

Terminating Pregnancies in difficult situations

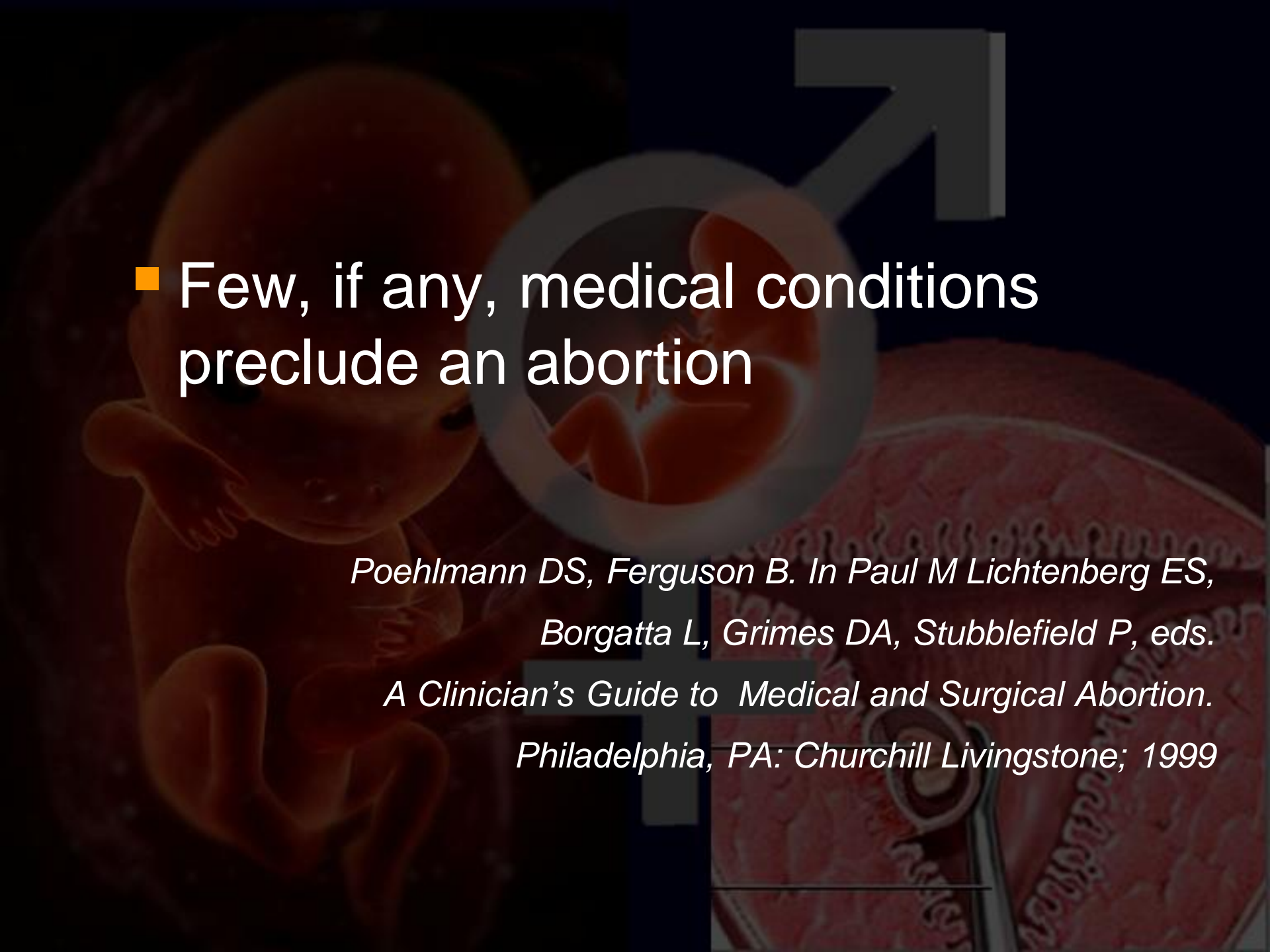
Dr. Jaydeep Tank

MD, DNB, DGO, FCPS, MICOG.

Ashwini Maternity and Surgical Hospital
Center for Endoscopy and IVF

K J Somaiya Medical College,
Hospital and Research Center.

Chairman, MTP Committee FOGSI
Convener – Sub Committee on Unsafe Abortions - AOFOG
Chairman, Family Welfare Committee MOGS
Member Reproductive Endocrinology Committee - AOFOG
Member Managing Committee MOGS

- 
- Few, if any, medical conditions preclude an abortion

*Poehlmann DS, Ferguson B. In Paul M Lichtenberg ES,
Borgatta L, Grimes DA, Stubblefield P, eds.
A Clinician's Guide to Medical and Surgical Abortion.
Philadelphia, PA: Churchill Livingstone; 1999*

Safe Abortions benefit Women's Health

- Safest abortions are performed early by trained medical practitioners in hygienic settings within the appropriate legal framework
- Risk of procedure related death
 - Safe abortion < 1/100,000
 - Pregnancy & childbirth 6-26 / 100,000

