JABALPUR OBSTETRICS & GYNAECOLOGICAL SOCIETY

Jigyasa

The Curiosity..

MEDICO LEGAL CHALLENGES

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Foreword

It is indeed my privilege to write a foreword to the souvenir of MP State Conference on “Medico legal Challenges in day today practice”.

In the clinical practice the doctors are known to use their skills to solace the sufferings of their patients and in the recent days due to vast consumer awareness and the patients' rights, sometimes doctors become liable to face medico legal litigations on account of medical mistakes.

The souvenir consists of articles whichcover the important aspects on medical law of negligence and ethical aspects, informed consent, medical documentation. Moreover, remedial approach supported by the recent judgments on medical negligence from the National Commission and Hon'ble Supreme Court of India.
I congratulate the editorial team for their efforts in bringing out this important souvenir to understand the concept of standard duty of care, Doctor Patient Relationship, Documentation etc.

15 March 2022

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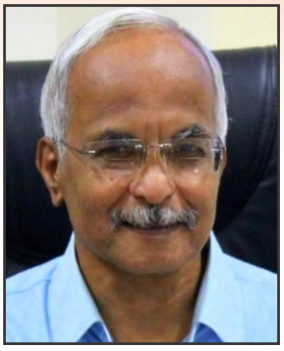

DEAN'S MESSAGE

It is matter of great privilege that we are organizing the state conference on Medico-legal challenges.

I appreciate the efforts taken by Department of Obstetrics and Gynaecology NSCB Medical College Jabalpur in organizing the conference and would like to appreciate the editorial team for their efforts in releasing the journal, which will be important for the participants to practice with ethics.

With the galaxy of medical legal luminaries participating as faculty in this two day conference, it will be a great learning experience for all the participants. I am sure that the teachings they will gain during these two days will help them to overcome future problems that they might face in their day to day practice. However, I pray that none of them would ever be in a medico-legal mess.

Thank you.

Dr. P. K. Kasar
DEAN
N. S. C. B. Medical College
Jabalpur

PROF. DR. GITA GUIN
President
(JOGS 2021-22)

प्रिय एवम सम्मानीय JOGS बंधु

मेरे ह्रदय में आभार के जो भाव हैं उन्हें व्यक्त करने के लिए शब्द ढूंढते ढूंढते जब मैं थक रही हूं तो अनायास ही मन कर रहा है कि आप सबको एक जादू की झप्पी दूं और कहूं, ह्रदय से धन्यवाद स मेरे एक साल के कार्यकाल में मैं आप लोगों को क्या दे पाई? आपके ज्ञान में मैंने क्या योगदान किया ? इसका तो मुझे कोई आकलन नहीं है परंतु मैंने स्वयं को इस तरह निखारा, इतने दोस्त बनाएं और जिस तरह का अनुभव हासिल किया यह अभूतपूर्व, अतुलनीय एवं अन्यथा असंभव थास मैं अपने द्वारा किए गए कई वादों को निभा पाई और कईयों को उस तरह से नहीं कर पाई जैसा मैं चाहती थी आशा है आप सभी मेरी इस खामी के लिए मुझे क्षमा दान करेंगे स मेरे द्वारा चाहे जितनी भी गलतियां हुई हो, मेरे साथी इस कदर डटे रहे और इतनी फुर्ती और क्षमता से अपनी अपनी जिम्मेदारी निभाते रहे कि मैं यदि पीछे मुड़कर देखती हूं तो मुझे उनमें एक भी कमी नजर नहीं आती है शहर के सभी स्त्री एवं प्रसूति रोग विशेषज्ञ भी इस तरह हमारे सभी आह्वान पर जुड़े कि लगा घर के मेहमानों को बिटिया की शादी के लिए निमंत्रण भेज रही हूं और सब अपने अपने व्यवहार का थाली सजाए मुझसे और मेरे साथियों से आकर जुड़ रहे हैं मुझे अफसोस है कि मैं जो करना चाह रही थी वह कर नहीं पाई, पर मैं जानती हूं मेरे आने वाले साथी इससे भी बेहतर काम करेंगे और जो अधूरा काम हम सबसे छूटा है, उस काम को और आगे ले जाएंगे मेरे कार्यकाल के आखिरी वैज्ञानिक संगोष्ठी के लिए मैंने मेडिकोलीगल चुना ताकि आप एक निश्चित भाव से अपने मरीजों की सेवा कर सके दोबारा मैं आप सबको धन्यवाद देना चाहूंगी कि आप मेरे सभी आयोजनों के भागीदार रहे और आपने बहुत सारे खामियों के साथ हम सब को दिल से स्वीकारा स ह्रदय से धन्यवाद।

पुन: मैं नतमस्तक होकर इस भीषण कठिन माहामारी में, आपने मानवता के लिए किए गए निस्वार्थ सेवा का जो अप्रतिम उदाहरण पेश किया , उसके प्रति स्वयं के एवं JOGS के तरफ से आभार वयक्त करती हूं।

असम्भावनाओं को संभावनाओं में बदलने के मेरे साथी, आपका धन्यवाद

ईश्वर से आपकी स्वास्थ्य और समृद्धि की प्रार्थना एवं शुभेच्छा संग

डॉ. गीता
अध्यक्ष
जबलपुर स्त्री एवं प्रसूति रोग संघ

DR SONAL SAHNI
Secretary
(JOGS 2021-22)

Dear friends,

Greetings from Team JOGS 2021-22

“Education is the key to unlocking the world, a passport to freedom". Foremost, a big applause to all fraternity members for their sheer dedication towards the service of patients amidst the Covid pandemic. When we assumed office in April 2021 ,it seemed a mammoth task to plan & execute our academic and social-service pursuits.

Our motto “Teamwork makes the Dreamwork”, enabled us to navigate seamlessly through this journey and as we draw towards the end of our tenure, we feel indebted to all fellow JOGSIANS for their unwavering patronage and support at every step. We had woven our plans for strengthening the roots of women healthcare and successfully reached out to the masses through our social connect campaigns encompassing vital issues like Safe Motherhood, Contraception, Save The Girl Child, Adolescent Health, Sexually Transmitted Diseases, Cancer Screening & Prevention, Save The Uterus ,Healthy Diet And Nutrition etc. To quench our unending thirst for knowledge and pursuit of excellence, we oranised Continuous Medical Education programs throughout the tenure, utilizing both online and offline modes circumstantially. We roped in eminent speakers from all corners of India who deliberated valuable insights about recent advances in our stream & engaged in fruitful discussions on burning topics.

Benchmarks had been already set by our extremely efficient predecessors and we strived hard to prove ourselves worthy of the heritage. It has been a learning, interactive, enriching and enjoyable experience all through.We wish the best to the incoming team and hope to see the JOGS flag higher in the near future With heartfelt thanks

Dr Sonal Sahni
Secretary

DR JIGYASA DENGRA
Editor
(JOGS 2021-22)

HELLO AND GREETINGS FROMS JOGS 2021-2022

I would really like to appreciate all the efforts of yours standing in between COVID and patient care and salute all the front line warriors for standing bravely.

Human multitasking is the concept that one can split their attention on more than one task or activity at the same time and the best example of multi tasker is a gynecologist who deals with patients unable to conceive on one hand to patients who don't want pregnancy on other, and apart from patents also have to see administration and complete n number of forms and reports to be sent to respected authorities. So, not only clinical, the medico legal responsibilities are also more on gynecologist head.

We have 2 new acts ART ACT and SURROGACY ACT to follow and fulfil the responsibility. We have thought of sharing some important aspects of medicolegal rules, principles, ethics, acts and responsibilities through this journal.I will like to thank all the dignitaries and chief and special guest coming to enlighten us and help us to keep ourselves updated about this medico legal laws and rules.

I must say that we are blessed with the president DR GEETA GUIN madam and secretary DR SONAL SAHNI madam who have always encouraged us and kept our morale high. THANKS to both of them.

I will also like to thank my co-editor DR BHUMIKA for helping me throughout.

Special thanks to DR DEEPTI GUPTA for her help.

Dr Jigyasa Dengra
Editor
JOGS 2021-22

MEDICOLEGAL ISSUES IN HYSTERECTOMY

Prof Dr Gita Guin
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Hysterectomy is one of the most common gynaecological surgeries performed on women. It is used to treat a range of women's health conditions including heavy or painful menstrual bleeding, fibroids, cancer , endometriosis and emergencies during birth. Hysterectomy is either total or subtotal, with or without the adnexae and depending on the way performed: abdominal, vaginal, and laparoscopic or laparoscopic assisted vaginal hysterectomy.

Historically, Soranus of Greece is credited with performing the first hysterectomy in 120 AD, by removing an inverted uterus that had become gangrenous. The first planned vaginal hysterectomy was performed by Conrad Langenbeck in 1813, the first subtotal abdominal hysterectomy by Walter Burnham in 1853, The first elective abdominal hysterectomy by Clay and Koeberle in 1863 and the first laparoscopic hysterectomy by Harry Reich in 1988. These gentlemen, all visionaries of their times, would not have been successful had their thoughts, hands and means stifled by medico-legal litigations. Therefore every medical innovation rides on multitudes of failures. We learn from our mistakes and grow wiser. But mistakes happen by chance and not because one happens to be negligent.

In present day practice, medico-legal issues in hysterectomy arise from either

A) Indication for the surgery

B) Relating to the procedure as in

1. Consent and Counselling
2. Complications
3. Competence of the operating surgeon

INDICATION FOR SURGERY:

There is increasing awareness amongst women regarding the importance of the female reproductive system in maintaining feminism, youth and optimal health, courtesy the multitude of literature available in the web and elsewhere. Also, various social and medical organisations have been relentlessly campaigning against unwanted operative procedures, particularly hysterectomy. “SAVE THE UTERUS” is a commonly heard of social activity of different bodies of gynaecologists.

It therefore is prudent to expect that all gynaecological surgeons have made an utmost effort to save a uterus and have resorted to operative intervention only as the last unavoidable resort. However, in practice, my perception though, 6 out of 10 hysterectomies are unindicated or prematurely-indicated. The menace becomes graver as we move from cities to the countryside.

Thus follows the story of poor farm workers, as young as 25 and 30 getting their uteri removed to avoid the inconvenience of menstruation and loosing out on wages. Then there are those who are offered the surgery and often coerced to undergo the same as the reimbursement for the procedure is covered by numerous government welfare schemes. There are, nonetheless, many who justify removing the uterus of a village woman as she is unlikely to follow up and therefore may land up in a worser health crisis in the future! To justify any of these is regressive and inhuman medical practice. What do we tell the world, we remove the

wombs of our women because our health care system cannot live up to the expectations of her health. Alas! This is not the India of my dreams and not the India of many a dreams! So is the need to strike a right balance between what is right and what is not so right. What is wrong, can never be right!

Thus in M/s Amba Hospital & others vs Ramapathi and others (2008) which faltered on issues of

1) consent
2) surgery without appropriate diagnosis
3) unindicated Hysterectomy

The State Consumer Disputes Redressal Commission opined " It is obligatory for a doctor to rule out a malignancy before performing a hysterectomy" and "Until the immediate and long term effects of hysterectomy are not available, we should reevaluate our philosophy and develop respect to uterus as an important endocrine organ and not merely as a child bearing pouch."

CONSENT AND COUNSELLING:

To do something to the patient without generating enough knowledge in him/her to understand and evaluate its impact on his or her general health would amount to walking the years of emergency, something we have always feared to imagine. Yet rarely are women made well aware of the nature of the procedure or its impact on her health before operating on her. Consent is obtained by creating baseless fears in the women and it is not rare to come across patients who choose to get the procedure done just because their neighbour or relative have got it done. A pseudo sense of freedom from the dreaded cancer is created and they know little that worser health issues await them. Commonly the uterus being referred to as "bacchadani" or the "baby pouch" makes it sound almost useless to have a nuisance creating organ once the babies are born!

In Samira Kohli Vs Dr Prabha Manchanda (2008), the Hon'ble Supreme Court set the guidelines for consent as under

1. Before proceeding to treat a patient (including operative treatment), the doctor must obtain a valid and real consent. For that, the woman must be able to understand and comprehend what is being told to her about the nature of the treatment. Also, importantly "ADEQUATE INFORMATION" about the treatment must be provided to her.
2. The adequate information that will be provided by the doctor or an assistant must include
    a) All details and manner in which the treatment is proposed to be carried out
    b) All possible and substantial, but not remote or theoretical complications likely to arise during the course of the treatment.
    c) All other alternative treatments available and those that are asscessible to the patient
    d) The likely fallout of the patient not choosing to undergo the treatment.
    e) The consent so obtained will be specific to a certain procedure. Under no circumstances, except when such extension of procedure is warranted for saving the life of the patient, will the treatment or operation be expanded to do a collateral procedure. Thus, a consent for a diagnostic procedure must not be extended to include a corrective procedure.

However, whenever anticipated, a consent can be obtained for an operative and diagnostic procedure or any multiple procedures to be carried out simultaneously, provided the patient has consented for the same is full senses and understanding.

Consent for blood transfusion must be obtained separately, whenever contemplated.

The Hon'ble Court has stressed the need of striking a balance between what is absolutely necessary for the patient to know and what is not so essential, so that a patient is not coerced into favoring one form of treatment over the other through fear or otherwise. The counselling and manner in which the consent is obtained must be of the degree of an ordinary prudent doctor.

In Jayshree Choudhary and another vs B. M. Birla Heart Institute and Another (2010), the State CDRC has

ruled that the operating physician must interact with the patient to allay her fears and anxiety. Where the OP is not available, his assistant who is himself capable of performing the surgery must obtain the said consent. Operating without valid consent amounts to assault on the patient.

Until there is sufficient ground to believe that an adult patient is not in the frame of mind or of unsound mind to give valid and real consent, there is no justification of obtaining the consent from any relative. They can, however be witness to the consent.

Also, ideally, a separate and real consent for the anaesthesia to be administered must also be obtained.

