RAMA UNIVERSITY

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FACULTY OF NURSING

PRINCIPLES OF ETHICS

Beneficence

Beneficence is to act in the best interests of the patient, and to balance benefits against risks. The benefits that medicine is competent to seek for patients are the prevention and management of disease, injury, handicap, and unnecessary pain and suffering and the prevention of premature or unnecessary death.

Autonomy

Autonomy means to respect the right of the individual. Respect for autonomy enters the clinical practice by the informed consent. This process usually understood to have 3 elements, disclosure by the physician to the patient's condition and its management, understanding of that information by the patient and a voluntary decision by the patient to authorize or refuse treatment.

Non maleficence

It means that a health personnel should prevent causing harm and is best understood as expressing the limits of beneficence. This is commonly known as primum non nocere' or first to do no harm.

Justice

Justice signifies, to treat patients fairly and without unfair discrimination, there should be fairness in the distribution of benefits and risks. Medical needs, and medical benefits should be properly weighed.

Confidentiality

Confidentiality is the basis of trust between health personnel and patient. By acting against this principle one destroys the patient trust.

PATIENT RIGHTS

- The right to be treated with respect and dignity without reference age, marital,
- socio-economic, ethnic, national, political, mental, physical or religious status.
- The right to use informed choice is care, by having access to relevant information upon which decisions are based.
- The right to freedom from coercion in decision making.

- The right to accept or to refuse treatment.
- The right to full disclosure of financial factors involved in her care.
- The right to know who will participate in her care and obtain
- additional consultation of her choice.
- The right not to be abandoned, neglected or discharged rom care without an opportunity to find other health provider.
- The right to absolute privacy except where this right is pre-empted by law.

LEGAL AND ETHICAL PRINCIPLES IN THE PROVISION OF HEALTH SERVICES

1. Informed decision making.

Patients or individuals who require health care services have right to make their own decision about the opinions for treatment or other related issues. The process of obtaining permission is called informed consent.

The health care provider should disclose the following details:

- The individual is currently assessed health status regarding the general or reproductive health.

- Reasonably accessible medical, social, and other means of response to the individual's conditions including predictable success rates, side effects and risks.
- The implications for the individual's general, sexual and reproductive health and lifestyle declining any of the options or suggestions.
- The health provider's reasoned recommendation for a particular treatment option or suggestion.

Autonomy:

- Autonomous persons are those who, in their thoughts, work, and actions, are able to follow norms chosen of their own without external constraints or coercion by others. It is to be noted that autonomy is not respect for patient's wish against good medical judgement. Simply put, a health provider can refuse a treatment option chosen by the patient, if the option is of no benefit to the patient.

Surrogate decision makers:

Surrogate decision makers[parents, caregivers, guardians] may take the decision if the affected individual's ability to make a choice is diminished by factors such as extreme youth, mental processing difficulties, extreme medical illness or loss of awareness.

2. privacy and confidentiality

- A patient's family, friend or spiritual guide has no right to medical information regarding the patient unless authorized by the patients. The following points of confidentiality are to be kept in mind:
- health care providers duties to protect patient's information against unauthorized disclosures.
- Patient's right to know what their health care providers think about them.

- Health care provider's duties to ensure that patients who authorize releases of their confidential health related information to others, exercise an adequately informed and free choice.

3. Competent delivery services:

- Every individual has a right to receive treatment by a competent health care provider who knows to handle such situations quite well. According to the laws, medical negligence is shown when the following 4 elements are all established by a complaining party.
- A legal duty of care must be owed by a provider to the complaining party.

Breach of the established legal duty of care must be shown, which means a health care provider has failed to meet the legally determined standards of care.

- Damage must be shown.
- Causation must be shown.

4. Safety and efficacy of products:

Health care providers are responsilble for any accidental or deliberate use of products that differs from their approved purposes or methods of use, for instance, the dosage level for drugs. Look for the drug contraindications, drug expiry, damage of diluted sterilization solvents etc.

5. Code of ethical midwifery practice

Midwives rights:

 The right to refuse care to patients with whom no midwife- patient relationship has been established.