Henshaw, 1999

Figure 1
Direct Obstetric Deaths

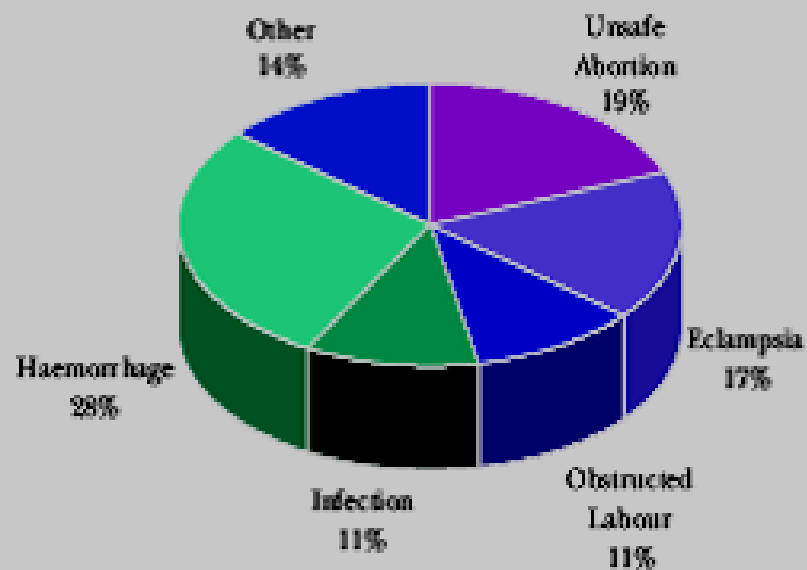
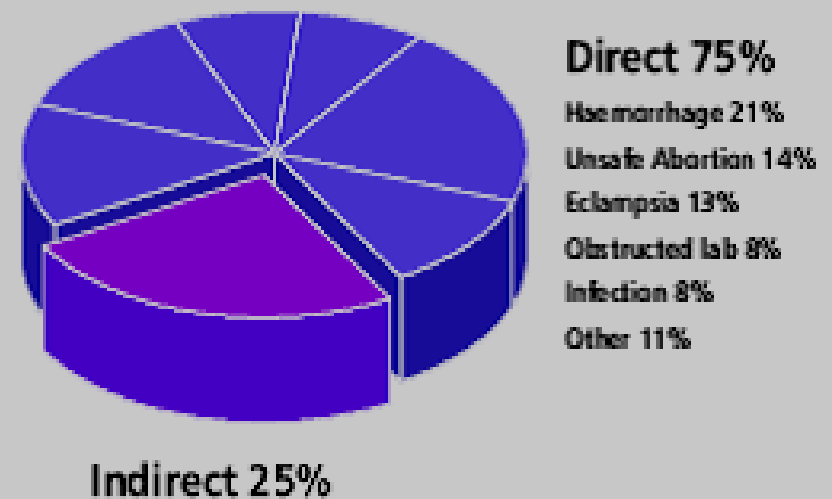


Figure 2
All maternal Deaths





How many total maternal deaths in India per year ?

- 1 billion people
- At 400 MMR -> 104,000 Maternal deaths
- At 500 MMR -> 130,000 Maternal deaths

356 deaths per day !!!!

More than 25,000 deaths per year from unsafe abortions alone

Challenges

The background of the slide is a composite image. On the left, there is a reddish, translucent illustration of a fetus in a curled position. In the center, a large, semi-transparent grey female symbol (a circle with a vertical line and a horizontal line) is overlaid. To the right, there is a medical ultrasound image showing a fetus in a womb, with a probe visible at the bottom right.

- **Medical challenges**
- **Legally challenging situations**
- **Social challenges**
- **Bureaucratic challenges**

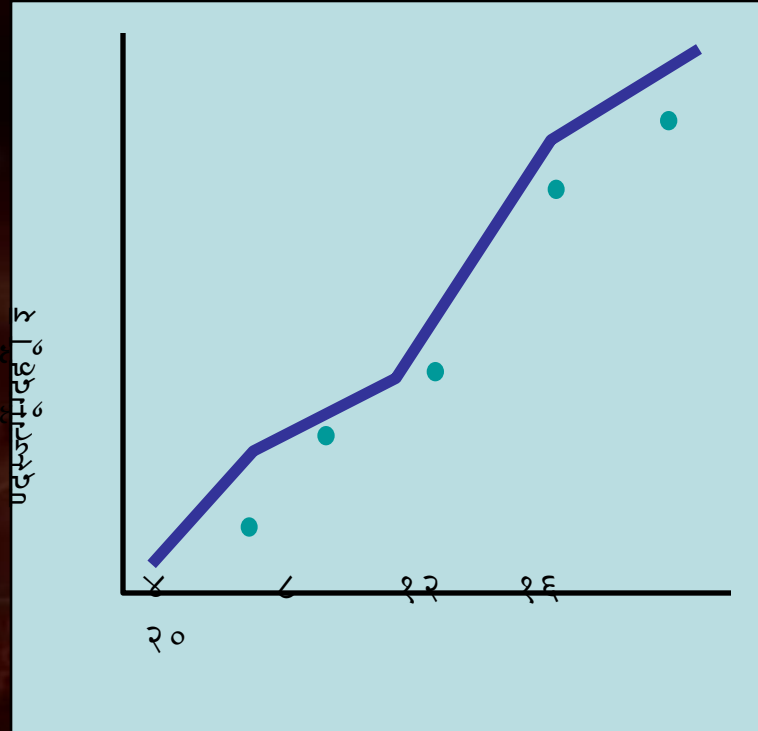
Preferred Methods of Abortion

Safe Abortion:
Technical and
Policy Guidance
for Health Systems



Upto 9 weeks	9 to 12 weeks	Beyond 12 weeks
Manual Vacuum Aspiration	Manual Vacuum Aspiration	Dilatation and Evacuation
Medical Abortion	Electric Vacuum Aspiration	Mifepristone followed by prostaglandins
Electric Vacuum Aspiration		Prostaglandins alone or analogues

Safe Abortions - Earlier the Better



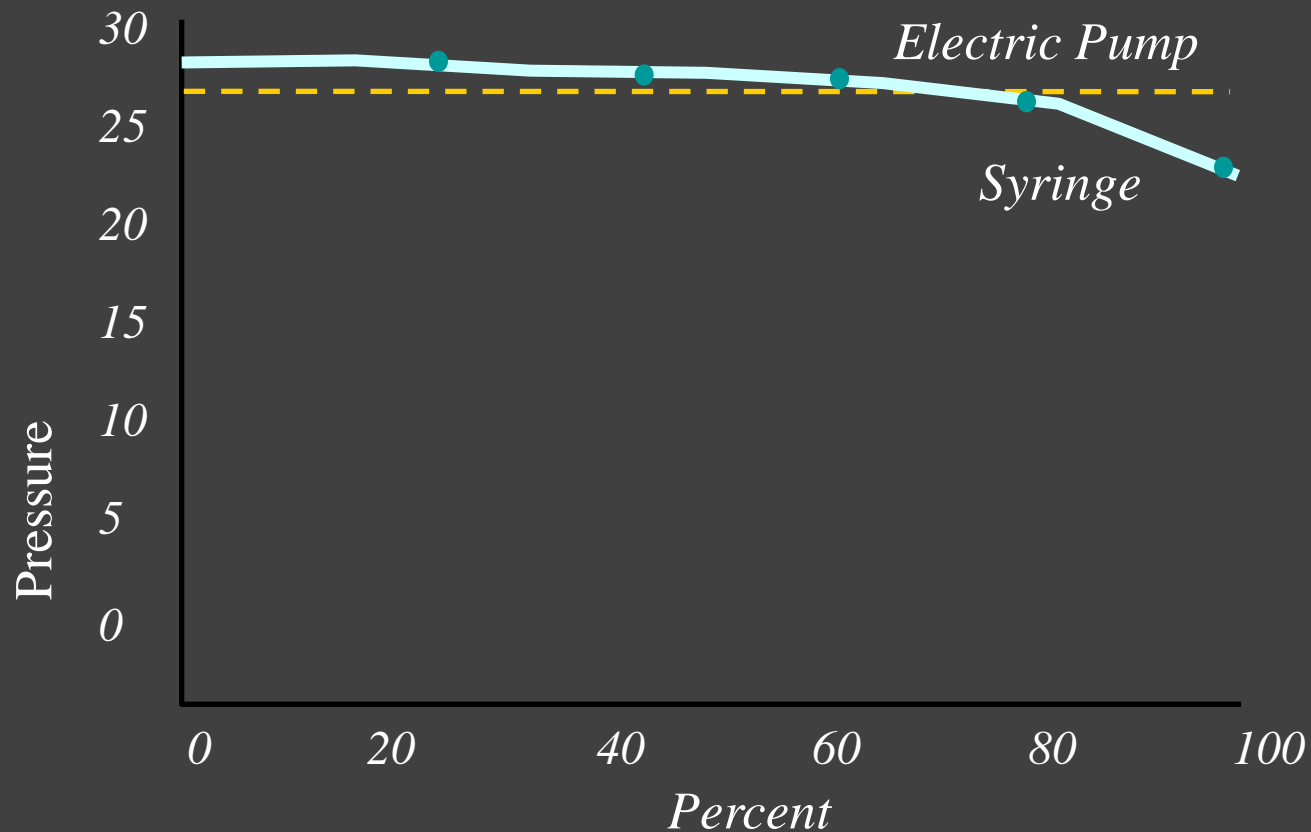
Four fold rise in complications with late abortions

