amount to contravention of provisions of Section 5 or Section 6 of the Act unless contrary is proved by the person conducting antenatal ultrasonography.

Thus, any deficiency or inaccuracy in record may invite litigation, sealing of ultrasound machine and suspension or cancellation of registration of PCPNDT.

### Challenge 4

Maximum cases filed against the doctors are on the grounds of inaccuracy or deficiency of records or of not preserving records properly.

Therefore, persons doing sonography are under obligation to maintain records properly as per the provision of the Act. The doctors should remember that prevention is always better than cure and ignorance of the law cannot be an excuse.

### Registration of Certificate

- Registration of the centre is mandatory either as genetic counselling centre, genetic laboratory, genetic clinic and/or ultrasonography centre/imaging centre.
- **No centre can function without registration**
- One cannot buy, install or use USG machine for antenatal sonography unless the centre is registered and details of the sonography machine/s are intimated to the authority.
- As such, there is registration of place and not the person or the machine

- Only details of persons working in the centre (name, qualifications with Medical Council registration number) and machines installed (make, model, manufacturer) are to be provided
- However, many appropriate authorities insist separate registration for each machine with registration fees which is wrong interpretation by appropriate authority.

One copy of Form B is to be displayed at a conspicuous place at the place of business [Rule 6(2)]

### Challenge 5

In certificate of registration, details of sonography machine is to be included.

In many cases, ground of the case is 'there was no detail of sonography machine in form B, i.e. Certificate of Registration'. If there is change in sonography machine (buy/sell), it is to be intimated to appropriate authority. Certificate of registration should also be sent to appropriate authority for necessary change.

**Renewal of Registration of certificate:** One should apply for renewal 30 days before the date of expiry of Certificate of Registration [Rule 8(1)]

**Deemed Renewal [Rule 8(6)]:** In event of failure of the appropriate authority to renew the Certificate of Registration or to communicate within a period of **90 days** from the date of receipt of application for renewal of registration, the certificate of registration shall be deemed to have been renewed.

### Challenge 6

For renewal of registration, one may apply before 30 days of expiry.

Provision of deemed renewal only applies if there is no communication from appropriate authority in regards to either renewal or rejection within 90 days. Thus, if the appropriate authority does not take any decision, then after 30 days any registered centre stands unregistered.

### Maintenance and Preservation of Records [Rule (9)]

- A doctor is bound to produce records when asked by the appropriate authority and the Court and if he does not, adverse inference might be drawn.
- Good record is good defence, poor record is poor defence and no record is no defence.
  - It is mandatory to duly fill and sign prescribed forms:
  - Form D for Genetic Counselling Centre [R9(2)]
  - Form E for Genetic Laboratory [R9(3)]
  - Form F for Genetic Clinic/Ultrasonography Centre/ Imaging Science Centre [R9(4)]
  - Form G for Invasive Procedures [R 10(1)] with declaration from patient duly signed.
  - Form H: Appropriate authority shall maintain a permanent record of applications for grant of renewal of certificate of registration. Letter of intimation of every change of employee, place, address and equipment installed. [R9(5])

You can send specimen for investigation to registered genetic laboratory only. Genetic laboratory can receive specimen from registered centre only. It shall not be necessary for genetic laboratory to obtain a fresh consent if consent is taken by genetic clinic.

## Challenge 7

Cases filed against doctors are on the grounds that signature of patient on declaration form is not taken or doctors doing sonography have not signed the declaration.

It is mandatory for the patient undergoing the sonography and the person doing the sonography to sign the declaration.

**Declaration of patient is mandatory for any ultrasound or invasive procedure irrespective of the gestational age** as under

"I, Ms. ..... declare that by undergoing ultrasonography/image scanning, etc, I do not want to know the sex of my foetus"

Signature/Thumb Impression of pregnant woman
Thumb impression is to be identified by proper person
Copy should be given to pregnant woman

**Declaration of person doing the sonography is also mandatory** on Form F or G (as per case) and on report of sonography/imaging scanning as under:

"I, Dr. ..... declare that while conducting ultrasonography/image scanning on Ms. ....., I have neither detected nor disclosed the sex of her foetus to anybody in any manner."