 The right to discharge patients from her acre, provided adequate information from patients upon which caring is based.

 The right to receive honest, relevant information from patients upon which
caring is based.

 The right t receive reasonable compensation for services rendered.

Midwives responsibilities:

- The obligation to serve as the guardian of normal birth, alert to possible complications, but always on guard arbitrary interference in the birthing process for the sake of convenience or the desire to use human beings in scientific studies and training.
- The obligation to honour the confidence of those encountered in the course of midwifey practice and to regard everything seen and heard as inviolable, remembering always that a midwife's highest loyalty is owed to her patient and not to her health care providers.

- The obligation to provide complete, accurate and relevant information to patients so that they can make informed choices regarding their health care.
- The obligation, when referring a patient to another health care provider, is to remain responsible for the patient until she is either discharged or formally tranfered.

- The obligation never to comment on another midwife's or other health provider's care without first contacting that practitioner personally.
- The responsibility to develop and utilize a safe and efficient mechanism for medical consultation, collaboration and referral.

- The obligation to pursue professional development through ongoing evaluation of knowledge and skills and continuing education including diligent study of all subjects relevant to midwifery.
- The responsibility to assist others who wish to become midwives by honestly and accurately evaluating their potential and competence and sharing midwifery knowledge and skills to the extent possible without violating another section in this code.

- The obligation to know and comply with all legal requirements related to midwifery practice within the law to provide for the unobstructed practice of midwifery within the state.
- The responsibility to maintain accountability for all midwifery care delivered under her supervision. Assignment and delegation of duties to other midwives or apprentices should be proportionate to their educational preparation and demonstrated proficiency
- The obligation to accurately document the patient's history, condition , physical progress and other vital information obtained during patient care

Unprofessional conduct:

- Knowingly or consistently failing to accurately document a patient's condition, responses, progress or other information obtained during care. This includes failing to make entries, destroying entries or making false entries in the records pertaining to midwifery care.
- Performing or attempting to perform midwifery techniques or procedures in which the midwife is untrained by experience or education.

- Failing to give care in a reasonable and professional manner, including maintaining a patient load, which does not allow for personalized care by the primary attendant.
- Leaving a patient intrapartum without providing adequate care for the mother and infant.
- Delegation of midwifery care or responsibilities to a person who lacks ability or knowledge to perform the function or responsibility in question.

- Manipulating or affecting a patient's decision by withholding or misrepresenting information in violation of patient's right to make informed choices in their health care.
- Failure to report to the applicable state board or the appropriate authority in the association, within a reasonable time, the occurrence of any violation of any legal or professional code.

ETHICAL DECISIONS AND REPRODUCTIVE HEALTH OF WOMEN

Ethics in gynaecologic practice

- Beneficence-based and autonomy-based clinical judgements in gynaecologic practice are usually in harmony, like management of ruptured ectopic pregnancy. Sometimes they may come into conflicts. In such situation, one should not override the other. Their differences must be negotiated in clinical judgement and practice to determine which management strategies protect and promote the patient's interest.

Ethics in obstetric practice

- There are obvious beneficence-based and autonomy based obligation to the pregnant patient. While the health professional's perspective on the pregnant woman's interest provides the basis of beneficence based obligations, her own perspective on those intersts provides the basis for autonomy-based obligations. Because of insufficiency developed central nervous system, the fetus cannot meaningfully be said to possess values and on its interest. Therefore , there is no autonomy based obligation to the fetus.

- *Ethics and assisted reproduction:*

It involves many issues like donor insemination, IVF, egg sharing, freezing and storing of embryos, embryo research and surrogacy.still many ethical issues are involved in IVF. First there is a big question whether the in vitro embryo is a patient or not. It is appropriate to think that it is a pre-viable fetus and only the woman can give it the status of a patient. Hence pre-implantation diagnostic counselling is non-directive and counselling about how many embryos to be transferred should be evidenced based

Donor insemination raises the issue whether the child should be told about his genetic father or not. Egg sharing is also surrounded by many ethical issues. Ethics changes from time to time keeping pace with changing social values, the surrogacy issue being example. It was considered unethical few years back, now in recent issue of India today, a lengthy article has appeared supporting surrogacy with the name of the center, the photos of the physician and number of happy surrogate mothers.