WHO, Tech Report., 1997

MVA Instruments and Supplies

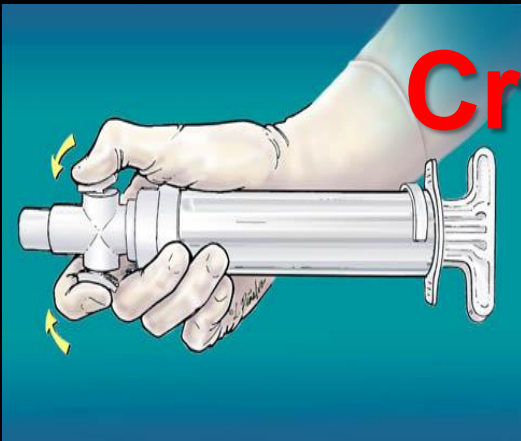


Vacuum in MVA Syringe

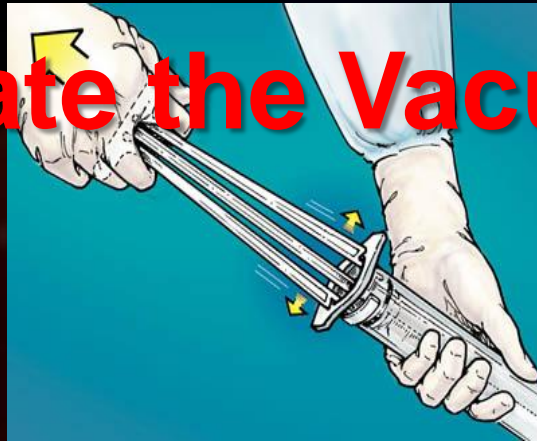


Greensdale et al, MVA Ipas,
1993

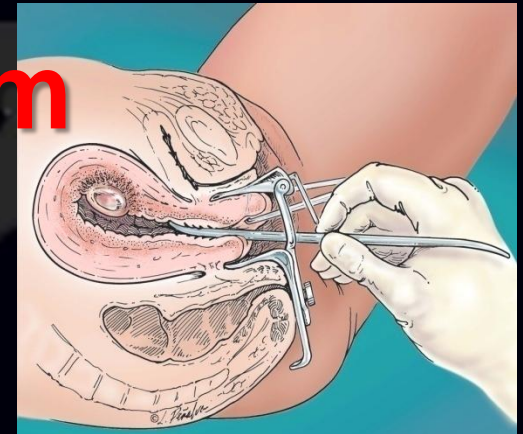
Create the Vacuum



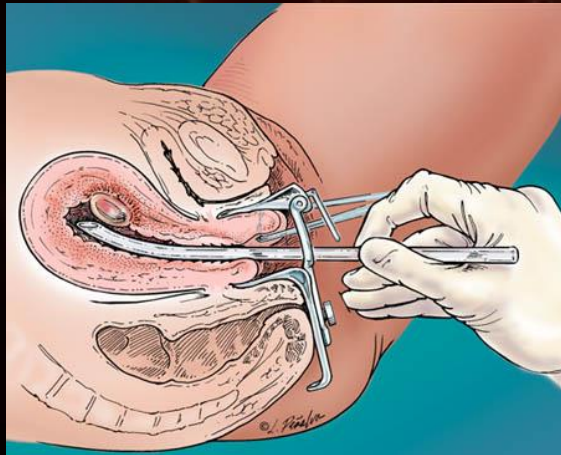
**Prepare the
Syringe**



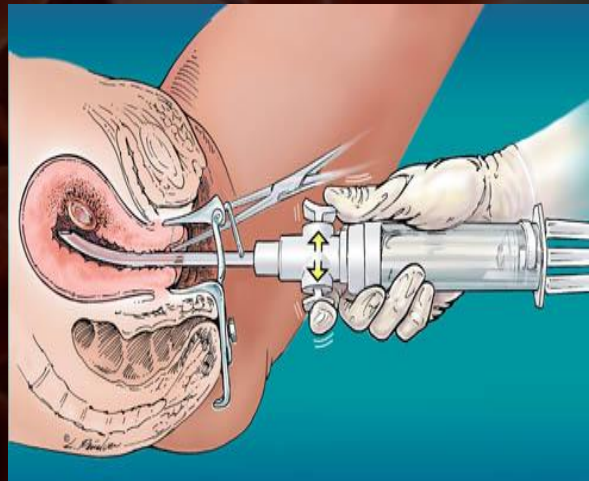
Create the Vacuum



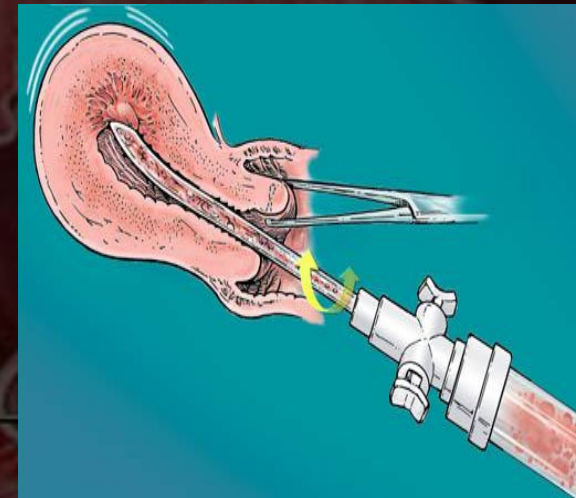
Dilating the Cervix



Inserting Cannula



**Releasing the Pinch
Valve**



**Evacuating the
Uterus**

Adjuncts to make abortions safer

- Ultrasound guided evacuation
- Antibiotic prophylaxis
- Rh prophylaxis
- Role of Prostaglandins