Signature

Form should be filled up in duplicate

- One copy to be kept for office record [R 9(4)]
- One copy to be sent to the Appropriate Authority every month before 5th of next month. [R 9(8)]

## Challenge 8

Records can be preserved in any media but a copy of the record shall be taken and will be authenticated by person responsible for such record.

Thus, even after preserving record in any media, hard copy is required.

## Preservation of Records

- One can preserve records on computer or any electronic equipment [Rule 9(7)] but printed copy of records shall be taken and preserved after authentication by a person responsible for such records
- Records are to be preserved for two years from the date of completion to date of counselling, prenatal diagnostic procedure or prenatal diagnostic test.
- In event of any legal proceeding, records should be preserved till the final disposal of case or for two years whichever is later.

### Submission of Records

One copy of respective form is to be submitted to appropriate authority every month before 5th of next month **[Rule 9(8)].**

### Online Submission

In some states, authorities insist on submitting respective forms online in a given prescribed period.

### Online Submission of Nil Report

In some states, authorities insist on submitting 'NIL' report within a stipulated time, if there is no sonography during the respective month.

### Challenge 9

In some states, the appropriate authority insists on to maintain register with all the details of form F.

There is no provision to support this demand as per the Act.

### Register [Rule 9(1)]

Register having four columns should be maintained, i.e.

1. Sr. No
2. Name and Address of the woman and the relative given genetic counselling, subjected to prenatal diagnostic procedure or pre-natal diagnostic tests
3. Name of spouse/father and
4. Date on which they first reported for such counseling, procedure or test

### Challenge 10

Consent of patient:

- Written consent of pregnant woman is mandatory, if one does ultrasound examination or invasive procedure irrespective of gestational age.
- One copy should be given to pregnant woman

### Referral Chits/Letters

- If patient is referred from outside, referral letter is to be preserved with respective form
- If it is self reference, then copy of case paper is also to be preserved with referral chit with indication/s (made by person advising ultrasound examination) with respective form

**Intimation of change** [Rule (13)] of employee, place, address, equipment installed to be intimated at least 30 days in advance of the expected date of such change by person in whose name registration is.

### Non-use of Machine

- If the ultrasonography machine is not working, it is for repairs, permanent non-use or is given back to company, the appropriate authority must be intimated.
- If it is permanent non-use, machine can be disposed off (demolished) in presence of appropriate authority or his representative.

### Doctor Visiting as a Sonologist [Rule 3(3)]

Every Medical Practitioner qualified under the Act to conduct ultrasonography in a genetic clinic/ultrasound clinic/imaging centre shall be permitted to be registered with a maximum of **TWO** such Clinics/Centers **within a district.**

The consulting hours for such medical practitioner shall be clearly specified by each clinic/centre.

### Public Information (Rule 17)

1. Every genetic counselling centre, genetic laboratory, genetic clinic, ultrasound clinic and imaging centre shall prominently display on its premises a notice in English and in the local language or languages that "*Disclosure of the sex of foetus is prohibited under law*" for the information of the public, e.g.

**NIRU MATERNITY AND NURSING HOME**
34, Manjushree Society Ranna Park,
Ghatlodia. Amdavad 380061
ANTE natal Sex Determination is Punishable Offence
Sex Determination is Not Done Here

2. *Copy of Act:* At least one copy, each of the Act and the rules shall be available on the premises of every genetic counseling centre, genetic laboratory, genetic clinic, ultrasound clinic and imaging centre and shall be made available to the client *on demand for persual*.
   It should be available in English and preferably in the local language.

### Rule 18(8)

Display his/her name and designation prominently on the dress worn by him/her to avoid litigation which had happened in Ganganagar, Rajasthan.