In Dr Suchita Choudhary vs State of Bihar and Anr (HC of Bihar, 2006), the commission held the doctor guilty of removing the ovary without consent

In Saroj Chandhoke vs Ganga Ram Hospital & Anr (2007) consent was taken for abdominal hysterectomy in a patient with history of previous two caesarean section but the operation was attempted from the vaginal route leading to grave complications. The commission held the operating surgeon liable for not complying with the mentioned abdominal hysterectomy in consent and instead proceeding with a vaginal hysterectomy.

COMPLICATIONS ARISING OUT OF THE PROCEDURE

Like any other surgical procedure or for that matter any treatment, hysterectomy, irrespective of the indication, route and competence of the surgeon can land in complications. Simply because a complication has happened does not imply that the surgeon or anaesthetist has been negligent. As a matter of fact, every complication, frequent or remote, that is enumerated in the text books are so enlisted because they happen at times. What is expected of the physician is that

a) he shall be vigilant in complying with all preoperative protocol

b) the OP or his assistant shall not make any false claims regarding the competence of the surgeon or make false promises of cure

c) intraoperative steps will be as per the prescribed norms for the case; deviating from the routine when the situation so demands will depend upon the available resources and competence of the OP.

d) Whenever a complication is foreseeable by virtue of the nature of the disease eg ureteric injury in a broad ligament fibroid

1) counselling and consent of the patient informing the same, duly witnessed must be obtained;

2) precautions necessary to avoid such complications

3) vigilance and early recognition of complications and indulgent care.

4) Whenever needed other specialists should be called on board and if need be, the patient should be duly shifted to another hospital complying with all requirements of referral.

e) Whenever blood loss is anticipated, blood should be kept ready. If the patient is of a rare blood group, it may be prudent to keep a compatible blood cross matched even when too much of blood loss in not anticipated.

In Smt B. Jyothi Vs Geetha Maternity Nursing Home (July 2010, AP SCDRC) were Hysterectomy for Fibroid uterus with Previous LSCS was complicated by Ureteric injury and VVF and in Nirmala Gupta vs Combined Medical Institute (2013 Uttarakhand, SCDRC) were rectal injury complicated the procedure performed while operating on a patient with endometriosis, the commissions were satisfied that the OP were vigilant in performing the surgery, diagnosing and treating the complication, hence not liable.

In Shri Satyanarayan Agarwal and Anr Vs Dr (Mrs) Alaka Goswami and Others (2013), the Commision has held the OP and hospital liable on certain grounds

a) Consent was obtained for laparotomy but a TAH with BSO was performed, hence the consent was NOT REAL and VALID.

b) The patient supposedly died of acute pulmonary edema and acute renal failure. No Postmortem was

done to rule out other causes such as anesthetic or narcotic overdose or to establish the mentioned cause.

c) The physician called in as cardiologist was not a duly qualified cardiologist and so also the nephrologist.

d) The hospital was not well equipped to undertake the surgery.

As such, to perform a surgery without adequate facilities for general anaesthesia may be like riding a motorcycle without a brake, it will only be sometime before you land in an accident.

COMPETENCE OF THE OPERATING SURGEON

Repeatedly have the courts and commissions reiterated that none must profess to know what one does not know. The question in point in Reena Bhattacharya vs Dr Narayan Choudhary and others (September 2008) was that a bladder injury leading to a vesicovaginal fistula occurred in a patient. Here the doctor discharged the patient with the catheter in situ without informing of the bladder injury. Later when the VVF occurred, the OP dillidallied in acknowledgeing the complication and referred her to a urosurgeon. The Commission ruled that the OP (and everyone trained in gynaecology) should have identified and repaired the bladder injury and communicated the same to the patient. In the instant case, the preoperative D&C had yielded insufficient material, evidence in itself that no effort was made to establish a proper diagnosis before proceeding with the hysterectomy.(4,50,000/- awarded as compensation).

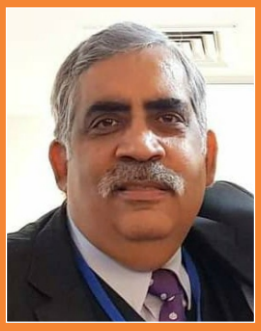
Ajay Prabhakar Paranjpe vs State of Maharashtra and Anr (August 2021), in this instant case, the OP, here a general surgeon performed a vaginal hysterectomy and the patient eventually succumbed to septicaemia. A team of experts opined that the surgery may well have been performed by a gynaecologist and that standard and quality care was not given to the patient. The OPs argument is that even though he is not trained in gynaecology, he had, over the years, gained enough surgical experience in performing hysterectomies. He has been granted bail as his arrest was not deemed necessary for the investigation that he must subject himself to. It remains to see whether his claims eventually stand the tests of the laws of the land.

Thus it is for every honest and prudent doctor to understand that when the intentions are clean, the hands are optimally and legitimately trained and skilled , the mind is equipped and updated with knowledge, the eyes are vigilant and each of these is sprinkled with a liberal topping of empathy, the courts and commissions shall always respect the good intentions. Thus every doctor can sleep peacefully at night when he has worked honestly and prudently by the day.

Rarely, misfortune will befall most of us. Appropriate action, counselling and communication, documentation of all such actions together with a strong and trustworthy relationship with professional brethren and an appropriate and reliable professional indemnity and smart legal help will help us all to sail through.

THE LEGALITY AND ETHICS OF REFERRAL IN MEDICAL PRACTICE

Dr Neeraj Nagpal
Convenor, Medicos Legal Action Group, Managing Director MLAG Indemnity,
Ex President IMA Chandigarh
Director Hope Gastrointestinal Diagnostic Clinic, Mohali



India is a country where about 70% of healthcare is provided in Private Small and medium health care establishments which means in clinics, small nursing homes and hospitals less than 30 beds. The scale of operations of these establishment is restricted and they individually are not adequately equipped for all types of medical and surgical emergencies. Though some of them may even be providing high quality tertiary care in their own restricted field but even these super specialty but small establishments are also grossly deficient in other fields. This type of healthcare system has developed over time in India due to the entrepreneurship of individual doctors when faced with the gradual abdication by the Government of its responsibility to provide healthcare and preserve life of its citizens though enshrined in the constitution as a fundamental right under Article 21.Unfortunately few erratic judgments have penalized nursing homes and hospitals for not having ICU, NICU, Ventilators and other equipment. The rapid development in medical sciences has created many subspecialties and superspecialties all of which are impossible to be available in all hospitals. Even large tertiary hospitals may not at times be providing all specialty medical services and may need to refer a patient to a different establishment. Given the situation, the SMHCEs and even the larger hospitals provide what services are available with them and thereafter refer to other similar establishments or even larger hospitals if the situation so demands. With no codified law which encompasses this referral and transfer process one is left with Indian Medical Council Regulations 2002 , the Charter of Patient's rights provided by National Human Rights Commission and to some extent the Clinical Establishment Act to deal with the matter. Few odd case laws on the issue also exist but the need for a regulatory mechanism for such transfer and referral is urgent need of the hour. As per The Indian Medical Council (Professional Conduct, Etiquette And Ethics) Regulations, 2002 Section 2.1

A physician can refer a patient to another physician; however, in case of emergency a physician must treat the patient.

However, when a patient is suffering from an ailment which is not within the range of experience of the treating physician, he may refer the patient to another physician. As per Section 3.6

- When a patient is referred to a specialist a case summary of the patient should be given, and the specialist should communicate his opinion in writing to the attending physician.

Section 4.3 When a physician has been called for consultation, the consultant should normally not take charge of the case, especially on the solicitation of the patient or friends. The consultant shall not criticize the referring physician. He/she shall discuss the diagnosis treatment plan with the referring physician. As per the Charter of Patients Rights the NHRC expects that

The Right of a patient to proper referral and transfer, which is free from perverse commercial influences, is upheld.

According to the charter, the patient has the right to continuity of care, and the right to be duly registered at the first healthcare facility where treatment has been sought, as well as at any subsequent facilities where care is sought.

- When being transferred from one healthcare facility to another, the patient / caregiver must receive a complete explanation of the justification for the transfer, the alternative options for a transfer and it must be confirmed that the transfer is acceptable to the receiving facility.
- The referral process must not be influenced by any commercial consideration such as kickbacks, commissions, incentives, or other perverse business practices. A SMHCE in India usually comprises of a single doctor / doctor couple who are the only full time medical staff of the establishment supported by a few visiting consultants if any. Judicial expectation of ensuring that a patient referred reaches the destination without deterioration means the SMHCE should have an ambulance which is well equipped (plus maybe a spare) , a driver available round the clock, and a doctor who accompanies the patient. Since the SMHCE has only a single doctor or doctor couple that would mean the owner of the SMHCE should accompany the patient abandoning other patients who may be under his care. Obviously neither

is it practical nor is it feasible. More than 95% of the SMHCEs in India will not have an ambulance and 99 percent would not have a driver available 24 hours round the clock. Besides the transfer is also the issue of providing complete transfer papers which in themselves would not be difficult were it not for the fact that these papers have to be generated by the SMHCE's only doctor while simultaneously managing the medical emergency and personally accompanying the patient. The luxury of time is one thing a doctor does not have and unlike the judiciary which can take months to provide a written judgment , doctors need to do their paperwork in extreme emergencies while simultaneously counseling the patient's relatives regarding the need to transfer and maybe also dealing with some degree of violence.

The elective referral of a patient to another doctor or medical establishment has its own issues which have ethical and legal ramifications.

- The Indian Medical Council regulation of 2002 Section 6.1 prohibits the doctors from advertising. In the absence of advertising they are expected to depend on word of mouth for sourcing their patients.
- Specialists, superspecialists, Diagnostic Centers and even Hospitals have gradually evolved the system of cuts and commissions to develop this patient pool.
- As per the Indian Medical Council Regulations 2002 Section 6.4.1 Asking for or Giving any gift, in return for the referring, any patient is punishable. However Technological developments and sky rocketing costs of this technology has shifted the ownership of medical establishments from professional doctors to businessmen who may or may not be doctors. Ethics is either a non entity for these businessmen or then it takes a backseat when the issues are of investment and return on investment. Government has also not helped matters in the sense that there is “bury your head in sand” approach.
- If an establishment or a doctor could advertise and reach potential patients directly they would not have to

rely on touts and middlemen to source their patients. Also no cost accounting of procedures and investigations has ever been done in our country. If an establishment can do a procedure for a cost lower than what is calculated as “fair price” and still wishes to reward those who send them patients then the issue of ethics does not arise. As long as the consumer gets a fair deal the doctors and hospitals need not be held guilty of corrupt practices regarding how they source their patients. There is then an issue where a business owner of a medical establishment is free from the shackles of Indian Medical Council Ethics regulations and to compete in open market even ethical doctors are forced to do in Rome what Roman's do. Including doctors in the Consumer Protection Act has already established doctors to be traders of services and Hospitals to be shops, in the patients minds. Under the circumstances ,how and why the customers are coming to these shops and traders should be no one's business as long as the consumer gets a fair deal. All Insurers give a commission to the agents who source business for them. The 'cut' exists even in the legal field, in construction business, and probably in all other trades and professions. Even the Police offer “reward” for information. One cannot have one's cake and eat it too. Either we are a “noble Profession” or we are shopkeepers , traders and service providers. If we are in a noble profession where is any shred of immunity which noble professional's deserve. he illusion of nobility of the profession may seduce a youngster to join the profession but he is bound to question the rationale of investing huge amounts to gain education which is grossly overpriced and not expect a return on investment. The Government in its wisdom has permitted medical colleges to charge crores or imparting medical education. Besides the cost of education is the huge investments needed today to set up medical establishments. A table, chair an examination couch and a stethoscope was all the investment which was needed 20 years ago. Today the scenario has totally changed and it is not fair to judge doctors with lenses of yesteryears. What is needed is a pragmatic approach to the issue of cost of medical education, compliances needed to be met for establishing SMHCE, issue of advertising by healthcare establishments whether owned by doctors or by businessmen, and notification of fair price of various procedures based on professionally sourced and audited data of good private hospitals.

DOCUMENTATION & COUNSELING: REFERRAL OF PATIENTS

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The practice of medicine is dynamic and an ever changing concept. The management of a patient including history, examination, investigation, treatments and referrals has to be individualized and differs from patient to patient. A trust based doctor- patient relationship; communication skills and documentation are important elements of medical practice when we are referring a patient from one hospital to another. A referral on time may prevent many allegations of negligence in future and save precious time spent in litigations.

When to refer: A physician should care for the patient as per the standard practice of his field of expertise, his own experience, knowledge and skills and within the limits of practice in his specialty. He should not exceed his competency or skills under any circumstance. Only exception to this is while giving emergency care. Also, wherever better or expert care is easily available, early referral to such an expert or centre must be considered.

Where to refer:

If we feel that the particular patient is beyond the scope of our specialization or skill then the patient shall be referred to a place where he can get proper treatment in terms of expertise, facilities or both. The referral can be to a public or private hospital and preferably to a higher center. It is however prudent to make sure that a private hospital is willing to accept a particular patient. In no circumstances the patient is to be allowed to venture from hospital to hospital, except when the patient does so on his own whims and not due to non acceptance from the place where he was primarily referred.

How to refer:

Decide the reason for referral. If that is non availability of appropriate treatment at the present facility and there is genuine need for DOCUMENTATION & COUNSELING: REFERRAL OF PATIENTS the referral, make sure that the same is available at the referral hospital. Inform the patient, every time s/he is in a stable state of mind to comprehend what is being told to him/her and as well as some of the near relatives or decision makers that the treatment at the present facility may not be sufficient and it will be in the best interest of a patient, that he or she be referred to a higher center. Communicate with the relatives by following the principles of communication skills and inform them the reasons for the referral. As far as possible, convince the relatives to shift the patient before s/he deteriorates or becomes critically ill. Therefore, timely than late referral must be the rule, except when such delay is due to noncompliance on the part of patient party or due to unavoidable circumstances such as natural calamities making transportation impossible. Formalities for referral Once decision for the referral is taken, the patient can be:

1) Referred with a proper referral slip and procedure: Whenever we are referring any patient, we should follow some basic guidelines of referral. The referral slip must mention a brief summary of the patients' condition, treatment given and the need for referral. Whenever possible, the same should be informed to the hospital where the patient is being referred, on phone. This can make receiving the patient at the other hospital smooth, can provide for sufficient time to inform concerned specialists

and make some special arrangements, eg provisions for blood transfusions, special medications etc.