Medication Abortion

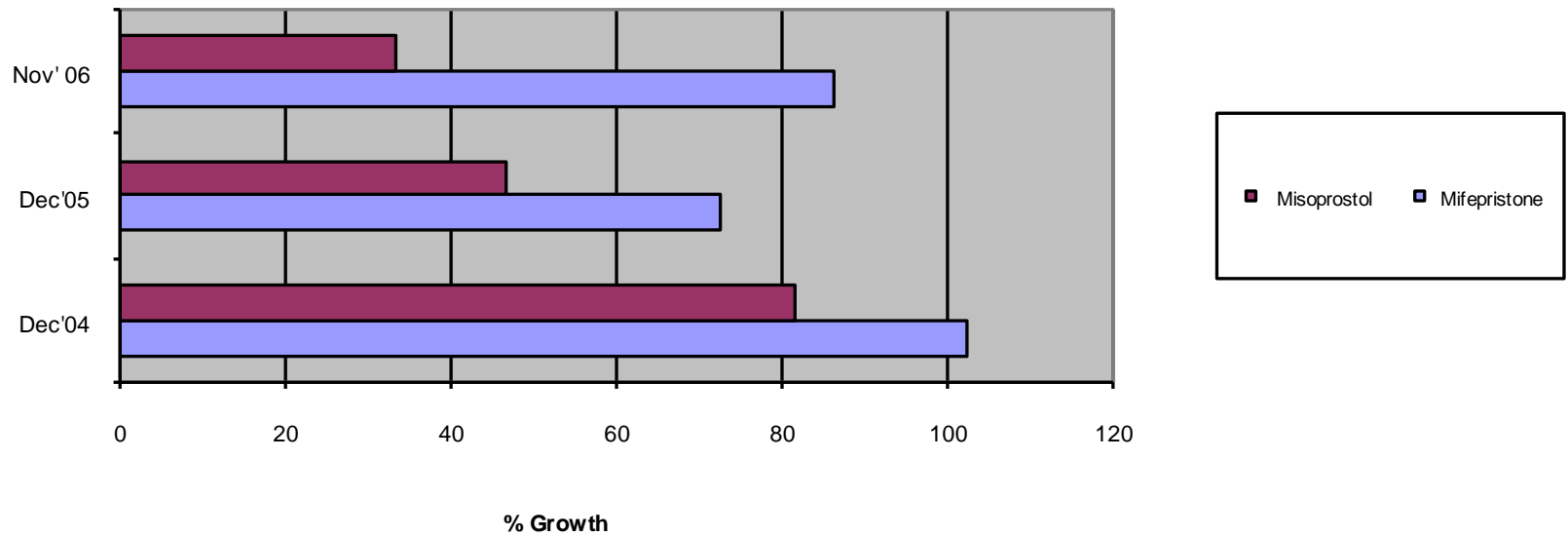


Medical Agents After One Year in INDIA

- More than 1 million tablets of Mifepristone from a single company

Data from Zydus Cadila

Market Growth % of Mife - Miso



ORG MARG Data
Courtesy Sun
Pharma

	Gr%	Company
MIFEPRISTONE	63.8	
MT PILL	52.9	CIPLA
MIFEGEST	63.5	ZYDUSCADILA
UNWANTED	60.5	MANKIND
MIFYRON	-12.9	GERMAN REMEDIES

ORG MARG Data Nov 2007
Courtesy Zydus

Medication Abortion

- Use of the agents no longer “off label”.
- MTP Rules allow for the use of the medical agents up to 49 days of pregnancy i.e. 7 weeks from LMP.
- *Medical methods for termination of pregnancy not exceeding seven weeks, may be prescribed by a registered medical practitioner as prescribed under Section 2 (d) and Rule 3, having access to a place approved by the Government under Section 4 (b) & Rule 5 of MTP Rules. RMP should display a certificate to this effect from the owner of the approved place*
- MTP act applies in all respects.
- Consent vital
- Ultrasound is not mandatory



File No.04-103/2001-DC
Government of India
Central Drugs Standard Control Organisation
Directorate General of Health Services
Nirman Bhawan, New Delhi - 110 011 (INDIA)

Form-46

(See rules 122-B and 122-D and 122-DA)

Permission / approval for manufacture of new drug formulation

Number of the permission and date of issue **MF----7059/06**

A/s. Cipla Ltd., Mumbai Central, Mumbai-400 008.(address)

s hereby granted permission/approval to manufacture the following new drug formulation under rule 122-B/~~122-D~~/~~122-DA~~ of the Drugs and Cosmetics rules-1945,- namely:-

) Name of the drug	: Misoprostol Tablets.
) Dosage Form	: Tablet.
) Composition	: Each uncoated tablet contains:- Misoprostol----25/100/200mcg.
) Indication	: For cervical ripening, prevention of post partum hemorrhage and first trimester abortion with mifepristone.

ate: **10 DEC 2006**

Signature:

(Dr. M.Venkateswarlu)
Drugs Controller General (India)
(Name & Designation of Licensing Authority)



Contd----2

Difficult Situations...