### Section 30

Under the provision of this section, appropriate authority or the person designated by appropriate authority suomotu or on complaint may visit the Centre for inspection, search and seizure of documents and/or sonography machine (as per Rule 12 of the Act), if he has reason to believe that centre is violating provisions of the Act.

## Section 20

Under the provision of this section, appropriate authority may suspend or cancel the registration after due procedure, i.e. notice, giving opportunity of being heard or without notice, in public interest, can proceed for suspension but reasons are to be recorded in writing.

Thus, under provisions of the Act, appropriate authority has power to proceed accordingly.

## Important Points

- Always co-operate with the authority whenever they visit clinic for inspection
- Never panic or get excited
- Be careful before giving any signature or commission of offence on inspection
- Take time to consult your medical legal advisor, if required
- If your ultrasonography machine is sealed, keep records of all papers with valid signature of the government authority in file and select an intelligent medicolegal lawyer.
- Always reply show cause notice within the time given by appropriate authority as prescribed in notice (e.g. 7 to 10 days)

## Remedies

When are they required?

- Notice issued
- Court case filed
- Sonography machine sealed
- Registration of centre suspended/cancelled

## Appeal under Section 21 Rule 19 of the Act

- Aggrieved person may prefer appeal within 30 days
- If it is preferred after 30 days, the appropriate authority may condone the delay on satisfaction of the sufficient cause of delay.
- If one is aggrieved by the decision of subdistrict appropriate authority, he can prefer appeal before district appropriate authority
- If one is aggrieved by the decision of district appropriate authority, he can prefer appeal before state/UT level appropriate authority.
- Similarly, appeal can be referred to state government for decision of state appropriate authority and central government for decision of central appropriate authority.
- Each appeal shall be disposed off by the district appropriate authority or by the state/union territory appropriate authority, as the case may be, within 60 days of its receipt. [Rule 19 (3)].

## Challenge 11

Usually, the appellate authority does not dispose off the appeal within 60 days.

## Judicial Remedies

One can prefer appeal before Judicial Magistrate first class or Metropolitan Magistrate or Sessions Court or High Court or Supreme Court in succession as the case may be.

## What FOGSI does?

- Harassment of FOGSIans by appropriate authority in some cases due to wrong interpretation of the provisions of the Act has come to the notice of FOGSI.
- FOGSI is always on toes to be helpful and to guide members in any given situation. There is a PCPNDT cell in FOGSI to take care of these issues.
- Regular meetings of cell are held to discuss problems of members related to PCPNDT Act.
- Regular CMEs and workshops are organised through member societies to update members and make them vigilant to not end up in litigation and if required, then solutions to get rid of them.

FOGSI preferred a writ petition before the Supreme Court with a panel of learned advocates headed by Soly Sorabjee and Shyam Diwan (both learned and senior advocates in Supreme Court). The main objective was to convince the Supreme Court that clerical errors were not synonymous with sex determination.

The following points were requested:

1. There should be graded punishment.
2. Punishment could not be equal for sex determination and inaccuracy in record
3. There should not be criminal complaints for inaccuracy of record keeping
4. There should not be action on appeal by Appropriate Authority by the Medical Council merely on framing of charge and before conviction.
5. Renewal of registration should not be withheld merely on grounds of pending case against member.

However, FOGSI was unlucky.The Supreme Court did not allow the appeal.

## Take Home Message

- Please do not get involved in pre-natal sex determination or pre-conceptional sex selection.
- Comply with the provisions of the Act to avoid litigation under PC PNDT Act.

Have a litigation free practice!!!!

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Chapter

8



# Recent Judgments and Legal Update

❍ Sanjay Gupte ❍ Arati Shah ❍ Sanuja Oke

Landmark judgments by the Supreme Court are important to medical practitioners in day-to-day practice as they form the case law. As far as Indian judiciary is concerned, there are two types of laws:

1. *Statutory laws:* These are the laws actually enacted by the parliament.
2. *Case laws:* These are the decisions by Supreme Court which become binding on all the lower courts.

As far as hospitals and medical practitioners are concerned, there are more than 100 statutory laws pertaining to our profession.