2) Discharged on request (DOR): Discharge on request should be avoided in present circumstances, since patient or relatives may later on allege that they didn't understand the severity of the situation and it was the doctors' or hospitals' responsibility to guide them appropriately. Whenever DOR is contemplated, it will be wise practice to take a written undertaking to the same effect that is dulywitnessed.

3) Left/ discharged against medical advice (LAMA, DAMA): In this situation the patient is discharged against the advice of health care provider or he leaves the hospital without informing the hospital staff. A new terminology is used by some of us, “taken against medical advice” (TAMA). The meaning of these words many times overlap but legal issues may be almost similar with very narrow margin of interpretation. Whenever the patient leaves the hospital without following the due procedure, it is imperative that written information be sent to the higher authorities informing the same.

REASONS FOR REFERRAL

1) Referral for further investigations: Sometimes all the investigations, especially those dependent on newer gadgets or technologies may not be available at the treatment center. Such patient's diagnosis may be delayed because of delayed referral to a better equipped center. Hence, it is vital to refer the patients to a center where the various latest diagnostic gadgets may be available at an affordable cost or where an unaffording patient can get the benefit of the various Government Yojanas, like the Ayushman Yojana.

2) Referral for Second Opinion: We are in the era of specialization and super-specialization. In bigger cities or metros super- spec iali s t s like cardiologi s t s , neurologists, infertility experts, oncologists, endocrinologists, robotic surgeons, a long list of consultants are now available. Human rights of individuals are well defined and it is the right of the individual to get the best possible medical care. Hence, whenever dealing with cases with complicated, complex issues of diagnosis or treatment and whenever it is feasible to get a second opinion from a specialist/super-specialist we shouldn't hesitate in referring the patient. In M A Gafoor v. Medwin Hospital I(09) CPJ 167, A 29 yrs, hale and hearty individual who was being treated for fracture had acute respiratory depression after Fentanyl but surgery was continued. There was allegation that doctors were not diligent enough in post- operative treatment. Patient was not referred to Pulmonologist for respiratory depression and Nephrologist for renal failure. The patient was discharged in spite of continued vomiting and dyspnea was re-admitted within two days for renal failure, dialysis was done but expired. Deficiency in duty and negligence was proved.

3. Referral for superior treatment Sometimes better treatment in terms of facilities, expertise or simply backup may necessitate a referral. Often single specialty, smaller nursing homes with all facilities of, for eg gastro- intestinal treatment may have to refer a patient to a multispecialty hospital in the event of anticipated or real complications or comorbidities. Should we follow-up at referred hospital? On most occasions, our responsibility doesn't end with simple referral. If possible, especially if we know someone at referred place, it is better to have a follow-up of the patient. This increases the confidence of the relatives or patient that the primary physician is continuing to take care and follow-up with the referred hospital. The doctor at referred hospital will also have feeling of more responsibility and commitment to the referring doctor as well as the patient since he may be, to a certain extent, answerable for the overall outcome of the patient. Delayed referral: Delayed referral can lead to delayed diagnosis and treatment ultimately resulting in unexpected outcome. This may result in allegations of deficiency in service and medical negligence. Hence referral should not be hesitant and unnecessarily delayed. In Dr. Rakesh Jain v. Rakesh Kumar Khare I (2003) CPJ 27, negligence was held because 09 in a child with rising bilirubin levels, pathological tests were not done at proper time, proper phototherapy was not given and referral was delayed. It was held that the treatment was not according to accepted norms and hence it

resulted in permanent disability. In M Vijayan v. Vishwanathan I (12) CPJ 43, a child with burn injuries was operated, got infected resulting in septicemia. The 3rd degree burns is a major problem and the case must have been referred to a special burn center. It is serious negligence in not referring the child and according to Plastic Surgeon, substandard treatment was given. A compensation of 3 lakh + 7% interest was granted in the particular case. Communication skills: It is important to record and document the need of referral in a proper manner. One must note down the reasons for referral to a specific center. Communicate with the patient and relatives regarding the facilities available at the referring center and advantages of shifting the patient. Be empathetic rather the sympathetic while explaining the reasons for referral. Always explain the disadvantages of not seeking treatment at the referred center. Follow the basic principles of communication skills and confidence building. It is important to convince the relatives that you are acting in good faith for the patient's benefit and better outcome. Documentation and record maintenance: The documents &records related to the particular patient who was managed and then referred shall be properly maintained as per the existing guidelines/ recommendations. Note every evidence pertaining to treatment, counseling and consents, whenever applicable in the records. In, L Meena v Dr. S Mathur III 2001 CPJ 200, the documents came to the rescue of treating pediatrician. In this case a newborn with physiological jaundice discharged on 5th day of life, alleged deterioration and came again on 6th day; after refusal of admission, went to another hospital, was treated there but became handicapped. In defense doctors produced proper documents while the complainant produced fabricated documents. He took discharge against medical advice (DAMA) from 2nd hospital and went to 3rd hospital. This case was dismissed with costs in favor of pediatrician.

Carry Home message:

- In critical cases, always refer after completing life saving measures.
- Don't exceed your level of competence. Don't care beyond one's qualification, skill, experience etc. Behave in a compassionate, sensitive and humanely manner.
- Inform and record the reasons for the referral in indoor documents after giving all relevant information. It is patient's right to have proper explanation for referral.
- Hand over a proper referral letter
- Continue follow-up with the referred hospital, whenever possible.
- Indications and criteria for referrals differ from patient to patient.
- The discharge card as far as possible shall be patient friendly. Avoid unnecessary medical jargon and very elaborate notes.
- Timely referral may prevent many allegations of negligence.
- Follow the principles of communication skills. This prevents avoidable mis interpretation, mistreatments & misunderstandings.

Medical Termination of Pregnancy (Amendment) Act, 2021 No. 8 of 2021

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Medical termination of pregnancy Act 1971 was passed by the Indian Parliament as a health measure . It came into force in 1972 and later, with revised provisions in 1975. Broadly, the act provides for the termination of pregnancy on medical, social, humanitarian and eugenic grounds, upto 20 weeks of gestation in a safe environment, by the recognizedregistered and adequately qualified medical practitioner. MTP Act 1971 was first amended in 2002 and recently in 2021.

MTP (Amendment) Act, 2002, Rules& Regulations2003

Key features:

- Term Lunatic was substituted with the words "Mentally ill person".
- Approval of site for termination by district level committee chaired CMO/DHO
- Strict penalties for dubious MTP and rigorous punishment (2-7 years)
- Owner of the place also responsible if defaulter
- Inclusion of Medical abortion upto 7 weeks termination using drugs Mifepristone &Misoprostol

In a historic move to provide universal access of reproductive health services, India amended the MTP Act 1971 to further empowerwomenby providing comprehensive abortion care to all.Thenew law came into force from 25th March 2021. It expands the access to safe and legal abortion services on therapeutic, eugenic, humanitarian and social grounds.

MTP (Amendment) Act, 2021

Key features:

- **Termination due to Failure of Contraceptive Method or Device–**
- Under the Act, a pregnancy may be terminated up to 20 weeks by a married woman in the case of failure of contraceptive method or device.
- It alsoallows unmarried women to terminate a pregnancy for this reason.
- **Opinion Needed for Termination of Pregnancy–**
- Opinion of one Registered Medical Practitioner (RMP) is required for termination of pregnancy up to 20 weeks of gestation and
- Opinion of two RMPs for termination of pregnancy of 20-24 weeks of gestation.

- Opinion of the State-level Medical Board is essential for a pregnancy to be terminated beyond 24 weeks in case of substantial foetal abnormalities.

▪ **Upper Gestation Limit for termination–**

- Upper gestation limit increasesfrom 20 to 24 weeks.
- Upper limit further can be extended on recommendation of the Medical Board
- The extension of upper limit upto 24 weeks is given for special categories of women, including survivors of rape, victims of incest and other vulnerable women (differently abled women, minors).
- Upper gestation limit is not applicable in cases of substantial foetal abnormalities diagnosed by Medical Board.
- The Board will consist of a gynaecologist , a paediatrician, a radiologist or sonographer and any number of members as notified by the State govt.

■ **Confidentiality –**

- The "name and other particulars of a woman whose pregnancy has been terminated shall not be revealed", except to a person authorised in any law that is currently in force.

■ **Specialisation -**

- Only doctors with specialisation in gynaecology/obstetrics can perform abortions

MTP Act & Amendments	1971	2021
Indications(Cp failure)	Only applies to married women	Unmarried women are also covered
Gestation age limit	20 weeks for all indications	24 weeks for rape survivors Beyond 24 weeks for substantial fetal abnormalities
Medical practitioner opinions	One RMP till 12 weeks Two RMPs till 20 weeks	One RMP till 20 weeks Two RMPs till 20-24 weeks Medical Board approval after 24 weeks
Breach of woman"s confidentiality	Fine upto Rs 1000	Fine and/or imprisonment of 1 year

Strength:

The newMTP law wouldcontribute towards ending preventable maternal mortality to help meet the Sustainable Development Goals (SDGs) 3.1, 3.7 and 5.6.

SDG 3.1 pertains to reducing maternal mortality ratio whereas SDGs 3.7 and 5.6 pertain to universal access to sexual and reproductive health and rights. It will increase the ambit and access of women to safe abortion services and will ensure dignity, autonomy, confidentiality and justice for women who need to terminate pregnancy.

Weakness:

At thesame time itleave issues regarding –

1. Termination of pregnancy as the choice of the pregnant woman vis-à-vis foetus right.
2. Writ Petition, the only recourse for termination of pregnancy due to rape and exceeding 24 weeks.
3. The Act requires abortion to be performed only by doctors with specialisation in gynaecology or obstetrics.As there is a 75% shortage of such doctors in community health centers in rural areas, pregnant women may continue to find it difficult to access facilities for safe abortions.

Way Ahead

- Though a commendable bold stand by the Central Government, it leaves women with various conditionalities, which in many cases become an impediment in access to safe abortion. Need of uniformity in all norms and standardised protocols in clinical practice to be followed in health care institutions across the country.
- Abortion needs to be decided on the basis of human rights, the principles of solid science, and in step with advancements in technology.
- Since it has now become an act, one can be assured that the country is on the road to advancement, addressing women issues more fiercely than ever.

She Believed.....She Could.....So She did

REFERRING MOTHERS IN INDIA FROM WHERE WE ARE TODAY TO THE ROAD AHEAD

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Globally, an estimated of 810 mothers die from preventable causes of Child birth every day. Out of this 94% are from the low and middle income countries, India being amongst them [1] Since 2015,as part of the UN Resolution, India is committed to achieve a Maternal Mortality ratio of 70 by 2030 under the Global Sustainable Development Goal 3.[2] The country observes over 30 million pregnancies every year. Most of these pregnant women are from low income, rural and even remote areas of the vast landscape of the country. Therefore, making Case Specific Obstetric Services available at the Right time to the Right woman, at the Right facility by the Right Health Care provider is a tough task, inbred with huge obstacles, given our current position where majority of the population still depends on the Public Health System. Like most public health systems globally, even India has a Hierarchal Public health System in place, both for Rural and Urban settings. The hierarchal systems are meant to provide care and treat clients at their facility with the best of their capabilities and the available resources. They are expected to identify the ones requiring specialized care and ensure that they are referred to the respective Higher Centers depending upon the individual need of the High Risk Pregnant Woman (HRPW). In context of Obstetric care, WHO has described the management of obstetric complications at the district level (WHO Revised Guideline, 2017) [3], but unfortunately the use of these guidelines at different levels of facilities are poorly understood and even worst executed. Because, mostly the lower and middle level facilities are poorly manned with either inadequate staff (OT nurse or technician not available after morning shift) or inadequately trained staff (staff not confident enough). At the facilities which do have appropriate staff to manage and take decisions, the resources at the facilities disarm the manpower with apparently petty but real life situations, like ambulance not available to bring the on call doctor at odd hours. As most of the complications in pregnancy cannot be predicted or prevented, but they can only be successfully detected and timely treated, it is easy to understand that Emergency Obstetric services have to be really robust and streamlined at all levels with a seamless referral system. The job responsibilities of each level of facility and health care provider should be clearly spelled out and defined with strict adherence and compliance to SOPs. National Committee on Confidential Enquiries into Maternal Deaths reveal that though the defined level of Emergency Obstetric Care(EmOC), namely Comprehensive Emergency Obstetric Care(CEmOC) and Basic Emergency Obstetric Care(BEmOC) are in place, it is observed that