- Does medical abortion have a learning curve?
- Medical abortion for women with a previously scarred uterus
- Medical abortion for women with a missed abortion
- Does providing medical abortion mean a loss of income?
- Medical abortion for women staying in remote areas



**Table 1. Compliance With the Protocol in Three Studies
of Medical Abortion in India**

<u>Study</u>	<u>Site</u>	<u>Cases, n</u>	<u>Followed Protocol Exactly, n (%)</u>
1	Urban research center	250	247 (99)
2	Urban family planning clinic	612	582 (95)
3	Rural health station	300	294 (98)

Coyaji Kurus
JAMWA 2000, Vol.55, No.3

“Poor does not mean stupid”

Current Recommendations - 1st Trimester

- The GOI allows the use of medical agents to terminate a pregnancy up to 7 weeks gestation (49 days from LMP).
- Regimen:
 - Day 1
 - History*
 - Examination*
 - Counselling, consent and what to expect*
 - 200 mg mifepristone orally*
 - Day 3
 - 400 or 600 micg of misoprostol vaginally.*
 - Follow up after 7 days or earlier if required for post abortion care.



Second Trimester Abortion



Second trimester Abortions

- Three distinct parts of the second trimester

12 to 14 weeks	Cervical ripening – misoprostol + MVA / D&E
14 to 16 weeks	Mife + Miso + D&E / MVA
> 16 weeks	Mife + Miso



Current recommendations 2nd trimester

- **Drugs to be used**
 - **Mifepristone**
 - **PG and analogues like Misoprostol, gemeprost, PGF2 alfa.**

Use one agent at a time and give that agent time to act

Late Second Trimester and MTP's

- There are occasions when a lethal malformation may be diagnosed later than 20 weeks of gestation.
- How are we placed legally to terminate this pregnancy?

When Pregnancies may be Terminated

Duration according to Section 3 (2) based on opinion formed in good faith

1. Pregnancies not exceeding 12 weeks with single opinion
2. Pregnancies between 12 to 20 weeks require opinion of not less than 2 medical practitioners

Implication

Any induced abortion after 20 weeks is illegal, except to save maternal life as per Section 5

The background is a dark, textured collage. On the left is a large, realistic illustration of a fetus in a curled position. In the center, a large, semi-transparent female symbol (a circle with a vertical line and a horizontal crossbar) is overlaid. To the right of the female symbol is a large, semi-transparent male symbol (a circle with an arrow pointing diagonally up and to the right). Below the female symbol is a large, semi-transparent plus sign. On the right side, there is a medical ultrasound image showing a fetus inside a uterus, with a probe visible at the bottom.

Unmarried Women who seek MTP

When Pregnancies may be Terminated

Grounds for terminations as per Section 3 (2) allowed for the following indications:

1. Risk to life or risk of grave injury to physical or mental health

Where any pregnancy occurs as a result of failure of any device or method used by any married woman or her husband for the purpose of limiting the number of children, the anguish caused by such unwanted pregnancy may be resumed to constitute a grave injury to the mental health of the pregnant woman.

2. Substantial risk of physical or mental abnormalities if the child were born

Implication

Responsibility to judge the necessity & indication to opine in good faith regarding valid legal indication

- **The Act is physician centric – abortion is not a right in our country.**

Consent

Valid legal consent as per Section 2 (4) is mandatory

1. Termination of pregnancy in minors or mentally ill persons only with consent of guardian
2. Termination of pregnancy in adult women over 18 years age with their valid consent

Implication

- *Consent must be informed & recorded in Form C.*
- *An adult woman requires no other person's consent under law except her own*

FORM C*
(See rule 8)

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

Signature

Place:

Date:

(To be filled in by guardian where the woman is lunatic or minor)

I, son / daughter / wife ofaged about
..... Years ofat present residing
at (permanent address)
do hereby give my consent to the termination of the pregnancy of my
ward Who is a minor/lunatic at(place
of termination of pregnancy).

Signature

Place:

Date:

*Under the MTP Act.

The background is a dark, reddish-brown composite image. On the left, a fetus is shown in a curled position inside a translucent womb. In the center, a large, light gray female symbol (a circle with a vertical line and a horizontal crossbar) is superimposed. On the right, a medical ultrasound probe is shown, with a small circular inset displaying a fetal profile. The text "Unmarried girls who are below the age of consent" is written in a bold, orange, sans-serif font across the middle of the image.

**Unmarried girls who are below
the age of consent**

Consent

No pregnancy of a woman, who has not attained the age of eighteen years, or, who, having attained the age of eighteen years, is a lunatic, shall be terminated

except with the consent in writing of her guardian.

Section 3

Clause 4 (a) (1)

- **Definitions - In this Act, unless the context otherwise requires,**
 - (a) “guardian” means a person having the care of the person of a minor or a lunatic;**
 - (c) “minor” means a person who, under the provisions of the Indian Majority Act, 1875 (9 of 1875), is to be deemed not to have attained his majority;**

The background is a dark, reddish-brown composite image. On the left, a fetus is shown in a curled position, held gently by two hands. In the center, a large, semi-transparent female symbol (a circle with a vertical line and a horizontal crossbar) is superimposed. Inside the circle of the symbol, a fetus is visible in a fetal position within a womb. On the right, a cross-section of a human torso shows internal organs, including the uterus and ovaries, with a fetus visible inside the uterus. The overall tone is somber and medical.

Registration Woes and more....

The Place of Private Health Care

- India spends less than 1 percent of its GDP on health.
- Only Pakistan spends less among its South Asian neighbors.
- Sri Lanka and Bhutan which are poorer than India spend 6 percent and 10 percent respectively of their GDP on health.

Gross underutilization of 'free' care

- In general, in India people depend more on the private sector for health care than they do on the public sector.
- The private health sector in India is one of the largest in the world: 80 percent of all qualified doctors, 75 percent of dispensaries and 60 percent of hospitals in India belong to the private sector

Narayan et al, 2003.

- According to the NFHS II, only 23.5 percent of urban residents and 30.6 percent of rural residents choose to visit a government health facility as their main source of health care services.

Where Pregnancies may be Terminated Registration

Section 4 of the MTP Act defines settings.