- Laws governing commissioning of hospital
- Laws governing qualification/practice and conduct of professionals
- Laws governing sale, storage of drugs and safe medication
- Laws governing management of patients
- Laws governing environment safety
- Laws governing the medicolegal aspects
- Laws governing professional training and research
- Laws governing safety of patients, public and staff within the hospital premises
- Laws governing the business aspects

As far as medical practice in India is concerned, significant case law started with the case in 1969. Interestingly, in this case, one doctor sued another doctor and pursued the matter till the Supreme Court. This case was as follows:

### Dr Laxman Balkrishna Joshi v/s Dr Trimbak Bapu Godbole and Another (1968)[1]

A patient, who was the son of Dr Godbole, suffered from fracture of the femur. The accused doctor while putting the leg in plaster used manual traction and used excessive force during traction, with the help of three other men although such traction is never done under Morphine alone but should have been done under proper general anesthesia. This led to severe shock causing the death of the boy. On these facts, the Supreme Court held that the doctor was liable to pay damages to the parents of the boy.

This case laid down certain legal principles to define medical negligence which are still rightly followed by the Indian courts till this day.

These principles were:

- A person who holds himself out ready to give medical advice and treatment impliedly holds forth that he is possessed of skill and knowledge for the purpose.
- Such a person when consulted by a patient owes certain duties, namely a duty of care deciding whether to undertake the case, a duty of care in deciding what treatment to give, and a duty of care in the administration of the treatment. **A breach of any these duties** gives a right of action of negligence against him.
- The medical practitioner has discretion in choosing the treatment, which he proposes to give to the patient, and such discretion is wider in case of emergency, but he must exercise a reasonable degree of care according to the circumstances of each case.

The second case which totally altered the medicolegal scenario was as follows:

### Indian Medical Association versus VP Shantha and Others (1996)[2]

This landmark judgment decided that service rendered by medical professionals comes under Section 2(1)(0) of the Act and hence the Consumer Protection Act was applied to the medical practitioners.

It defined conditions such as

- Who is a consumer?
- What is negligence?
- What is deficiency in service?
- What are the patent conditions under which medical practitioners can be held responsible, e.g.
  - Removal of the wrong limb;
  - Performance of an operation on the wrong patient;
  - Giving injection of a drug to which a patient is allergic without looking into the out-patient card containing the warning;
  - Use of wrong gas during the course of an anesthetic, etc.

Interestingly, this decision had enumerated the above conditions where the Consumer Protection Act should be applied and also explicitly mentioned that complex medical situations should be sent to the civil courts! However, in the following years, these directions have been modified by the further decisions.

The third important case for medical practitioners was as follows.

### Poonam Verma versus Ashwin Patel and Others (1996)[3]

This significant case was decided in 1996. This was regarding cross pathy practice. Here, a homeopath doctor treated a patient with allopathic drugs; though the treatment given was not actually wrong, the court decided that a doctor who has a qualification in Ayurvedic or Homeopathic medicine will be liable if he prescribes Allopathic treatment which may or may not cause any harm and the court defined this as a negligence 'per se' meaning thereby that even if no actual harm occurs, it will still be held as negligence.

The professional may be held liable for negligence on the ground that he was not possessed of the requisite skill which he professes to have.

Again, as the days passed, this directive also stands modified in the actual practice.

The next landmark judgment is by NCDRC.

### Sarwat Ali Khan versus Prof R Gogi and Others (1997)[4]

There are camps of cataract operations. In one such camp, 52 cataract operations were performed between 26th and 28th September 1995 in an Eye Hospital. 14 patients lost their vision in the operated eye because of infection. An enquiry revealed that in the operation theatre two autoclaves were not working properly. The courts decided that the onus was on doctors. They should have checked all these sterilization processes and equipment. This equipment is absolutely necessary to carry out sterilization of instruments, cotton, pads, linen, etc., and the damage occurred because of its absence in actual working condition. The doctors were held liable. This is a very important decision as though normally doctors do not carry out the sterilization process, they are vicariously held responsible.