- The designated EmOC centers are actually not able to provide the laid out G 11 services. Health care workers from such settings are often not able to manage complications, not able to perform risk assessment, stabilize complicated cases and rather" Prefer to Refer" the patient to functional higher levels.
- Interview enquiries with Medical Officers over various CHCs and PHCs revealed that the search of a Functional FRU was the major deciding factor of their referral point rather than any laid guideline or protocol. It was noticed that though the training Manuals of SBAs , do mention the criteria and guideline for referrals, in real time working of FRU, BEmOC and CEmOC, these guidelines work out to be far from real because most of these centres are not supported by appropriate resources in the Health System. In such

a condition the onus of referring the pregnant woman whether electively (High Risk Pregnancy) or in Emergency (in case of ante, intra or Postpartum complication) remains largely on the referring Health Care Worker. Even state wise survey performed including poor and better performing states, reveal, that the providers in rural health care have sub– optimal knowledge of and poor practice for screening common high risk conditions and assessing complications in pregnancy. Therefore, in the absence of efficient referral system and communication the health care workers feel that it prudent for these women to receive antenatal care at the advanced centre (often far) where they should deliver. [4] With this kind of functioning scenario, it zeroes down that a high proportion of between 25 and 52 % of all antenatal women end up being referred. [5] To refer a patient should ideally be a very careful precisely weighed Medical decision, but the complexity of it, in our system, is only disturbingly aggravated by the absence of laid guidelines, protocols and resources. The end result is a large proportion of unnecessary referrals, done inappropriately with inadequate communications and low compliance. This ultimately leads to gaps and delays in the provision of Emergency Obstetric Care. Undeniably, the type of the obstetric complications does determine the level of care needed and the place to be referred to and this further make the referral pathways complex. [6] Maternal death reviews from India suggest that most of the mothers who died had gone through multiple referrals before reaching the appropriate facility [7, 8] where they were either brought dead or in an irreversible stage. Going further into the details of referral chains system and understanding the gaps in the referral chains ,it repeatedly surfaces that even basic conditions which can be managed within the existing system of primary health care and closer to the community are unnecessarily referred to the Emergency Rooms of Tertiary care Centers. In addition, secondary level of care is bypassed when people and even the referring health personnel prefer specialist services for seemingly normal condition, thereby increasing attendance at tertiary centers. Private hospitals also shift high risk pregnancies and women in labor in order to avoid poor outcomes. [9] The major disastrous result of this kind of working culminates into gross underutilization of the lower and middle levels of the Health system with unmanageable extents of overcrowding of tertiary centers, thereby diluting the quality of care which would otherwise be provided for more critical conditions [10]. Not to mention , despite of the all collaborative efforts of all agencies ,global, national, non government , India fails to give the expected outcomes because this unequal utilization of the Health Care system dilutes all efforts , benefits of efforts being unable to reach uniformly to all , contributing to the third answer of the question of" Why do mothers die ?", of the Safe Motherhood program. Because there is delay in receiving care, even after they have overcome the first two delays of decision taking and reaching to the point of care. [10]. that is the reason why despite of an initial annual reduction of 4% in our MMR India is now on the plateau of its curve and meeting its target is appearing difficult. Taking lessons from our own existing referral system as well as from other LMIC it is proposed that · if we really wish to reach the SDG3 ,then, in addition to ensuring the functionality of low and middle levels of Public Health , both in terms of logistics and manpower , · Building up of a very strong, sound and streamlined referral system will play a pivotal role in ensuring that every mother in need gets the desired services. · Sincere efforts to upgrade all levels of health care facilities with a smooth two way Referral System including government run referral transport facilities would be required .Added to supervision and accountability for quality of care with capacity to monitoreffectiveness and policy support. Keeping with the same efforts, the MoHFW has revisited its earlier MCTS (Mother and Child Tracking System) application and upgraded it into an enhanced version called RCH portal, released by NHM by the name of Anmol portal on 1/4/2016.This portal is meant to meet the diverse requirement of the RCH program by allowing Batching and Matching of High Risk Pregnant women. The program targets to tag 100% High Risk Pregnant women with their gynecologist and Health institutions for safe delivery by batching of HRPW with healthfacility for treatment and matching them with delivery points as per high risk factor for safe institutional delivery. This intends to register all ANCs by the use of RCH portal. Furthermore, use of Referral management software is also proposed. The Dashboards of such

system contain digital records of and clear presentations of the key steps in the process such as

(1) Referral is entered

(2) Referral is acknowledged

(3) Patient contacted

(4) Appointment confirmed. Using app less mobile communication such systems not only ensure two way referral systems but also increase the accountability and answerability of both the referring facility and the receiving facility, while being completely transparent.

In Indian settings though it is not difficult to understand that given the diversity of health systems, geographical conditions and existing infrastructure , it is not easy to develop a generally applicable blue print for referral systems. Still, what cannot be denied is that for 13 any team to be able to produce effective outcomes, it is imperative that every individual at every level of the team identifies their importance in the team and simply justifies their role. This level of awareness and efforts right from the level of family members of pregnant woman to the level of policy makers across the health care providing channels is bound to save mothers in our country thereby, bringing down our MMR to expected respectable levels.

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REFERRAL PRACTICES- A LONG DUE DEBATE!

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Stigma to an evolving modern India is the poor quality of obstetric services; a lot of women still die during pregnancy and childbirth. As per estimates, for every maternal death, about 15% pregnancies develop complications that require tertiary obstetric care. On one hand, a timely referral can help improve maternal/ perinatal outcome, on the other, unnecessary referrals add to the burden of tertiary care institutes hampering the delivery of quality of services. Because the referrals involve a high risk parturient and / a compromised fetus, these are high-risk patients from medico-legal standpoint as well, often being the cause of troublesome law suits. Therefore, we conducted an online survey using Google forms to understand the perception of practitioners about safe referral practices with a pre structured questionnaire. Our aim was to start the debate which hopefully will see some SOP evolve! Majority of the 248 respondents (193) were gynecologists, though we also got inputs from anesthesiologists and intensivist. 86% respondents had more than 10 years' experience. * Under pressing circumstances, one is obliged to admit a high risk patient? And such admissions are protected under law. 57.1% of the respondents believe we are while 39.3% respondents think we can refuse to admit a patient. 39.3% of the respondents thought that such a situation is protected by law; an equal number 39.3% thought it is not. 21.4% of the respondents had no idea of legal stand.

Those respondents, who agreed to admitting, enumerated few such situations as patient in shock due to any reason, myocardial infarction, a mother booked under their care, an unstable patient who may collapse en route, severe sepsis, antepartum hemorrhage, and postpartum hemorrhage. Most thought such high risk patients need to be admitted for stabilization and triage; fetal causes like fetal jeopardy and imminent delivery and pressure of local authorities, COVID-19cases when the hospital is a COVID hospital could be other situations. *Respondents views of safe practice in such situations included Good counseling of concerned family members/ attendants, written documentation of same and necessary consents, team approach where needed, protocol-based management. Most opined, if there's no multispecialty support or ICU then perhaps it is always safe to refer the patient to a tertiary institute immediately or after stabilization. Having good rapport with colleagues and informing local authorities if attendants seem to be troublesome also helps. * Should low risk referrals be questioned by local authorities, especially in the Government set up? As per 50% respondents, questioning low risk referrals by local authorities is right; 28.6% didn't think it necessary and 21.4 % weren't sure.

*The reasons for low risk referrals were varying. Lack of manpower/ facilities or due to financial constraints or simply the referring clinician's decision to shun away and escape from the responsibility, they definitely add to burden of tertiary care units. Some also thought it could be for referral bribing! Many believe that it's more of a defense mechanism, as obstetric complications are often unanticipated or predicted and small nursing homes with past bitter experience perhaps try to be safe.

*Almost 65% respondents believe, securing IV access before referring is a good practice. 25% think it's desirable. 10% don't see it as universally necessary.

*In cases like severe anemia or septic shock, 65% respondents opined that referring facility should withdraw baseline blood samples and25% endorsed it as desirable practice as many investigations can be rendered futile by the preliminary treatment given there.

*75% agree that a referral for labor indication like failed induction/ non- progress/ obstructed labor should be complimented with supporting partogram and 21% think it's desirable. Many unnecessary interventions can be avoided

or better labor management is aided by the partogram.

*A common dilemma is where to refer, based on distance or next in hierarchy or as per treatment needed by patient? Majority think it should be decided by treatment needed by patient. Next common answer was let patient decide. Government hospitals agreed to next in hierarchy of referral. Some think distance should be the deciding factor.

*On being asked about the need for existence of full neonatal services at every obstetric unit, 50% agreed its desirable, 18% think it should be. However, 21% think it's impractical and 11% don't think it's needed at all. However, almost all respondents agreed that an obstetric unit can have basic neonatal services and have tie-up for advance services.

* 71.4%, a huge majority think it should be the hospitals duty to arrange for ambulance/ conveyance for further referral. However, most agreed that it quite difficult at times and can lead to unnecessary suspicions. With regards to minimum desirable services in ambulance, respondents felt it should have skilled health worker, oxygen delivery system, first aid and emergency drugs, Ambu bag, tray, ed pan and blankets, at least.

*To the query, what if a standalone unit is unable to provide accompanying personnel in ambulance, suggested options were to have trained ANM, call government ambulance, to communicate by phone and transfer with detailed documents, inform attendants regarding this and seek help of another hospital nearby, self-escort, provide verbal instructions to untrained attendant or relative of patient. All agreed that it is a very challenging situation and the various governing bodies must work to provide for a reasonable solution.

*78.6% think we should have standardized proforma for referrals, especially obstetric referrals so that diagnosis, treatment given etc. are not missed and available at a glance. Another 17.9% think it's desirable.

*On being asked about the minimum information to be given on every referral, respondents suggested patient details, obstetric history, relevant clinical findings at admission and referral, treatment given, duration of stay, investigations if any, reason for referral, contact number of referring facility or doctor.

*Suggestions of some precautions to be exercised by receiving unit in case of inadequate / no referral information were. Emergency triaging with video recording of vitals and conversations with relatives, Taking thorough history and examining meticulously, Written documentation of all such information that is due witnessed by relatives. Call referring hospital if possible and collect information from patient and relatives.

*82% thought it's a good idea to have guidelines/ minimum norms regarding services and facilities available at various level obstetric units or hospitals. To another tricky dilemma on what is to be done when patient to be referred has blood on flow, answers were. Disconnect and refer risking damage 17.8% Finish and then refer risking delay 14.3% Discard, then refer risking wastage 10.7% Disconnect and hand over in cold box for later use risking inadvertent transfusion reaction 57.1% Likewise, at receiving facility, What should be done when patient comes with half transfused blood, there are varying suggestions- while some think if documents are in place it can be reconnected some think it depends on patient's clinical status and need for BT. There were many who would like to cross match with their pathology then transfuse and some who'd simply discard. All suggested that an important point of consideration would be time of travel, condition of patient, need of further transfusions, time anticipated to arrange more units of blood. To the query, what to do when mother is to be referred and baby is in NICU, answers were. Refer only mother 57.1% Refer both mother and baby 42.9% 92% agreed that a written consent should be taken from family before referral. In the event of dispute between physician preference and family preference for higher center, most respondent's think patient/ family choice should be respected and patient may be referred after counseling and documenting the same with written consent. As for choice between referral to public sector or private sector consensus seems to be on factors affecting patient outcomes like distance, available facilities, patient's financial condition and preference. On the query of referring physician having any financial liability towards patient after referral, 82% physicians were unsure. More than anything this survey brought out few things very clearly

- Obstetrics is an uncertain unpredictable field with two lives at stake.
- India is far from the MDG goals
- If we have to ensure timely and appropriate referrals then a robust two way referral system is the need of the hour.

ART ACT AND RULES

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ART Act came to enforcement since 25 January 2022 and following are the rules which is given Ministry of Health and Family Welfare which are to be published in a gazette.

The need of the act was to bring uniformity in the practice of ART and prevent unethical and substandard practice. The act will be regulated by 3 tier system to conduct smooth functioning of act. Registration will be mandatory to practice ART.

It is an act An Act for the regulation and supervision of the assisted reproductive technologyclinics and the assisted reproductive technology banks, prevention of misuse,safe and ethical practice of assisted reproductive technology services foraddressing the issues of reproductive health where assisted reproductivetechnology is required for becoming a parent or for freezing gametes, embryos,embryonic tissues for further use due to infertility, disease or social or medicalconcernsand for regulation and supervision of research and development andfor matters connected therewith or incidental thereto.

The act has been addressed in form of six chapters which sate

CHAPTER I: PRELIMINARY(which has definitions of various terms used in this act)

CHAPTER II:AUTHORITIES TO REGULATE ASSISTED REPRODUCTIVE TECHNOLOGY(It guides about the 3 tier system of guiding the ART)

CHAPTER III:PROCEDURES FOR REGISTRATION(It guides about how to get registered under this act)

CHAPTER IV:DUTIES OF ASSISTED REPRODUCTIVE TECHNOLOGY CLINIC AND ASSISTEDREPRODUCTIVETECHNOLOGY BANK(It is about the responsibilities of the ART clinics and banks)

CHAPTER V:OFFENCES AND PENALTIES(This chapter is about offences and if not followed the penalties which will be enforced)

CHAPTER VI: MISCELLANEOUS(This chapter deals with other aspects like power of state and central government,etc.)

The rules of this act are released last week only which are as follows;

1. Short Title and Commencement

1.1 These rules may be called the Assisted Reproductive Technology (Regulation) Rules, 2022.

1.2 They shall come into force on the date of their publication in the Official Gazette.

2. Definition

In these rules, unless the context otherwise requires:

2.1 'act' means the Assisted Reproductive Technology (Regulation) Act, 2021;

2.2 'form' means a form appended to these rules;

2.3 'section' means a section of the Act;

2.4 'words' and 'expression' used herein and not defined in these rules but defined in the Act, shall have the meaning, respectively, assigned to them in the Act;

2.5 'ART' means Assisted Reproductive Technology;

2.6 'collection" means the collection of sperms from Males without any surgical procedure.

2.7 "storage" means the procedure adopted for storage of gametes or embryos or ovarian tissues

3. The other powers and functions of the National Board under clause (g) of section 5

3.1 The National Board shall, subject to provisions of this Act, rules and regulations made thereunder, take measures to develop new policies in the area of assisted reproductive technology and to assist the State Boards in accreditation, supervision and regulation of services of assistedreproductive technology clinics and banks in the country.

3.2 To encourage and promote training and research in the field of assisted reproduction.

3.3 To assist the central government in issuing guidelines, notifications and orders pertaining to Assisted Reproductive Technology.

3.4 Any other activities as directed by central government.

4. The other powers and functions of the State/UT Boards under clause (b) of sub-section (2) of Section 8

4.1 The State/UT Board shall, subject to provisions of this Act, rules and regulations made there under, shall assist the National Board to develop new policies in the area of assisted reproductive technology.

4.2 The State/UT Board shall supervise the accreditation and regulation of services of assisted reproductive technology clinics and banks in their respective states/UTs.

4.3 Any other activities as directed by central government.

5. Annual Report

The National /State Board shall prepare as per the prescribed format, its annual report, giving a full account of its activities during the previous financial year, and submit a copy to the Central / State Government.

6. Other functions of the National Registry under clause (d) of section 11

6.1 National Registry shall undertake analysis and management of the data provided to it as per the Act. The National Registry may involve other central government institute/s for the analysis and management of this data.