1. A hospital established or maintained by the Government.
2. A place for the time being approved for purpose of this Act by the *government or a district level committee* constituted by the government with the CMO or DHO as the chairperson

- The Gazette of India - Extraordinary, Dec 2002

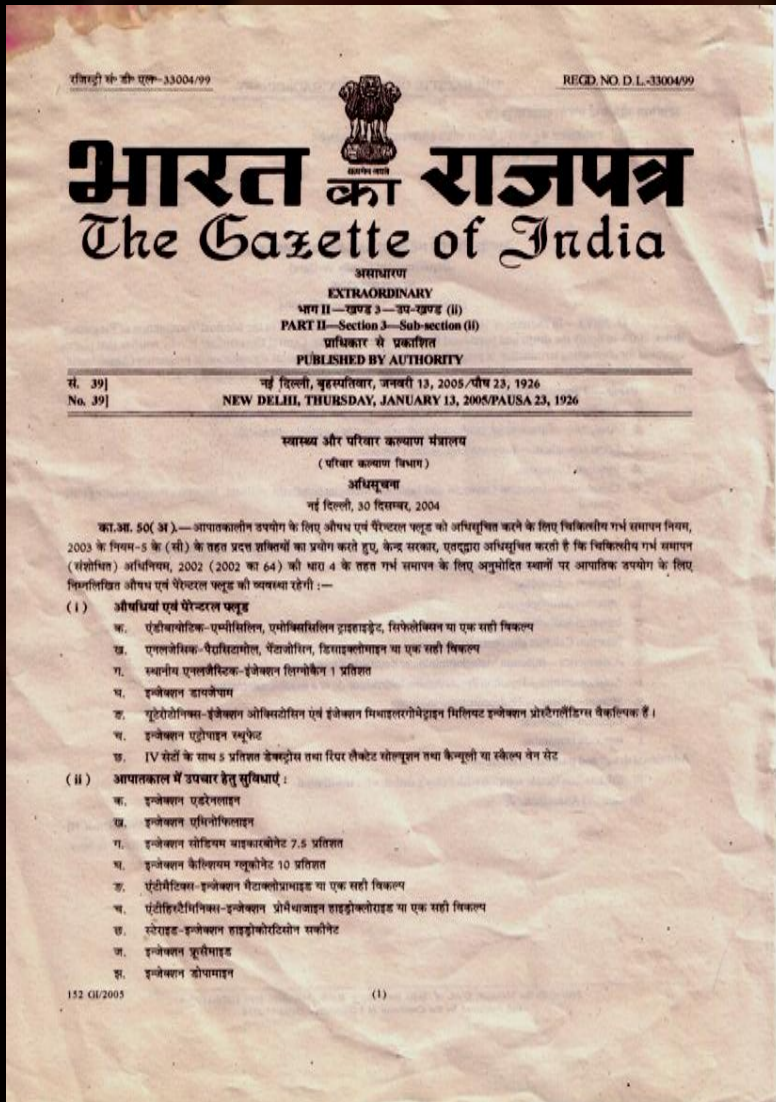
Composition And Tenure Of District Level Committee

- **One member of the district level Committee shall be the Gynaecologist/ Surgeon/Anaesthetist and other members from the local medical profession, non-governmental organization, and Panchayati Raj Institution of the District. Provided that one of the members of the 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.**

***Rule 3
The Gazette of India - Extraordinary,
Dec 2002***

MTP (Amendment) Act, 2002

MTP Rules, 2003



1. Government should be satisfied with safety & hygiene
2. The following facilities should be provided

First trimester terminations

- Gynecology / labour table, backup for treating shock & facilities for transportation

Second trimester terminations

- OT table & instruments for abdominal & gynecological surgery, anesthetic equipment

All terminations

- Resuscitation & sterilisation equipment, drugs & parenteral fluids

निम्नालिखित आयुर्वेद एवं परेन्टरल फ्लूड का व्यवस्था रहगा :-

(i) औषधियां एवं परेन्टरल फ्लूड

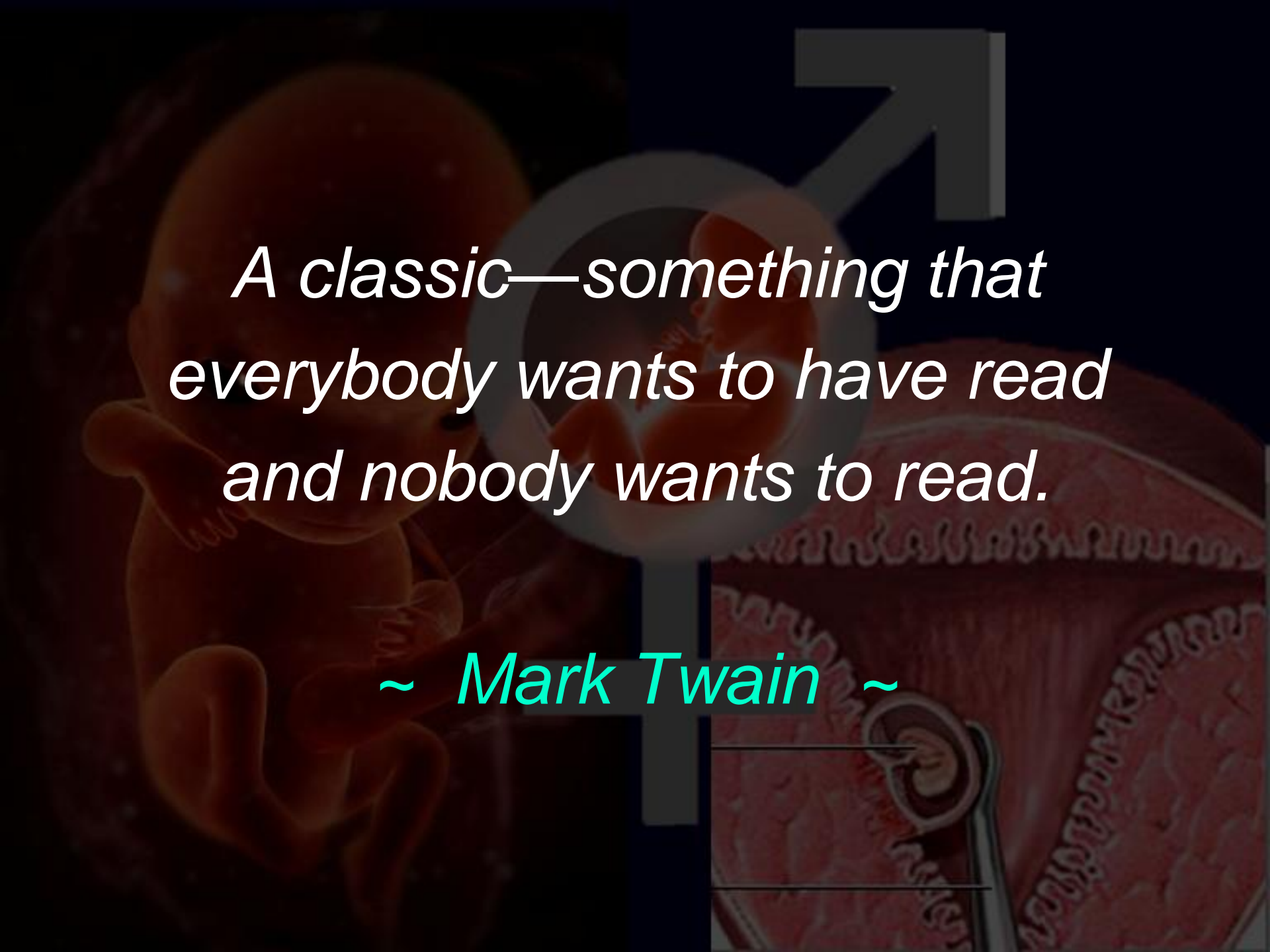
- क. एंडीबायोटिक-एम्पीसिलिन, एमोक्सिसिलिन ट्राइहाइड्रेट, सिफेलेक्सिन या एक सही विकल्प
- ख. एनलजेसिक-पैरासिटामोल, पेंटाजोसिन, डिसाइक्लोमाइन या एक सही विकल्प
- ग. स्थानीय एनलजैस्टिक-इंजेक्शन लिग्नोकैन 1 प्रतिशत
- घ. इन्जेक्शन डायजेपाम
- ङ. यूटेरोटोनिक्स-इंजेक्शन ओक्सिटोसिन एवं इंजेक्शन मिथाइलरगोमेट्राइन मिलियट इन्जेक्शन प्रोस्टैगलैण्डिन्स वैकल्पिक हैं।
- च. इन्जेक्शन एट्रोपाइन स्थूफेट
- छ. IV सेटों के साथ 5 प्रतिशत डेक्स्ट्रोस तथा रिपर लैक्टेट सोल्यूशन तथा कैन्यूली या स्कैल्प वेन सेट