### Dr Sr Louie and Another versus Smt Kannolil Pathumma and Another (1992)[5]

An interesting case of Dr Louie, an MD from Germany, Freiburg, a German Degree which is equivalent to an MBBS degree in India. In India, she practiced Obstetrics and Gynecology. When the case went to the courts, the National Consumer Commission held that Dr Louie showed herself as an MD although she was only MD by German qualification. She was guilty of negligence in treating a woman and her baby who died during delivery. In this case, there was failure of vacuum application, and the baby was delivered in an asphyxiated condition. The courts held her guilty for misrepresentation of her skills.

### Pt Parmanand Katara versus Union of India and Others[6]

In this case, the courts decided about emergency medical care which should and has to be given by all the doctors whenever emergency cases are brought to them. In this case, an accident victim was sent from one hospital to another and finally succumbed. The doctors and hospital were reluctant to take this case as the hospitals and doctors did not want to get involved in the police proceedings which they perceived as being hazardous as it was going to be a Medicolegal case. So,the Supreme Court decided that treatment must be given by any hospital where the patient goes to at that particular moment to save the life of the patient.

The facts of this case were as follows.

The petitioner referred to a report published in the newspaper "The Hindustan Times" in which it was mentioned that a scooterist was knocked down by a speeding car. On seeing the profusely bleeding scooterist, a pedestrian picked up the injured and took him to the nearest hospital. The doctors refused to attend the patient and told the man that he should take the patient to another hospital located 20 kilometers away authorized to handle medicolegal cases. The injured was then taken to that hospital but by the time he could reach, the victim succumbed to his injuries.

Importantly in this decision, the courts had also directed the police to respect the medical profession and cause minimal hassles to the doctors and hospital in such cases.

### Spring Medows Hospital and Another versus Harjol Ahluwalia through KS Ahluwalia (1998)[7]

This case decided the 'vicarious' liability so called on the doctor. A minor child was admitted by his parents to a nursing home as he had fever. The doctor diagnosed typhoid fever and gave medicines for typhoid fever. A nurse asked the father of the patient to get injection Chloroquine instead of Chloromycetine which was to be administered. The nurse administered the injection to the patient who immediately collapsed and suffered brain damage. The National Commission held the doctor negligent in performing his duty as instead of administering the injection himself, he permitted the nurse to give the injection. He did not check the injection to be given. Both the doctor and nurse were held negligent and the hospital was also held liable as it was decided that the hospital will be held liable for the employees if they commit wrong and the doctors will be vicariously held liable if they do not supervise the action which is to be supervised by them.

### Sethuraman Subramaniam Iyer versus Triveni Nursing Home and Another (1998)[8]

In another significant case, a small operation was being carried out on the nasal septum under local anesthesia. Unfortunately, the patient had cardiac arrest and died on the table. In this case decided by National Consumer Forum in 1998, the forum rightly said that the bad outcome doesn't always mean negligence by the doctor. All the necessary precautions and effective measures to resuscitate the patient were taken and that's why the doctor was not held negligent and the complaint was dismissed. The State Commission relied on the affidavits of four doctors who opined that there was no negligence. The complainant had not given any expert evidence to support his allegation. But, as we will discuss later, the scenario has changed in later cases.

### State of Punjab versus Shiv Ram (2005)[9]—Failure of Sterilization

Decision in this case came as a great relief to gynecologists. We, gynecologists, are worried about sterilization failure. This can happen in spite of all due care and when failure happened in cases before this particular one, doctors were held liable for the failure.

This case finally decided and Supreme Court said the failure of sterilization is always a possibility and the surgeon cannot be held liable if it fails, unless, a patent negligence was proved (like by laparoscopy) in blocking the tubes.

The decision stated that—merely because woman having undergone sterilization operation became pregnant and delivered child, the operating surgeon or his employer cannot be held

liable for compensation on account of unwanted pregnancy. Claim is sustainable only if there was negligence on part of surgeon in performing surgery or surgeon assured 100% exclusion of pregnancy after surgery.