6.2 Any other activities as directed by central government/National Board.

7. Other functions of the Appropriate Authority under clause (h) of section 13.

7.1 In case required advisory committee may be constituted for addressing local issues related to ART clinics and banks.

7.2 Any other activities as directed by the Central Government, National Board, State Board.

8. Other powers of Appropriate Authority clause (d) of sub-section (1) of section 14.

8.1 Appropriate Authority will have the power to question any person involved in violation of the provisions of the Act and take necessary action as per section 14 of the Assisted Reproductive Technology (Regulation) Act, 2021.

8.2 Any other powers as delegated by the Central Government, National Board, State Board.

9. Code of conduct to be observed by Appropriate Authority

9.1 All Appropriate Authorities notified under the Act, inter-alia, shall observe the following code of conduct with respect to the Advisory Committee: -

9.1.1 ensure that a person who is the part of investigating machinery in cases under ART(Regulation) Rules, 2022, shall not be nominated or appointed as a member of the Advisory Committee;

9.1.2 ensure that no person shall participate as a member or a legal expert of the Advisor Committee if he or she has conflict of interest;

9.2 All Appropriate Authorities notified under the Act, inter-alia, shall observe the following code of conduct for processing complaints and investigations, namely: -

9.2.1 maintain appropriate diaries in support of registration of each of the complaint or case under the Act;

9.2.2 attend to all complaints and maintain transparency in the follow-up action of the complaints;

9.2.3 initiate investigation on each of the complaint within twenty-four hours of receipt of the complaint and complete the investigation within seven working days of receipt of such complaint.

9.3 All Appropriate Authorities notified under the Act, inter-alia, shall follow the following financial guidance, namely:

9.3.1 maintain a separate and independent bank account operated by two officers jointly;

10. ART Clinics and Banks

10.1 Levels of ART Clinics

10.1.1 Level 1 ART Clinic

These would be ART clinics where preliminary investigations are carried out including diagnosis of type, cause of infertility and only IUI is carried out as part of treatment.

10.1.2 Level 2 ART Clinic

These would be ART clinics where all/advanced investigations, diagnostic and therapeutic procedures in ART are carried out. Such clinics may also undertake research.

10.2 ART Banks

10.2.1 ART banks will be responsible for screening, collection and registration of the semen donor and cryopreservation of sperms.

10.2.2 The screening and registration of oocyte donor.

10.2.3 The ART banks may operate as Semen banks or oocyte banks or both.

10.2.4 ART Banks will maintain the records/data of all the donors and will regularly update the National Registry as per Section 23, 27, 28 of the Assisted Reproductive Technology (Regulation) Act, 2021.

11. Qualification of the employees in ART Clinics and Banks

Minimum requirement of staff and their qualification for the two levels of ART clinics and the ART Banks shall be as specified in Schedule I, Part-1.

12. The format for granting of licenses to the clinic or bank by the appropriate authority under sub-section (2) of section 14;

The format for granting license to ART clinics and banks is specified under Form 1 & 2.

13. The form and manner in which an application shall be made for registration and fee payable thereof under sub-section (2) of section 15;

An application for registration shall be made by the ART Clinics to the Appropriate Authority in duplicate, in Form 3 and by the ART Banks in Form 4.

Every application for registration shall be accompanied by an application fee of: -

i) Rupees 1,00,000 for Level 1 ART Clinic

ii) Rupees 5,00,000 for Level 2 ART Clinic

iii) Rupees 1,00,000 for ART Bank

PROVIDED that if an application for registration of any ART clinic or ART bank has been rejected by the Appropriate Authority, no fee shall be required to be paid on re-submission of the application by the applicant for the same body within 90 days of rejection:

PROVIDED FURTHER that any subsequent application shall be accompanied with the prescribed fee. Application fee once paid will not be refunded.

PROVIDED FURTHER that such establishments in the Government run institutes will not pay for application.

14. The facilities and equipment's to be provided and maintained by the clinics and banks under sub-section (4) of section 15.

14.1 Equipment in the ART clinics and Banks shall conform to the requirement as specified in Schedule 1, Part 2.

14.2 Minimum physical infrastructure/facilities for ART clinics shall conform to the requirement as specified in Schedule I, Part-3.

15. The conditions, form and fee for application of renewal of the registration of clinic or bank under section 17

15.1 An application for renewal of registration shall be made in duplicate in Form 3 & form 4, to the Appropriate Authority 60 days before the date of expiry of the certificate of registration.

15.2 The Appropriate Authority shall, after holding an enquiry and after satisfying itself that the applicant has complied with all the requirements of the Act and these rules, renew the certificate of registration, as specified in Form 3 & form 4, for a further period of five years from the date of expiry of the certificate of registration earlier granted.

15.3 Every application for renewal of registration shall be accompanied by an application fee of: -

Rupees 1, 00,000 for Level 1 ART Clinic

Rupees 5, 00,000 for Level 2 ART Clinic

Rupees 1, 00,000 for ART Bank

15.4 If, after enquiry and after giving an opportunity of being heard to the applicant, the Appropriate Authority is satisfied that the applicant has not complied with the minimum requirement of the Act and these rules, it shall, for reasons to be recorded in writing, reject the application for renewal of certificate of registration and communicate such rejection to the applicant as specified in Form 5 (ART Clinic) and 6 (ART Bank), within thirty days from the date of application for renewal.

15.5 In case of rejection, the applicant would have the right to appeal to the State Board against the decision of the Appropriate Authority, stating clearly the reasons for making the appeal, within 30 days of receiving the decision of the Appropriate Authority. The State Board should take a view on the appeal within 60 days of its receipt.

15.6 On receipt of the renewal of the certificate of registration in duplicate, or on receipt of communication of rejection of the application for renewal, both copies of the earlier certificate of registration shall be surrendered immediately to the Appropriate Authority by the ART clinic and/or bank.

15.7 In case of failure of renewal of the registration, the clinics and or banks would be given time to complete the ongoing IVF procedures and continue maintenance of embryology lab till renewal is obtained up to 90 days, however new patient recruitment will not be allowed. If the renewal is not granted after 90 days, then the ART clinic and or bank would transfer all the stored gametes to another registered ART clinic and or bank.

16 Certificate of Registration

16.1 The Appropriate Authority shall, after making such enquiry and after satisfying itself that the applicant has complied with all the requirements, shall grant a certificate of registration, in duplicate, in Form 7 and Form 8 to the applicant. One copy of the certificate of registration shall be displayed by the registered ART Clinic or ART Bank at a conspicuous place at its place of business

16.2 In case of any violation of the provisions of the Act If, after enquiry and after giving an opportunity of being heard to the applicant the Appropriate Authority is satisfied that the applicant has not complied with the requirements of the Act and these rules, it shall, for the reasons to be recorded in writing, reject the application for registration and communicate such rejection to the applicant as specified in 5 and 6.

16.3 In case of 16.2 above, the applicant would have the right to appeal to the State Board against the decision of the Appropriate Authority, stating clearly the reasons for making the appeal, within 30 days of receiving the decision of the Appropriate Authority. The State Board should take a view on the appeal within 60 days of its receipt.

16.4 The certificate of registration shall be non-transferable. In the event of change of ownership or change of management or on ceasing to function as ART clinic or ART bank, both copies of the certificate of registration shall be surrendered to the Appropriate Authority.

16.5 In the event of change of ownership or change of management of the ART Clinic or ART Bank the new owner or manager of such clinic or bank shall apply afresh for grant of certificate of registration.

17. The manner in which an appeal may be preferred to the State Government or the Central Government under section 19;

The format for appeal will be as specified in Form 9.

18. The criteria for availing the assisted reproductive technology procedures

under clause (a) of section 21;

The criteria for availing the assisted reproductive technology procedures will be subject to the criteria mentioned under clause (j) of Section 2 of the Assisted Reproductive Technology (Regulation) Act 2021.

19. The medical examination of the diseases with respect to which the donor shall be tested under clause (b) of section 21. Sperm/oocyte donor is tested for the following diseases:

19.1 Human immunodeficiency virus (HIV), types 1 and 2;

19.2 Hepatitis B virus (HBV);

19.3 Hepatitis C virus (HCV);

19.4 Treponema pallidum (syphilis) through VDRL

19.5 Chlamydia

20. The manner of making a complaint before a grievance cell and the mechanism adopted by clinic under clause (f) of section 21.

Every clinic and every bank shall maintain a grievance cell in respect of matters relating to such clinics and banks and the manner of making a compliant before such grievance cell shall be such as specified in Form 10.

21. The manner of providing information by the clinics and banks to the National Registry under clause (j) of section 21

All clinics and banks shall provide all information related to:

21.1 Enrolment of the commissioning couple, woman and gamete donors;

21.2 The procedures being undertaken; and

21.3 Outcome of the procedures, complications, if any, to the National Registry periodically.

22. The amount of insurance coverage for oocyte donor under clause (b) of Subsection (1) of section 22.

An insurance coverage of (amount)……for a period of twelve months in favour of the oocyte donor by the commissioning couple or woman from an insurance company or an agent recognized by the Insurance Regulatory and Development Authority established under the provisions of the Insurance Regulatory and Development Authority Act, 1999.

23. The manner of maintaining record by the clinics and banks under clause 9(a) of section 23.

23.1 Every ART Clinic and or Bank shall maintain a record of the names and addresses of the couple/woman who underwent ART procedure/tests, the names of their spouse or father and the date on which they first reported for such counselling, procedure or test.

23.2 All case related records, forms of consent, laboratory results, microscopic pictures, sonographic plates or slides, recommendations and letters shall be preserved by the ART Clinic/ Bank, for a period of ten years from the date of completion of ART procedures.

23.3 Every ART clinic/ bank shall send a complete report in respect of all ART related procedures/techniques/tests conducted by them in respect of each month by5th day of the following month to the National Registry.

24. The manner of collection of gametes posthumously under clause (f) of Section 24.

The collection of sperms posthumously shall be done only if prior consent of the

commissioning couple is available as specified in Form 11.

25. Other duties of the clinic under clause (h) of section 24.

25.1 Duties of ART Clinic

25.1.1 ART clinic shall ensure that all unused gametes /embryos shall be preserved by the assisted reproductive technology clinic for use on the same recipient and shall not be used for any other couple/woman.

25.1.2 ART clinics shall allow cryopreservation of oocytes, sperms for oncofertility patients undergoing treatment and for other such conditions, for duration longer than 10 years with permission from the National board.

25.1.3 Every ART clinic/ Bank shall intimate every change of employee, address and equipment installed, to the Appropriate Authority (at least thirty days in advance of the expected date of such change).

25.1.4 While retrieving oocytes, efforts should be made to retrieve not more than seven oocytes during one cycle from the donor. However, all formed follicles may be retrieved.

25.1.5 The Clinics shall ensure the controlled ovarian stimulation of woman in order to prevent ovarian hyperstimulation.

25.1 Consent forms to be maintained by the ART Clinics.

25.1.1 Consent Form to be signed by the Couple /woman as specified in Form 12.

25.1.2 Consent for Intrauterine Insemination with Husband's Semen / Sperm as specified in Form 13.

25.1.3 Consent for Intrauterine Insemination with Donor Semen as specified in Form 14.

25.1.4 Consent for Freezing of Embryos as specified in Form 15.

25.1.5 Consent for freezing gametes as specified in Form 16.

25.1.6 Assent for Freezing of Gametes Sperm/Oocytes & Parental consent as specified in Form 17.

25.1.7 Consent for withdrawal as specified in Form 18.

25.1.8 Consent for oocyte retrieval as specified in Form 21.

25.1.9 Any other duties as directed by the central government/ National Board & State Board

25.2 Consent forms to be maintained by the ART Banks

25.2.1 Record of use of Donor Gametes as specified in Form 19, 19 A, 19 B.

25.2.2 Results of screening of Semen Donors / Oocyte Donor as specified in Form 20.

25.2.3 Consent Form for the Donor of Sperm as specified in Form 22.

25.2.4 Consent Form for the Donor of Oocytes as specified in Form 23.

26. The examination of donors by the assisted reproductive technology banks for diseases under clause (c) of sub section (2) of Section 27

Sperm/oocyte donor is tested for the following diseases:

26.1 Human immunodeficiency virus (HIV), types 1 and 2;

26.2 Hepatitis B virus (HBV);

26.3 Hepatitis C virus (HCV);

26.4 Treponema pallidum (syphilis) through VDRL

26.5 Chlamydia

27. The manner of obtaining information in respect of a sperm or oocyte donor by a bank under sub section (6) of section 27.

Information about number of donors (sperm and oocyte), screened, maintained and supplied to the clinics shall be maintained and be provided to the National Registry regularly.

ART bank shall obtain all necessary information in respect of a sperm or oocyte donor as specified in Forms 24 A, 24 B.

28. The standards for the storage and handling of the gametes, human embryos in respect of their security, recording and identification under subsection (1) of section 28

28.1 Prior to the processing of patient gametes or embryos, intended for use in treatment or storage, the center must:

28.1.1 Carry out the following biological tests to assess the risk of cross contamination like HIV 1 and 2: Anti-HIV – 1, 2, Hepatitis B: HBsAg and Anti-HBc and Hepatitis C: Anti-HCV-Ab.

28.1.2 Semen culture shall be carried out on all semen samples before

28.1.3 Devise a system of storage of gametes and embryos clearly separating:

28.1.3.1 quarantined

28.1.3.2 unscreened

28.1.3.3 tested negative

28.1.3.4 tested positive

28.1.4 The center should have a separate storage facility of the gametes in case of HIV, Hepatitis, HCV and other such infected patients.

28.2 The center should ensure that the storage facilities for gametes and embryos:

28.2.1 are dedicated for the purpose, and adequate for the volume and types of activities

28.2.2 are designed to avoid proximity to ionizing radiation (radioactive material), any known potential source of infection and chemical/atmospheric contamination

28.2.3 have a storage-location system that minimizes the amount of handling required to retrieve gametes and embryos.

28.3 The center should also have procedures to deal with emergency situations that may cause damage to storage vessels, failure of storage conditions or both.

28.4 The center's documented procedures should also ensure that:

28.4.1 gametes and embryos are stored under controlled conditions that are validated and monitored.

28.4.2 gametes and embryos are packaged for storage in a way that prevents any adverse effects on the material and minimizes the risk of contamination.

28.4.3 records are kept indicating every occasion when gametes and embryos are handled during storage and release, and by whom.