(ii) आपातकाल में उपचार हेतु सुविधाएं :

- क. इन्जेक्शन एडरेनलाइन
- ख. इन्जेक्शन एमिनोफिलाइन
- ग. इन्जेक्शन सोडियम बाइकारबोनेट 7.5 प्रतिशत
- घ. इन्जेक्शन कैल्शियम ग्लूकोनेट 10 प्रतिशत
- ङ. एंटीमैटिक्स-इन्जेक्शन मैटाक्लोप्रामाइड या एक सही विकल्प
- च. एंटीहिस्टैमिनिक्स-इन्जेक्शन प्रोमैथाजाइन हाइड्रोक्लोराइड या एक सही विकल्प
- छ. स्टेराइड-इन्जेक्शन हाइड्रोकॉर्टिसोन सकीनेट
- ज. इन्जेक्शन फ्रूसैमाइड
- झ. इन्जेक्शन डोपामाइन

The background is a dark, composite image. On the left is a 3D rendering of a fetus. In the center, a large, semi-transparent female symbol (a circle with a vertical line) is overlaid. To its right is a large, semi-transparent male symbol (a circle with an arrow). In the bottom right corner, there is a medical ultrasound probe with a small screen showing a fetus. The text "The PC PNDT Act and The MTP Act" is centered in a bold, orange font.

The PC PNDT Act and The MTP Act

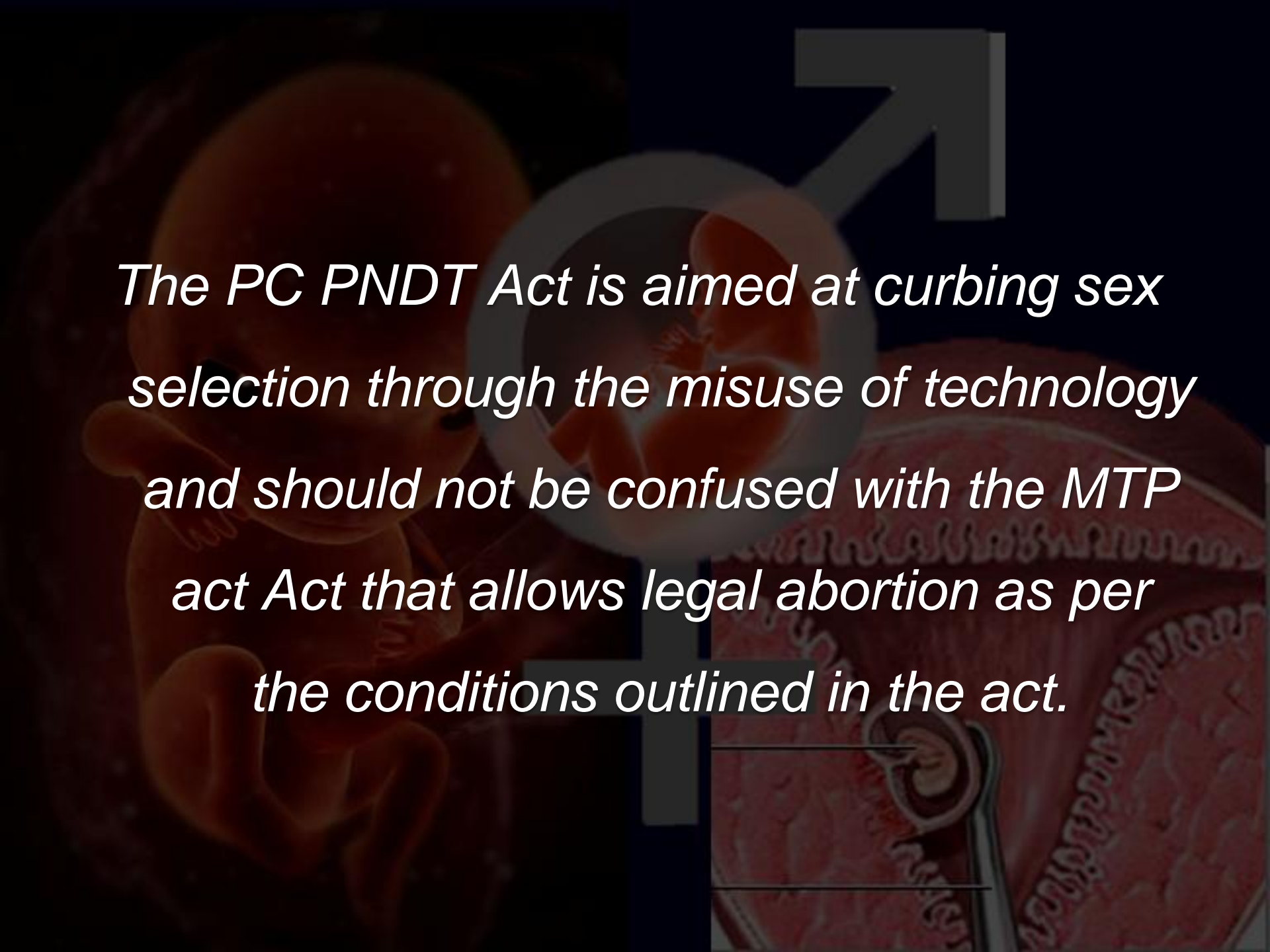


*A classic—something that
everybody wants to have read
and nobody wants to read.*

~ Mark Twain ~

The FOGSI Resolution 2002

“In keeping with its principled stand against sex selective abortions, FOGSI condemns the use of procedures to pre-select sex without a valid medical indication as these promote an unfair and abhorrent bias on the basis of gender”.