In spite of having undergone sterilization operation, if couple opts for bearing the child, it ceases to be unwanted child—compensation for maintenance and for upbringing of such child cannot be claimed.

## CONSENT FOR SURGERY

The matter of consent is extremely important for any medical practitioner in day-to-day practice.

Supreme Court of India has come out with very important judgment in case of **Samira Kohli versus Dr Manchanda.**[10]

An endometrosis case was taken up for laparoscopy and when the problem was seen to be very severe the doctor came out to obtain consent from patient's mother for hysterectomy and went ahead and did the hysterectomy surgery which was objected to later by the patient. Because rightly she was not mentally ready for such major surgery, which was not discussed with her beforehand. Even though it was in the interest of the patient herself, Supreme Court decided and put down certain principles which are very important. Firstly, the Supreme Court decided that consent must be "**real and valid**" which means that the patient has to have **capacity and competence** to give the consent. A patient under anesthesia does not have capacity to give consent. One should also bear in mind that a patient who is in pain may not be having capacity to give consent.

The patient must be given adequate information and this adequate information means

- Nature and procedure of the treatment, its purpose, benefits and effect
- Alternatives if any available
- An outline of the substantial risks; and
- Adverse consequences of refusing treatment.

All this should be included and informed to the patient before the consent. One good point the Supreme Court mentioned here was that this information may be given by a doctor or a member of his/her team and this is helpful as the assistant doctor involved in treatment may be able to give this information and that should be taken as valid.

The Court further said that there is no need to explain remote or theoretical risks involved, like in every case, one doesn't have to emphasize on cardiac arrest which may scare the patient and patient may not want to undergo even an indicated surgery. An important point in this decision was that **consent given only for a diagnostic procedure cannot be considered as consent for the therapeutic treatment.** The fact that an unauthorized additional surgery is beneficial to the patient, or it would save considerable time and expense to the patient or would relieve the patient from pain and suffering in future, are no grounds of defense.**The only exception to this rule is where the additional procedure though unauthorized is for a lifesaving procedure**. When one is anticipating such a problem, the solution is to discuss these possibilities and then to go ahead if that possibility arises later.

### Jacob Mathew versus Respondents: State of Punjab and Others (2005)[11]

Guidelines for prosecuting medical professionals under the criminal law.

The courts said that

- Cases of doctors (surgeons and physicians) being subjected to criminal prosecution are on an increase.
- Sometimes, such prosecutions are filed by private complainants and sometimes by police based on FIR lodged and cognizance taken. The investigating officer and the private complainant cannot always be assumed to have knowledge of medical science so as to determine whether the act of the accused medical professional amounts to rash or negligent act within the domain of criminal law under Section 304-A of IPC.
- A private complaint may not be entertained unless the complainant has produced opinion given by another competent doctor to support the charge of rashness or negligence on the part of the accused doctor. The investigating officer should, before proceeding against the doctor accused of rash or negligent act or omission, obtain an independent and competent medical opinion preferably from a doctor in government service qualified in that branch of medical practice who is expected to give an impartial and unbiased opinion.
- A doctor accused of rashness or negligence, may not be arrested in a routine manner (simply because a charge has been leveled against him) unless his arrest is necessary for furthering the investigation, for collecting evidence or on a suspicion that the doctor would not make himself available to face prosecution unless arrested.

## LOCUM ARRANGEMENT

### Nabhan Farhan Sah versus Dr Latha Sharma (2007)[12]

This is about the common scenario where the doctor sometimes has to make a locum arrangement. Here the baby was in NICU and the doctor had to leave town. He made arrangement for adequate care of the baby by keeping a locum doctor who was equivalent before leaving town. The relatives blamed this argument when baby died and alleged it as negligence by the doctor, but the courts said this cannot be called as negligence as adequate locum arrangements were made by the doctor.