28.4.4 records are kept indicating that gametes and embryos meet requirements for safety and quality before release.

28.5 The centers should store gametes and embryos in a designated area. Cryocans should be fitted with local alarms and be linked to an autodial or similar facility to alert staff to non-conformities outside normal working hours.

28.6 The center should have adequate staff and funding for an 'on-call' system for responding to alarms out of working hours, and adequate spare storage capacity to enable transfer of samples when required.

28.7 All the centers having facility should have emergency back-up plan to handle these gametes / embryos in case of power failure/ fire breakout.

28.8 A center storing gametes and/or embryos for patients whose future fertility may be impaired by a medical condition or procedure should divide individual patients' samples into separate storage vessels.

28.9 Transfer of stored gametes and embryos from one ART clinic to another ART clinic can be permitted after permission from the National Board along with transfer of all records with appropriate consent and acceptance of both ART registered clinics.

28.10 Make arrangements for storage for duration longer than 10 years for cases of oncofertility under special circumstances where permission has to be taken from the National Board.

29. The manner of obtaining the consent of the commissioning couple or individual for perishing or donating the gametes of a donor or embryo under subsection (2) of section 28

The consent form is as specified in Form 15 & 16.

30. The manner of performing research on human Gametes or embryo within India under sub section (2) of section 30.

30.1 The couples should provide consent for transfer of embryo/gamete to identified empaneled research institute and notified by the national board. as specified in form 15 & 16.

30.2 Research is permitted as per ICMR guidelines/ stem cell research guidelines/ and

biomedical ethics guidelines (subject to revision of the guidelines).

31. The manner of entry and search by the National Board, National Registry or the State Board or any officer authorized by it under sub section (1) of section 40.

Every ART Clinic / ART Bank shall allow inspection of the place, equipment and records to the National Board, National Registry, State Board or Appropriate Authority or any officer authorized in this behalf. Such an inspection of an already registered clinic may take place without any notice. It shall be ensured that entry and search procedure does not place at risk the gametes/ embryos stored in the facility.

32. Any other matter which is to be, or may be prescribed, or in respect of which provision is to be made under rules.

32.1 Public Information

32.1.1 At least one copy each of the Act and these rules shall be available on the premises of every ART Clinic/Bank and shall be

made available to the clientele on demand for perusal.

32.1.2 The Appropriate Authority, the Central Government, the State Government, and the Government/Administration of the Union Territory may publish periodically lists of registered ART Clinics/Banks and findings from the reports and other information in their possession, for the

information of the public and for use by the experts in the field while ensuring anonymity/ confidentiality of patients.

32.2 Meeting of the National/State Board

The Board shall meet at least once in six months and ensure that the quorum is maintained. The meeting may be conducted virtually or physically as per the instructions of the central government. The Board shall meet in place decided by the administrative ministry.

33. The board may co-opt the members for its meeting after approval of the central government for attending the proceedings of the said meeting

33.1 Any other functions/matter as directed by the Central Government.

Schedule 1 - Part 1

34. The staff requirements given below will be mandatory for all ART Clinics/Banks.

Level 1 ART Clinic - minimum staff requirement

01 Gynecologist with qualifications as specified below

01 Counselor with qualifications as specified below

Level 2 ART Clinic - minimum staff requirement

Director

02 Gynecologist with qualifications as specified below

02 Embryologist with qualifications as specified below (One Senior and one Junior

Embryologist)

01 Andrologist with qualifications as specified below

01 Anesthetist with qualifications as specified below

01 Counselor with qualifications as specified below

ART Bank - minimum staff requirement

01 Registered Medical Practioner trained in preparation and storage of semen sample

01 Counselor

35. Qualifications

35.1 Gynecologist

35.1.1 The gynecologist will be a medical post-graduate in gynecology and obstetrics and should have record of preforming 50 oocyte retrievals under supervision of a trained ART specialist (Records of procedures to be maintained) OR with three years of training in a registered ART center OR with superspecialist DM /fellowship in reproductive medicine or experience of not less than 03 years in reproductive medicine.

35.1.2 Understanding of the causative factors of male and female infertility.

35.1.3 Knowledge of the practice and use of diagnostic methods for determining the cause of infertility.

35.1.4 Knowledge of the clinical aspects of reproductive endocrinology and the reproductive defects caused by endocrine factors, and an understanding of the limitations of the currently used hormone assay methods, and of the techniques available for medically or surgically correcting endocrine disorders.

35.1.5 Competence in gynecological ultrasonography to diagnose reproductive tract anomalies; monitoring ovarian and uterine response to ovarian stimulation; picking up oocytes at the most appropriate time; and transferring embryos by any one of the several methods currently available to handle embryo transfer in 'difficult' cases.

35.1.6 Must be knowledgeable about the principles of ovarian stimulation and the management of complications arising thereupon.

The responsibilities of the Gynecologist will include

i) Interviewing of the infertile couple initially.

ii) History taking.

iii) Physical examination of the female.

iv) Recommending appropriate tests to be carried out, interpreting them and

treating medical disorders (such as infections and endocrine anomalies).

v) Carrying out gynecological endoscopy and ultrasonographic intervention for diagnosis and therapy of infertility.

vi) Carrying out ART procedure and other ancillary procedures as the case and facilities may warrant, based on diagnostic evidence.

vii) The ART specialist should do self-appraisal and maintain records for Audit.

35.2 Andrologist

35.2.1 The Andrologist in a clinic/ bank will be a urologist or a surgeon who has a post-graduate degree (MS General Surgery with training in Andrology that often takes on the task of treating male infertility along with some experience in the field of andrology or MCH/DNB Genitourinary surgery/Urology).

35.2.2 The additional experience includes:

35.2.2.1 training in diagnosis of various types of male infertility covering psychogenic impotence, anatomical anomalies of the penis which disable normal intercourse, endocrine factors that cause poor semen characteristics and / or impotence, infections, and

causes of erectile dysfunction.

35.2.2.2 knowledge of the occupational hazards, infections and fever that cause reversible or irreversible forms of infertility, and knowledge of ultrasonographic and Vaso graphic studies of

the male reproductive tract. He / she must also be wellversed in treating impotence and ejaculatory dysfunction.

35.2.2.3 he / she must understand the principles of semen analyses and their value and limitation in diagnosis of male fertility status. The andrologist must be able to collect semen by prostatic massage for microbial culture in cases where infection may lie in the upper regions (prostate, seminal vesicles) of the reproductive tract. He / she should also be able to collect spermatozoa through surgical sperm retrieval techniques, and be well-versed in the technique of electroejaculation. He must also be knowledgeable about the genetic implications of using poor-quality sperm for ICSI. He / she should be familiar with the surgical procedures available for correcting an anatomical defect in the reproductive system such as epididymovasalreanastomosis and varicocelectomy.

35.2.2.4 an individual may act as an andrologist for more than one clinic but each clinic where the andrologist works must own responsibility for the andrologist and ensure that the andrologist is able to take care of the entire work load of the clinic without compromising on the quality of service.

The responsibilities of the andrologist would include the following:

a) Recording case histories.

b) Prescribing appropriate diagnosis and treatment based on the diagnosis.

c) Carrying out such surgical procedures as warranted by the diagnosis.

d) Maintaining all the records, from the case history to the treatment given, and the patient consent forms.

e) Referring the couple to the Gynecologist for carrying out the appropriate ART procedure, if necessary, after the male factor has been duly investigated.

f) Referring the couple to the counsellor if necessary.

35.3 Senior Embryologist

35.3.1 Post graduate in clinical embryology (on site) / PhD holder (onsite) in clinical Embryology post-graduate degree(onsite) from a recognized university with additional one year of laboratory experiences of handling human Gametes and Embryos.

OR

Medical Graduate MBBS OR post graduate in life sciences/ clinical embryology/Biotechnology/Veterinary Sciences/Reproductive biology with minimal of 1 year on site clinical embryology certified training in addition to this have 2 years' experience of working in the Embryology lab of a registered ART level 2 clinic.

35.3.2 To ensure that all the necessary equipment's are present in the laboratory and are functional. He will be custodian of the laboratory and the functioning of the lab.

35.3.3 To perform all the procedures pertaining to processing, handling and culturing of gametes and embryos in the laboratory and hand over the embryo to the gynecologist.

35.3.4 To maintain records of all the procedures carried out in the laboratory.

35.4 Junior Embryologist

Graduate in Life sciences/ biotechnology/ reproductive biology/ veterinary science with three experiences in the relevant field OR Postgraduate in Life sciences/ biotechnology/ reproductive biology/ veterinary science.

35.5 Counsellor

35.5.1 A person who has at least a degree (preferably a post-graduate degree) in Social Sciences, Social work, Psychology, Life Sciences or Medicine, and a good knowledge of the various causes of infertility and its social and gender implications, and the possibilities offered by the various treatment modalities, should be considered as qualified to occupy this position. The person should have a working knowledge of the psychological stress that would be experienced by potential patients, and should be able to counsel them to assuage their fears and anxiety and not to have unreasonable expectations from ART. A member of the staff of an ART Clinic/Bank who is not engaged in any other full-time activity in the clinic can act as a counsellor.

35.5.2 The additional experience includes:

35.5.2.1 The counsellor must invariably apprise the couple of the advantages of adoption as against resorting to ART. An individual may act as a counsellor for more than one ART Clinic/Bank but each clinic where the counsellor works must own responsibility for the counsellor and ensure that the counsellor is able to take care of the entire counselling load of the clinic without compromising on the quality of the counselling service.

35.5.2.2 In ART Clinic/Banks carrying out pre-implantation genetic diagnosis or mitochondrial donation should ensure that patients have access to counsellors with appropriate knowledge and expertise in these specialisms, including a good understanding of the risks and implications for patients who have treatment involving mitochondrial donation techniques and any children that may be born following such treatment.

35.6 Anesthetist

Anesthetist should have a MD/ DA in anesthesia .The role of the anesthetist in a surrogacy clinic is to provide adequate comfort and pain relief to the patients during oocyte retrieval and embryo transfer procedures. The modality of the providing the same should depend on the patient cooperation. If the patient is comfortable, conscious sedation should be preferred. The ideal anesthetist technique should provide good surgical anesthetist with minimal side effects, a short recovery time, high rate of successful pregnancy, and shortest required duration of exposure. The key to anesthetist is to aim for pharmacological exposure of shortest duration with minimal penetration to follicular fluid anesthetist are also expected to have a broad general knowledge of all areas of medicine and surgery.

35.6.1 These include:

35.6.1.1 The management of airways and respiration.

35.6.1.2 The use of hemodynamic monitors to measure blood pressure.

35.6.1.3 The various methods of cardiovascular (heart) and pulmonary (lung) resuscitation should these organ systems suddenly fail

35.6.2 The role of the anaesthetist in IVF is to provide adequate comfort and pain relief to the patients during oocyte retrieval and embryo transfer procedures. The modality of the providing the same should depend on the patient cooperation. If the patient is comfortable, conscious sedation should be preferred. The ideal anaesthetic technique for IVF should provide good surgical anaesthesia with minimal side effects, a short recovery time, high rate of successful pregnancy, and shortest required duration of exposure. The key to anaesthesia is to aim for pharmacological exposure of shortest duration with minimal penetration to follicular fluid Anaesthesiologists are also expected to have a broad general knowledge of all areas of medicine and surgery.

35.6.3 There should be an anesthetic chart in the patient's notes, containing information such as:

35.6.3.1 Known drug allergies

35.6.3.2 Previous problems with an aesthetics or sedatives

35.6.3.3 Airway assessment

35.6.3.4 Whether the patient is taking any regular medication

35.6.3.5 Any post-operative instructions (e.g., whether the patient will need antibiotics).

35.6.4 The Clinics should ensure that their procedures are suitable for the type of anesthetic or sedative provided.

35.6.5 The Clinics should ensure that only an appropriately qualified person provides an anaesthetic. If an anaesthetic is used at remote sites clinics should have a resuscitation team led by an Advanced Life Support provider. Where this is not the case, the anaesthetists should provide competency-based evidence of their ability to provide both advanced life support and the safe transport of a patient requiring multi-system

35.7 Director

This should be a senior person who has had considerable experience in all aspects of ART. The director should be able to co-ordinate the activities of the rest of the team and ensure that staff and administrative matters, stock keeping, finance, maintenance of patient records, statutory requirements, and public relations are taken care of adequately. He / she should ensure that the staff are adequately trained and are keeping up with the latest developments in their subject, by providing them with information from the literature, making available to them access to the latest journals, and encouraging them to participate in conferences and meetings and present their data. The director should have a post-graduate degree in an appropriate medical or biological science. In addition, he / she must have a reasonable experience of ART.

Part 2

36. Requirement of Equipment and Facilities

36.1 ART Bank

36.1.1 A laboratory centrifuge

36.1.2 Laminar flow

36.1.3 Liquid nitrogen cans

36.1.4 Storage rooms and individual semen containers

36.1.5 A pharmaceutical refrigerator

36.1.6 Incubators

36.1.7 Microscope

36.1.8 Cryocans/ cryofreezers

36.1.9 Refrigerator

36.2 Level 1 ART Clinic

36.2.1 Centrifuge machine

36.2.2 Ultrasound machine

36.2.3 Laminar Air Flow

36.2.4 Binocular Microscope

36.2.5 Incubator

36.2.6 Semen wash processing facility

36.2.7 Refrigerator

36.3 Level 2 ART Clinic

36.3.1 Facility for control of temperature & humidity (Air handling unit)

36.3.2 Filtered air with an appropriate number of air exchanges per hour

36.3.3 Wall and floors are composed of materials that can be easily washed and Disinfected

36.3.4 A laminar flow bench with a thermostatically controlled heating plate

36.3.5 An IVF grade Stereo Microscope preferably with CCD camera and recording software

36.3.6 A routine high powered Trinocular light microscope (IVF grade and preferably with CCD camera and recording software)

36.3.7 A high-resolution inverted microscope with phase contrast or Hoffman Optics (with standard IVF grade objective), preferably with facilities for video recording

36.3.8 A micromanipulator

36.3.9 A CO2 incubator, preferably with a back up

36.3.10 A laboratory centrifuge

36.3.11 Equipment for freezing embryos

36.3.12 Liquid nitrogen cans for Screened Negative samples

36.3.13 Infected samples

36.3.14 A pharmaceutical refrigerator

36.3.15 Heating plates

36.3.16 Test tube heater

36.3.17 Heating blocks

36.3.18 Alloy blocks/ Plates

36.3.19 Biometrics (to restrict the entry)

36.3.20 Anaesthesia station and basic resusication equipment

36.3.21 VOC – Photoionisation detector

Part 3

37. Minimal Physical Requirements and Facilities for an ART Clinics and Banks

37.1 The clinics and banks should have facilities for reception, clinical and counselling activity, laboratory work, storage of confidential records, storing gametes and embryos, and staff.