The PC PNDT Act is aimed at curbing sex selection through the misuse of technology and should not be confused with the MTP act Act that allows legal abortion as per the conditions outlined in the act.

Dealing with the aftermath of problems....

- Complications would not occur only if no procedure would be done.
- But when complications do occur it poses major dilemmas for the client and the service provider.

Protection of Action taken in Good Faith

The MTP Act (Section 8) protects the medical practitioner from suits or other legal proceedings for any damage caused or likely to be caused by anything done in *good faith* under the act.

Implication

This last section of the *MTP Act* has profound implications. It protects medical practitioners diligently functioning within the limits set by the Act, Rules & Regulations, from being prosecuted under the IPC, or civil/consumer court action.

- “Action was done in good faith and therefore we are of the opinion that no suit or any other legal proceeding shall lie against the appellant who is a RMP for any damage caused or likely to be caused by anything done in good faith or intended to be done under the MTP act.”

25th July 2005

Consumer Disputes Redressal Commission

Maharashtra State,

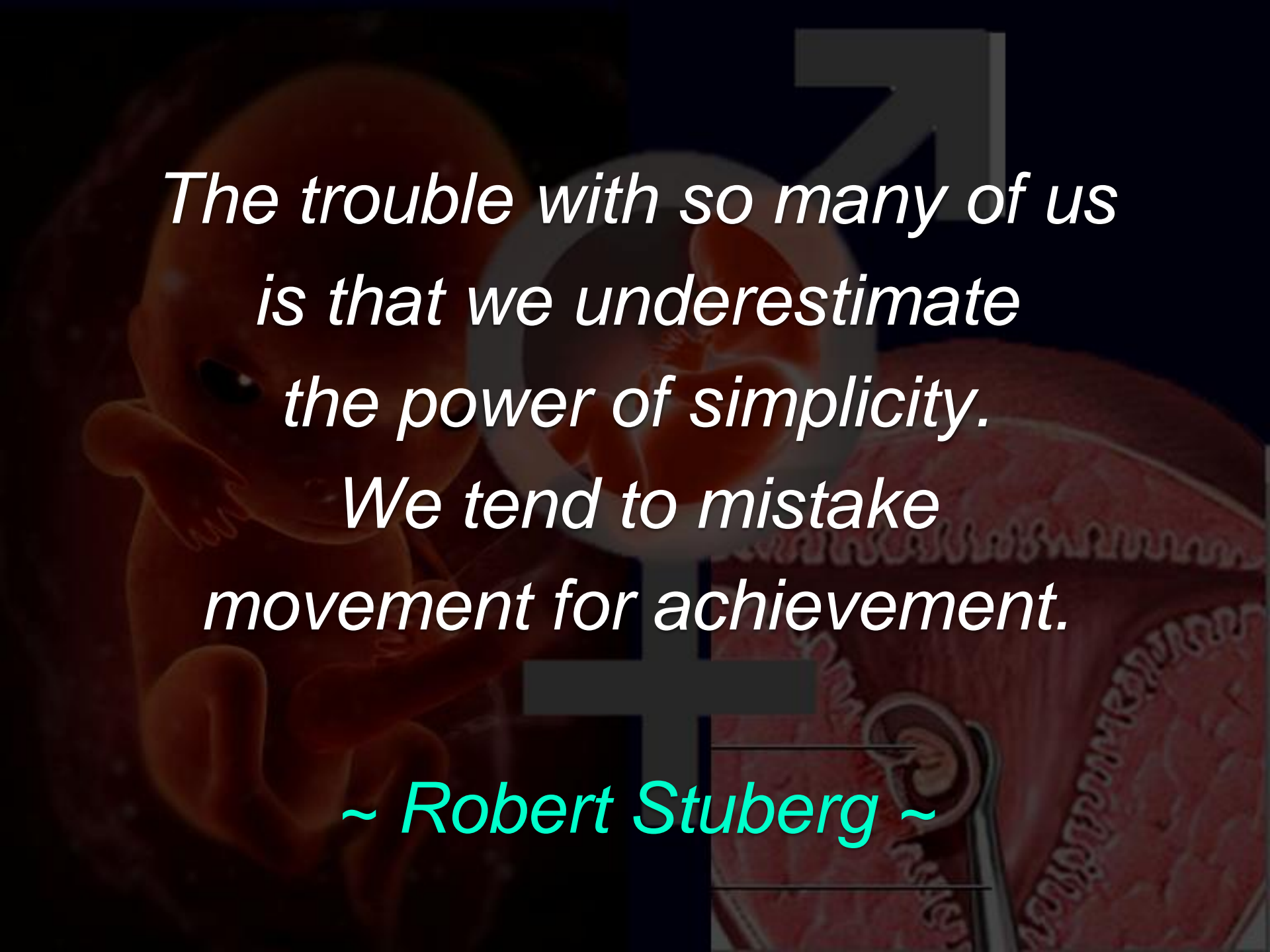
Appeal No 287 of 1997

in complaint no. 56 of 1995 District forum Dhule.

Difficult Clinical Situations

The background of the slide features a medical illustration of a fetus in a uterus. A large, semi-transparent female symbol (a circle with a vertical line and a horizontal crossbar) is overlaid on the image. The fetus is shown in a curled position, and the uterine wall is visible with some internal structures. The overall color scheme is dark with orange and white highlights.

- **Difficult cervical dilatation**
 - **Ultrasound guided evacuation**
 - **Cervical ripening**
- **Ectopic pregnancy detected after an MTP**
- **Prolonged bleeding PV post MTP**



*The trouble with so many of us
is that we underestimate
the power of simplicity.*

*We tend to mistake
movement for achievement.*

~ Robert Stuber ~