The next two cases deal with the matter of compensation for negligence. Before the below cases, the courts followed the "multiplier method" which was based on the method followed in road traffic accident so far. That means, whatever was the income of the patient, was multiplied by the life expectancy and accordingly, the compensation was calculated. Here, for the first case, the Supreme Court enunciated the principle of 'Restitutio in integrum.'

The facts of the case were:

Delivery of premature baby took place with birth weight of 1250 gm at Egmore, Chennai Govt hospital. Baby suffered blindness (ROP) due to 100% oxygen. Baby was not screened between 2–4 weeks as was mandatory. The doctors were held liable and the Supreme Court declared that the principle of awarding compensation that can be safely relied on is 'restitutio in integrum.' The said principle provides that a person entitled to damages should, as nearly as possible, get that sum of money which would put him in the same position as he would have been if he had not sustained the wrong. Compensation of Rs. 1,38,00,000/- was awarded.

### Balram Prasad versus Kunal Saha (2013)[13]

The same principle was used in the famous Kolkata case and this probably stands as the highest compensation awarded in a medicolegal case in Indian courts. Here, in similar situation, it was decided that Dr Kunal Saha's wife succumbed due to alleged negligence by the doctors and the courts decided held the doctors liable and decided compensation of Rs. 6,08,00,550/- with 6% interest amounting to 13 crores. The take home message is if doctors are involved in high risk practice, they have to think of insurance and sometimes the premium may be very high because the compensations methods have definitely changed.

### Nizam Institute of Medical Sciences versus Prasanth S Dhananka and Others (2009)[14]

This case decided two things. Here, 20 years old student had to undergo spinal tumor surgery which was in the grey zone of cardiothoracic and neurological surgery. The cardiothoracic surgeon operated on him and did not take help of neurosurgeon during surgery and the patient suffered from paraplegia. The court objected to this cross speciality practice, the compensation was calculated by the Restitution in integrum method and the doctors had to pay a big compensation.

Now, we will come to the case which we had referred to previously as a cardiac arrest case in which it was decided that if adequate measures were taken to resuscitate the patient after the cardiac arrest, then the doctor was not held liable. But in this below case, the courts have taken a different view of 'Res ipsa loquitur'.

### Shyam Sunder versus State of Rajasthan (1974)[15]

This was a case of cardiac arrest on the table. The courts applied the principle of 'Res ipsa loquitur'. The normal rule is that "it is for the plaintiff to prove negligence", but, in some cases, considerable hardship is caused to the plaintiff as the true cause of the accident is not known to him, but is solely within the knowledge of the defendant who caused it (e.g. as the cardiac arrest occurred inside the operation theatre where patient has no access).

This case forms the basis of the present thinking of the courts.

Now we come to final two very important judgments decided by the Supreme Court itself. The first case was as follows.

### Kusum Sharma and Others versus Batra Hospital and Medical Research (2010)[16]

In this case, the petitioner's husband had an adrenal mass which was removed by surgeon with "anterior" approach. There can be two approaches for this surgery: Anterior approach and posterior approach. The surgeon, while using the anterior approach, had difficulty and the pancreas were injured inadvertently and eventually a fistula developed. In spite of a lot of efforts to save the patient, the patient succumbed.

Both the parties had experts arguing for and against the approach that was used and so the court and none other than the very eminent Justice Dalveer Bhandari went into this case in detail and has given the decision. I think the principles that the court came up with are historic principles and I believe that they are going to stay with us for a long time.

The Supreme Court said that,

On scrutiny of the leading cases of medical negligence in our country, some basic principles emerge in dealing with cases of medical negligence. While deciding whether the medical professional is guilty of medical negligence, following well-known principles must be kept in view:

i. Negligence is the breach of a duty exercised by omission to do something which a reasonable man, guided by those considerations which ordinarily regulate the conduct of human affairs, would do, or doing something which a prudent and reasonable man would not do.