37.2 The clinics and banks should display a copy of its Certificate of Registration where it can easily be read by current and potential patients and donors.

37.3 The centre should ensure that its clinical facilities:

1. provide privacy and comfort for those:

37.3.1.1 considering donation and seeking treatment

37.3.1.2 undergoing examination and treatment, and

37.3.1.3 producing semen specimens.

2. are equipped with backup and emergency clinical facilities that:

37.3.2.1 are appropriate to the degree of risk involved in any planned procedure, and

37.3.2.2 can cope with emergencies known to occur in this clinical field.

37.4 Counselling facilities

The clinics and banks should ensure that counselling facilities provide quiet and comfortable surroundings for private, confidential and uninterrupted sessions. The clinics and banks should have on its premises laboratory services or outsource the laboratory services as required.

37.5 A well-designed ART clinic / ART banks should have a non-sterile and a strictly sterile area. Some of the spaces mentioned below could be combined (that is, the same space may be used for more than one purpose) as long as such a step does not compromise the quality of service. However, the space provision for the sterile area cannot be combined with that for the non-sterile area and vice-versa.

37.5.1 Reception & Waiting area

37.5.2 Consulting Room/ Examination Room - A separate examination room with privacy for interviewing and examining male and female partners independently is essential. Adequate measures must be taken to ensure that history taking and examination are carried out in strict privacy, maintaining the dignity of the patients. In case a male doctor examines a female patient, there must always be a female attendant present. The room must be equipped with an examination table and gynaecological instruments for examining the female per vaginum, and an appropriate ultrasonographic machine.

37.5.3 Semen Collection Room: This must be a well-appointed room with privacy and an appropriate environment; it should be located in a secluded area close to the laboratory. Such a facility must be available in-house rather than having the patient collect the sample and bring it to the laboratory for analysis as, in the latter case, semen quality and identity is likely to be compromised. Procedures for collection of semen as described in the WHO Semen Analysis Manual must be followed with special reference to the type of container used; these containers must be sterile, maintained at body temperature and nontoxic. This room must have a washbasin with availability of soap and clean towels. The room must also have a toilet and must not be used for any other purpose.

37.5.4 Semen Processing Laboratory: There must be a separate room with a laminar air flow for semen processing, preferably close to the semen collection room. This laboratory must also have facilities for microscopic examination of post-coital test smears. Good Laboratory Practice (GLP) guidelines as defined internationally must be followed. Care must be taken for the safe disposal of biological waste and other materials (syringes, glass slides, etc.). Laboratory workers should be immunized against hepatitis B and tetanus.

37.5.5 IUI Room: There must be a separate area/room with an appropriate table for Intra-Uterine Insemination (IUI).

37.5.6 General purpose clinical laboratory (in house/referral) with a Blood Collection Area - This can be inhouse/ referral. The ART Clinic/Bank must have ready access to laboratories that are able to carry out immunoassays of hormones (FSH, LH, Prolactin, hCG, TSH, Insulin, Estradiol, Progesterone, Testosterone and DHEA) and tests such as for HIV and Hepatitis B. Endocrine evaluation constitutes an essential diagnostic procedure to determine the cause of infertility. It is also necessary to estimate blood estradiol in samples taken from a woman undergoing controlled ovarian hyperstimulation, and have the result on the same day to determine the dose of drugs to be given for induction of ovulation. Accurate monitoring of endocrine response to controlled ovarian stimulation goes a long way in preventing ovarian hyperstimulation.

37.5.7 Microbiology and Histopathology - Another important facility in an ART clinic (or easily accessible to it) would be that of a microbiology laboratory that can carry out rapid tests for any infection, and a clinical chemistry laboratory. Facilities for carrying out histopathological studies on specimens obtained from the operation theatre would also be desirable.

37.5.8 Autoclave Room - A separate facility must be available for sterilizing and autoclaving all surgical items as well as some of those to be used in the in vitro culture laboratory.

37.5.9 Operation Theatre - This must be well equipped with facilities for carrying out surgical endoscopy and transvaginal ovum pick-up. The operation theatre must be equipped for emergency resuscitative procedures. We should have laparotomy set with suture material. There has to be an emergency tie-up with nearby hospital in case of complications.

37.5.10 Embryo Transfer Room- This room must be in the sterile area and have an examination table on which the patient can be placed for carrying out the procedure and then rest undisturbed for a period of time. The operation theatre can be used for this purpose. The Operation Theatre

and embryo transfer room should be directly connected with the embryology laboratory complex. 37.5.11 The IVF/Culture Laboratory Complex - The embryology laboratory must have facilities for control of temperature and humidity and must have filtered air with an appropriate number of air exchanges per hour. Walls and floors must be composed of materials that can be easily washedand disinfected; use of carpeting must be strictly avoided. The embryology laboratory must have the following:

i) A laminar flow bench with a thermostatically controlled heating plate

ii) A stereo microscopeA routine high-powered binocular light microscope

iii) A high-resolution inverted microscope with phase contrast or Hoffman optics, preferably with facilities for video recording

iv) A micromanipulator (if ICSI is done)

v) A CO2 incubator, preferably with a back up

vi) A hot air oven

vii) A laboratory centrifuge

viii) Equipment for freezing embryos

ix) Liquid nitrogen storage tanks

x) A refrigerator

xi) Appropriate steps need to be taken for the correct identification of gametes and embryos to avoid mix-ups. Preferably by using appropriate labelling system preferably with barcodes.

xii) All material from the operation room, culture dishes and Falcon tubes for sperm collection (including lids), must bear the name of the patient. In the incubator, identified oocytes and sperm should be kept together on the same tray and double-checked.

xiii) Pipettes used should be disposed off immediately after use. The embryology laboratory must have daily logbook in which all the day's activities are recorded, including the performance of the

equipment.

37.5.12 Store Room- A well-stocked store for keeping essential stock of especially those items that have to be imported, precluding the need to be caught short in the middle of treatment, is required. Facilities must be available for storing sterile (media, needles, catheters, Petri dishes and such-like items) and non-sterile material under refrigerated and non-refrigerated conditions as appropriate.

37.5.13 Record Room - Record keeping must be computerized so that data is accessible retrospectively for analysis or when called upon by the supervisory agency. The data must include essential details of the patient's records, it must contain history of the cause of infertility as diagnosed earlier, results of new diagnosis if relevant, the treatment option best suited for the particular patient, the treatment carried out and the outcome of treatment, and follow-up if any. Any other noteworthy point such as possible adverse reaction to drugs, must be recorded. The software must have archival, retrieval and multivariate statistical analysis capabilities.

37.5.14 Fireproof cabinets can be used maintaining records and fire safety arrangements.

37.5.15 Steps for Vermin Proofing - Adequate steps should be taken to make the whole clinic vermin proof, with suitable traps for preventing insects and other forms of unwanted creatures entering the clinic. This essential detail should be planned at an early stage because no pesticide can be used in a fully functional IVF clinic, as it could be toxic to the gametes and embryos.

37.5.16 Maintenance & Quality Checks of the Laboratories: Each laboratory should maintain in writing, standard-operating manuals for the different procedures carried out in the laboratory. It should be ensured that there is no “mix up” of gametes or embryos. The donor identity number should be clearly labeled on all the tubes, dishes and pipettes containing the gametes. All pipettes should be immediately discarded after use. Laminar flow hoods, laboratory tables, incubators and other areas where sterility is required must be periodically checked for microbial contamination using standard techniques, and a record of such checks must be kept. A logbook should be maintained which records the temperature, carbon dioxide content and humidity of the incubators and the manometer readings of the laminar air flow. All instruments must be calibrated periodically (at least once every year) and a record of such calibration maintained.

37.5.17 Quality of consumables used in the laboratory: All disposable plastic ware must be procured from reliable sources after ensuring that they are not toxic. Culture media used for processing gametes should be preferably procured from reliable manufacturers. Each batch of culture medium needs to be tested for sterility, endotoxins, osmolality and pH. The embryologist should know the composition of the media that are being used. Most media are supplemented with serum; they should, therefore, be tested for antibodies to HIV 1 and 2, Hepatitis B Surface Antigen and Hepatitis C RNA.

37.5.18 Back-up Facility- There should be no interruption in power supply to the incubator and to other essential services of the ART Bank. Given the power supply situation in India, it is, therefore, imperative that a power back up in the form of UPS systems and/or a captive power generation system is available in ART Bank

''नारी का भारत – आपका परिपेक्ष''

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मैं स्त्री हूँ, मैं नारी हूँ, मैं कली हूँ, मैं ही फूलवारी हूँ।
जब भी ये पंक्तियाँ मेरे जहन में आती हैं, तो मेरा रोम –रोम प्रफुलित हो जाता हैं। जी हाँ, "मैं हूँ नारी, और गर्व से कहती हूँ मैं सब पर भारी"।
एक माँ, एकपत्नी, एक बेटी, एक बहन आदि, अपने सभी रिश्तों को पूरे दायित्व, निष्ठा और तत्परता से निभाती।
एक शक्ति का रूप – नारी।
नारी प्रेम में राधा बने, गृहस्थी में जानकी।
काली बन कर शीश काटें, जब बात सम्मानकी.....।

यदि हम अपने अतीत को देखे तो यह समझ आएगा कि वह एक स्वर्णिम काल था, जिसमें भारत के ऋषिमुनियों ने नारी के महत्त्व को भली– भांति समझा। सीता, सावित्री, अनुसुया, शबरी जैसे ज्ञानी विदुषियों ने इस देश की भूमिको अपने ज्ञान से अलंकृत किया।

यत्र नार्यस्तु पूज्यन्ते, रमन्ते तत्र देवता।
अर्थात जहाँ स्त्रियों की पूजा होती हैं, वहाँ देवता रमण करते हैं।

फिर समय बदला, भारतीय नारी के इस वर्चस्व से पुरुष अहम को ठेस लगने लगी, परिणाम स्वरुप नारी के प्रति ..... उनका महत्त्व घटने लगा, उन परत रह–तरह की पाबंदियां लगा दी गई, कई बार सामाजिक, तोकई बार पारिवारिक आर्थिक। फिर तो उसे न शिक्षा का अधिका स्थान ही अपने विचार व्यक्त करने का।

नारी का इतना घोर पतन हुआ कि वह अपना अस्तित्व ही भूल गई। मैथली शरण गुप्त जी ने अपनी पंक्तियों में बड़ा ही स्वाभाविक वर्णन किया हैं,

अबला जीवन हाय तुम्हारी यही कहानी, आँचल में हैं दूध और आँखों में हैं पानी।

पर जैसे हर सांझ के बाद सबेरा होता हैं और सूरज की किरणों को आप कभी रोक नहीं सकते।

धीरे धीरे भारतीय एक सामाजिक लहर जागृत हुई, जिसमें महापुरुष जैसे राजा राम मोहन रश्वय, दयानन्द सरस्वती, स्वामी विवेकानंद, सरोजनी नायडू, महात्मा गाँधी का अभूत पूर्व योगदान रहा।

भारतीय समाज ने नारी के महत्त्व को समझना शुरू किया तथा उसके बंधन शिथिल होने लगे। उसकी भूमिका परिवार सामाजिक निर्णय में समझी जाने लगी।

"मुंशी प्रेमचंद जी ने कहा – स्त्री पुरुष से उतनी ही श्रेष्ठ हैं, जितना प्रकाश अँधेरे से श्रेष्ठ हैं।

भारतीय स्वतंत्रता के बाद तो नारी स्वयं अपने अधिकारों सर्वांगिक विकास के लिए लड़ी। सब से महत्वपूर्ण घटना यह हुई कि भारत के संविधान में नारी को पुरुषों में सामान अधिकार दिए गए शिक्षा जो कि एक मुलभुत अधिकार हैं, वह सभी के लिए सामान रूप से दी जाने लगी , नारी मूलत: प्रतिभाशाली तो होती ही हैं, इन्हे यह अधिकार स्वच्छंदता पूर्वक मिलने सेवन में एक स्वच्छंद पक्षी की तरह खुले आसमान में पंख फैला कर उड़ने लगी। आज चाहे वह घर हो या फिर शिक्षा क्षेत्र हो, कला, विज्ञान, राजनीति, फैशन, खेलजगत, सौंदर्य क्षेत्र, फ़ौज आदि सभी क्षेत्रों में नारी का वर्चस्व हैं, और यह पुरुषों ने स्वीकारा भी हैं, एक शिक्षित नारी सिर्फ अपने ही नहीं वरण अपने पुरे परिवार के विकास प्रगति का कारक हैं। पर एक ज्वलंत सत्य यह भी हैं कि आज भी भारत के ग्रामीण क्षेत्रों में नारी की स्थिति विचार जनक हैं, अभी यह पुरुष के अहम्टेलदबी हैं, इसमें हमें जागरूकता लानी हैं, अभी भी गावों में लड़कियों को अधिक पढ़ाया नहीं जाता, उन्हें मूलभूत सुविधाओं जैसे शिक्षा, माहवारी के समय उचित साफ़–सफ़ाई , अलग शौचालय, गर्भावस्था में उचित देख भाल से किसी हद तक वंचित हैं, पर इसका सकारात्मक पहलु यह हैं कि हमारी प्रगतिशील सरकार इस क्षेत्र में प्रयासरत हैं और मुझे यह पूर्ण विश्वास हैं कि हम सभी के सामूहिक प्रयासों से हम सभी एक ऐसा भारतीय समाज का प्रारूप बनायेंगे , जिसमे नारी स्वछंदता से एक पक्षी की तरह विचरण करेगी, और हम सभी नारिया कह सकेंगें – ये भारत देश हैं मेरा।

उपसंहार – भारतीय नारी शिक्षित, शक्ति का रूप, त्याग, परिपक्वता की मूर्ति अपने संयमता प्यार, दुलार, सकारात्मक सोच कुछ करगुजरने की चाह में आज पुरुषों के मुकाबले कई गुणा आगे हैं, फिर भी उसके पाँव जमीं पर हैं। उसमें संसार की अपूर्वशक्ति सम्माहित हैं, वह अनेक रूप हैं, आज 21वी सदी की भारतीय नारी समाज के हर क्षेत्र में अपना लोहा मनवा रही हैं, उसके उज्जवल भविष्य की कामना करते हैं।

शक्ति महिलाओं की प्रतिक हैं, वह प्रति की बेहतरीन और सब से सुन्दर रचना हैं, इसके बिना कोई निर्माण संभवन नहीं हैं।

मुझे हैं अधिकार औरों साही खड़े होने का अपने दोनों पावों पर।
मैं थक गयी सुन सुन कर जैसा हैं चलने दो
कल होगा नया दिन नहीं वह दिन आज हैं, अभी हैं,
मैं शक्ति, स्वरूपा, सम्पूर्ण, सक्षम धात्री हूँ।

नारी का भारत..

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देश का सम्मान प्रतीक है,
अपनी धरती अपनी भारत माता है.
युग युग मे इस जग मे अनेको बदलाव हुये..
दुनिया की विभिन्नता मे जो बदली नही वो नारी है
वो विधाता है!

नारी का भारत ये नारी से निर्मित है,
समाज के समुद्रमंथन से निकला पवित्र अमृत है.
जिसमे कडवा परंपराओ का विष भी घुला है,
ओर पावन धर्म का रस भी मिला है.
ये रत्नो से रचीत इतिहास की मूतह्न भी है,
ओर अनेक समय कर्तव्यों से उभरती आहुती भी है.

देश तो आजाद है अपना लेकीन नारी के लिये आजादी अभी भी हिस्सो मे बटी है,
उसके व्यक्तित्व को तराशने मे कई सदिया कटी है
कही आझाद मतलब मुक्ता स्वच्छंद है कोई
कही बस्स ख्वाबो के मकान बांध उसमे बंद है कोई.
यहा खोकली प्रथाओ से भरा प्राचीन अवशेष भी है
ओर नवनिर्माण पे सजा सफलता का भेष भी..

ये वही कल है जो नारी द्वारा इतिहास मे लिखा गया था.
ये वही आज है जो उसने अपने कर्तुत्व से रचा है.
यहा द्रौपदी का आक्रोश भी गुंजता है
जो धर्मस्थापना का संदेश बना
यहा सीता की अग्नीपरिक्षा भी झुलझती है
जिसने पवित्रता के प्रतीक को चुना.

एक पर्व यहा जब एक नारी ने पुरा देश चलाया है
आज वो गर्व भी है जो देश विदेशों मे जितकर कमाया है
यहा नारीयों के कुर्बानीयों की कहानी भी है
उस कुर्बानी की अहसास है और कामयाबी की निशाणी भी है.

कुछ ये पेहलू है नारी के कुछ और भी
जितनी सहज सरल दिखती है ये दुनिया उसमे कुछ गैर भी..

यहा वो सुबह होती है जहाँ आशाओ की रोशनी चमकती है
यहा वो कारात्र भी है असुरक्षितता का साया भी है
जहा सराहा गया सजाया गया है इसे गुडिया की तरह
वही खीलोना समझ के इसके साथ खीलवाड भी हुआ है
यहा न्याय की मूतह्न के आखों पर पट्टी भी है
अन्याय के डागो को घुंघट मे छिपती सक्ती भी है..

जहा भव्य शक्ती रूप को पुजकर धर्म को निभाया गया है
वही निर्मनुष्यता से ऊसी रूप के नन्हे अंश को दफनाया भी गया है
अगर वो कुदरत का करिश्मा है
वो कुदरत का कहर भी बन सकती है
वो सहिष्णुता की पराकाष्ठा है
वो अटल अविचल भी बन सकती है.

लढाई वो अभी तक लढ रही है यहा
रुकती नहीं है कभी थक जाना उसको रास नही .
ये दुनिया उसने बनायी है उसकी किमात क्यु चुकाये वो ये उसिकी कमाई है.
वो बदलती नहीं वक्त के हर पेहलु संग ढलती जाती है
वो पिघलती नहीं वो खुद ज्वाला बनके सुलघ जाती है
जितनी मासूम है उतनी भीषण भी
जितनी मधुर है उतनीही कठोर ओर तीक्ष्ण भी।

वो आज की नारी है ये आज का भारत है
उसमे अभिभी वही चिंगारी है वो अपने अस्तित्व की मशाल को कायम जलता रख सके.
वो हर रूप मे हर स्थिती मे शक्ती का प्रतीक है सम्मान है
नारी है तो सिद्ध ये जहान है.

नारी का भारत..

Dr. Sharda Mishra
Sr. Consultant Jabalpur

नारी का भारत कहे या भारत की नारी का महत्व ऋषि मुनियों के समय से ही महत्व पूर्ण रहा है जब हम नारी के भारत की बात करते है तो सीता,सावित्री ,अहिल्या, कुंती, द्रोपदी ,गागह्न, मैत्रयी,गांधारी जैसी नारियों का नाम खुद ब खुद जुबान पर आ जाता है जो किसी न किसी परिपेक्ष में अग्रणी रही उनके महत्व को ;षि मुनियों ने भी सराहना की ।उन्होंने भारत के नाम को रोशन किया ।जिनका नाम लेते ही सर गर्व से ऊंचा हो जाता है ।की उस समय भी नारी का कितना विकास हुआ उसे महत्व दिया जाता था ।

लेकिन मध्य काल में नारी का समय बहुत बदला, हमारे समाज की कुप्रथाओं ने नारी के महत्व को कम कर के देखा उसे सिर्फ भोग विलास की वस्तु ही समझा, उसके प्रति श्रद्धा कम हो गई विदेशियों के आने से इस पर और ज्यादा प्रभाव पड़ा, इसका परिणाम यह हुआ कि नारी ,नारी न रह कर पुरुष की भोग विलास की वस्तु वा उसकी जायदाद बन कर रह गई जिसे उसकी सुरक्षा के नाम पर चार दीवार में बंद कर दिया गया ।उसकी शिक्षा का अधिकार घर के किसी भी विषय में निर्णय लेने तक में उसकी कोई भागीदारी नहीं होती थी । वह सिर्फ पुरुष की वासनाओं को पूरा करने की वस्तु या कहे कटपुतली बन कर रह गई ।वह स्वयं अपने अस्तित्व को ही भूल गई वह जीवन भर पिता ,भाई,पति एवम पुत्र के ही संरक्षण में रहने लगी, वह खुद भी अपने आप को भूल गई की वो भी एक इंसान है उसकी भी कुछ इच्छाएं है वह पुरुष वर्ग की इच्छाओं की पूर्ति में अपने को धन्य समझती रही ।

लेकिन कहते है की हर चीज की एक सीमा होती है बीसवीं सदी के कुछ लोगो ने नारी की इस स्थिति को समझा कि यह नारी के साथ अन्याय है इसमें राजा राम मोहन राय, महर्षि दयानंद प्रमुख थे जिन्होंने पर्दा प्रथा तथा सती प्रथा को समाप्त करने में मदद की ।तभी से कुछ सामाजिक बदलाव शुरू हुआ नारी ने भी अपने सोए हुए सम्मान को जगाना शुरू किया। नारी पुन: शिक्षित होने लगी ,कई सामाजिक एवम राजनैतिक आंदोलनों में भी भाग लिया जैसे कस्तूरबा गांधी, सरोजिनी नायडू,विजय लक्ष्मी पंडित ,सावित्री बाई फुले जिन्होंने नारी शिक्षा को बढ़ावा दिया।

भारत की स्वतंत्रता के साथ ही नारी को भी कुछ स्वतंत्रता मिली उसको भी कुछ महत्व मिलना शुरू हुआ । पुरुष वर्ग को भी यह बात समझ आने लगा की नारी के विकास के बिना परिवार तथा समाज का विकास संभव नहीं है।और नारी ने भी शिक्षा ,विज्ञान,कला तथा राजनीति में अपनी भागीदारी दे कर अपने आपको साबित किया की वह पुरूषों से कही कम नहीं हैं ।

फिर भी इन क्षेत्रों में अपनी भागीदारी के साथ साथ उसे उन क्षेत्रों में भी अपने आपको साबित करना पड़ता है जो वह शुरू से कर रही थी जैसे बच्चों की परवरिश करना ,परिवार के लिए भोजन बनाना, घर के अन्य कार्य भी उसको ही करने होते हैं ।

इन सब परपेक्ष में अगर देखे तो वह पुरषो से अधिक ही कर रही है ।एक पुरुष सिर्फ परिवार के लिए पैसा कमाने के लिए नौकरी करता है तो एक नारी उसके इन कामों में उसके साथ कंधे से कन्धा मिलाकर बाहर भी करती है साथ ही अपनी घरेलु जिम्मेदारियों को बखूबी निभाती है ।

आज की नारी ने यह सिद्ध कर दिया की भारत की नारी संसार की किसी भी जाति की नारी से कम नहीं है चाहे शिक्षा ,बु) ,सौंदर्य या वीरता में ही हो ।जैसा आपने अभी हाल में ही देखा की नारी ने सेना में जाने के लिए कितनी कानूनी लड़ाई लड़ी और विजय हासिल कर सेना में अपनी वीरता के लिए भी जगह बनाई । पर आज भी सभी नारियां इतनी सौभाग्यशाली नही है विशेषकर ग्रामीण क्षेत्रों में उनकी स्थिति आज भी उतनी अच्छी नहीं है वह आज भी बहुत सी सामाजिक कुरीतियों का सामना करने को विवश है।लेकिन अब गांवों में भी शिक्षा का विकास हो रहा है अगर यही रफ्तार रही तो एक दिन भारत की सभी नारियां शिक्षित होंगी क्योंकि नारी जब कुछ करने की सोच लेती है तो वह कुछ भी कर सकती है बस आज अगर नारी पीछे है तो अपने शारीरिक संरचना के कारण जिसके लिए उसे आने वाली पीढ़ी को जूडो कराटे के प्रशिक्षण पर भी जोर देना चाहिए ।

स्त्री एवम पुरुष समाज के दो पहिए है जिनके कुछ नैसर्गिक गुण है जिसके महत्व को एक दूसरे को समझने की भी जरूरत है,कुछ चीजे जेनेटिक भी होती है, जिस पर भी हमे एक दूसरे को समझने की जरूरत है। आज भी अगर हम सब तरफ देखे तो नारी कुंए से पानी भरती,खेतो में काम करती ,मजदूरी करती से लेकर लड़ाकू विमान उड़ाती तक मिल जायेंगी बस जरूरत उनके अंदर छिपे हुए गुण को समझने की। नारियों के लिए बहुत सुधार भी हुए उन्हें घरेलू अत्याचार से बचाने के लिए कानून भी बनाए गए पर वही कुछ महिलाएं उन कानूनों का दुरुपयोग करती भी नजर आती है।

नारी जहां ममता रूपी है फूल सी कोमल है वही वह कठोर होने पर दुर्गा रूपी भी है । हमसभी को मिलकर नारी के सर्वांगीण विकास के लिए प्रयास रत रहने की ज़रूरत है उनको समाज में न्याय तथा उचित सम्मान मिले इसकी कोशिश करते रहना चाहिए ।

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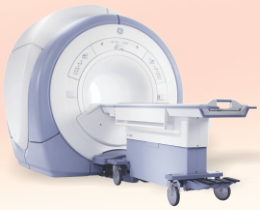

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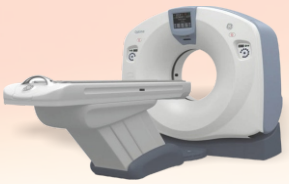

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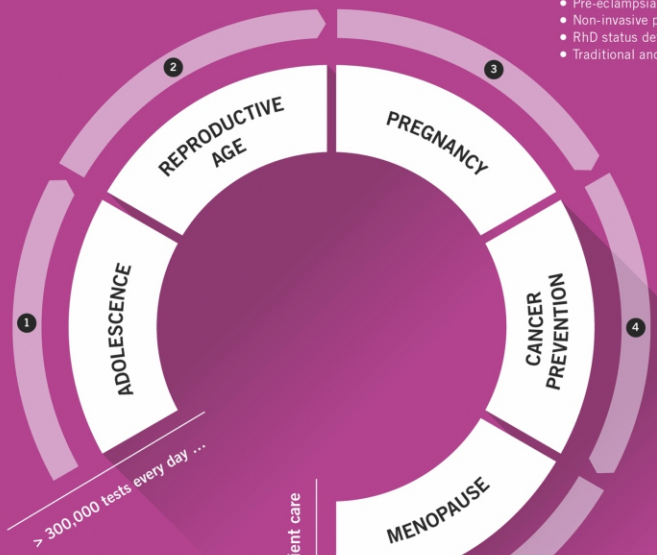
- Contraception – thrombosis profile
- Hemorrhagic diseases diagnosis (hemophilia, Willebrand disease and other)
- Wellness (skin problems, sports performance, stress)

2. REPRODUCTIVE AGE
- Fertility disorders: genetic and hormonal tests
- Endometriosis diagnosis
- Premature ovarian failure diagnosis
- Miscarriage: genetic, hormonal and immunological testing
- Medically assisted procreation

3. PREGNANCY
- First and second trimester maternal screening
- Fetomaternal infections: Toxoplasmosis, Rubella, Cytomegalovirus (CMV), Herpes simplex virus (HSV)
- Fetomaternal erythrocyte alloimmunization
- Open neural tube defects
- Pre-eclampsia testing
- Non-invasive prenatal testing (NIPT)
- RhD status determination via NIPT
- Traditional and molecular karyotyping



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