   This is the so called 'Bolam' principle,[17] which is recognized all over the world.

ii. Negligence is an essential ingredient of the offence. The negligence, to be established by the prosecution, must be culpable or gross and not negligence merely based upon an error of judgment.

iii. The medical professional is expected to bring a reasonable degree of skill and knowledge and must exercise a reasonable degree of care. Neither the very highest nor a very low degree of care and competence judged in the light of the particular circumstance of each case is what the law requires.

iv. A medical practitioner would be liable only where his conduct fell below that of the standard of a reasonably competent practitioner in his field.

v. In the realm of diagnosis and treatment, there is scope for genuine difference of opinion and one professional doctor is clearly not negligent merely because his conclusion differs from that of another professional doctor.

vi. The medical professional is often called upon to adopt a procedure which involves higher element of risk, but which he honestly believes as providing greater chances of success for the patient rather than a procedure involving lesser risk but higher chances of failure. Just because a professional looking at the gravity of illness has taken higher element of risk to redeem the patient out of his/her suffering and did not yield the desired result may not amount to negligence.

vii. Negligence cannot be attributed to a doctor so long as he performs his duties with reasonable skill and competence. Merely because the doctor chooses one course of action in preference to the other one available, he would not be liable if the course of action chosen by him was acceptable to the medical profession.

viii. It would not be conducive to the efficiency of the medical profession if no doctor could administer medicine without a halter round his neck.

ix. It is our bounden duty and obligation of the civil society to ensure that the medical professionals are not unnecessarily harassed or humiliated so that they can perform their professional duties without fear and apprehension.

x. The medical practitioners at times also have to be saved from such a class of complainants who use criminal process as a tool for pressurizing the medical professionals/hospitals, particularly private hospitals or clinics, for extracting uncalled for compensation. Such malicious proceedings deserve to be discarded.

xi. The medical professionals are entitled to get protection so long as they perform their duties with reasonable skill and competence and in the interest of the patients. The interest and welfare of the patients have to be paramount for the medical professionals.

The above principles enunciated by the justice have a great historic significance in defining the medical negligence in India.

However, even after the above almost doctrinal judgment, the next case has paved the way for paradigm change in the court's thinking.

### Arunkumar Manglik vs Chirayu Health and Medicare Pvt Ltd (2019)[18]

This case was apparently of dengue fever. Patient eventually died because of hemorrhagic complications due to low platelet count and leucopenia. The treatment administered was supported as correct by number of experts.

The discussion and dissection of law of medical negligence happened and a lot of evidence for and against what should have been done was given by the experts.

In this judgment, the Supreme Court commented on the Bolam case as: A doctor is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art. The "Bolam test" has been the subject of academic debate and evaluation all over world now. So far as there was support from other medical practitioners, the doctor was not held liable. Among scholars, the Bolam test has been criticized on the ground that it fails to make the distinction between the ordinary skilled doctor and the reasonably competent doctor. But now, House of Lords have decided Bolitho test.[19] House of Lords: The use of these adjectives—responsible, reasonable and respectable—all show that the court has to be satisfied that the exponents of the body of opinion relied upon can demonstrate that such opinion has a logical basis.

Even if the body which decides is a medical body of experts, the court will definitely have to go in the details of how this was decided, there was no bias, they applied proper mind to the situation at hand before accepting the opinion as being responsible, reasonable or respectable. The judge will need to be satisfied that, in forming their views, the experts have directed their minds to the question of comparative risks and benefits and have reached a defensible conclusion on the matter."

This is very important: Any practice guideline of any professional body will be blindly accepted. It has to be a kind of guideline where the doctors have really applied their mind and worked in the details.

The court also committed that in adopting a standard of care, Indian courts must be conscious of the fact that a large number of hospitals and medical units in our country, especially in rural areas, do not have access to latest technology and medical equipment."

In conclusion, these landmark cases guide us towards the correct practice. They not only define the medical negligence but also reassure us that reasonable and standard care is what the courts expect from a medical practitioner. Hence, we need not be unduly stressed while consciously treating our patients. However, the latest judgment indicates that, the courts are moving from "Bolam Test" to the "Bolitho Test" where the judiciary retains the prerogative on deciding what reasonable and standard care is.

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