Ultrsonography:

- There are many issues involved like competence and referral, disclosure, confidentiality and routine screening. The foremost issue is that the sonologist must be competent enough to give a definitive option. Now routine screening is adopted at 18-20 weeks, but prior to screening the prenatal informed consent for sonogram must be taken. Strict confidentiality should be maintained.

Genetics and ethics:

- The process of genetic research raises difficult challenges particularly in the area of consent, community involvement and commercialisation. However it must be recognized that many of these issues are not unique to genetics but rather represents variations and new twists on problems that arise in other types of research.

Results of genetic research should be provided to subjects only if the tests have sufficient clinical validity. Results should never be disclosed to relatives, except in case of pedigree research.

Policies regarding disclosure of test results should be included in the informed consent process. The genomic era posses challenges for the international community and research enterprises. Council for international organization of medical sciences[CIOMS] guideline should address the ethical issues of genetics. The goal is to care and protect greatest sources of human suffering and premature death and to relieve pain suffering caused by the disorder.

Conception and the young girl:

Sometimes teenaged girls request for oral contraception. They are already in an active sexual relationship. They do not want that their parents should know about them taking contraceptives.

Lord Fraser's ethical recommendations include:

- We should assess whether the patient understands advice.

- We should encourage the parent involvement.
- We should take into account whether the patient is likely to sexual intercourse without contraceptive treatment.
- We should assess whether the physical, mental health would likely to suffer, if contraceptive advice is not given.

Embryonic stem cell research and ethics:

This involves many ethical issues and first and fore most is, it is destroying a life by destroying the fertilized embryo. This raises the fundamental question of when life starts. Does human life begin at gastrulation[next step after blastula] , at neurulation[formation of a primitive streak, first signs of movement] or at the moment of sentience[consciousness]? When can embryo first feel pain or first suffer?. The goal should be minimize the exploitation of human embryos at any stage of development.

The impact of law on ethics:

- Ethics is involved with moral judgements, and the law, however, concerns public policy. At one level it defines what one can / cannot or must/ must not do to avoid risk of legal penalty. Ethics encompasses much more than law. Ethics can determine what is right in the sense that it is good. The intention of law is to define what is right in the sense that it is or is not permitted. It can be safely concluded that not only is determining that something is unethical, neither a necessary nor a sufficient reason to make it illegal, but also determining that something is lawful does not necessarily make it ethical. In many occasions the law assist clinical decision-making by setting parameters which helps both the patient and physician.

MEDICO-LEGAL ASPECTS OF OBSTETRICS

- **REASONS FOR OBSTETRIC LITIGATION**
- Displeasure against medical professional due to
- Lack of communication

Poor attitude or more so because of a poor outcome are causative factors for litigation.

POTENTIAL AREAS OF
LITIGATION IN OBSTETRICS:

- **Antepartum care:**

History collection:

Recently, pre-conceptional care is stressed more than only antenatal care, specially when viewed in the context of its effect on pregnancy. History taking right from the age of the patient with relevant complaints and relevant past and family history with special reference to the obstetrical history is very important. Only history can be a clue for further diagnosis and management of many cases. Avoidance of any relevant factors cause maternal and fetal hazards.

Diagnosis

- Clinical diagnosis of early pregnancy must be confirmed by biochemical and if necessary by USG.

Investigations

- One must not forget to do routine check-up like Hb, ABO, Rh, grouping, blood sugar, HbsAg, VDRL and HIV. HIV testing must be done only after informed consent; otherwise the patient may sue the doctor. High risk pregnancies are only picked up by through history taking, routine examinations and investigations. High risk patients and failure of timely referral creates medicolegal problems.

Subsequent visits:

Antenatal screening for congenital abnormalities

- In patients having history of congenital abnormal babies at least basic screenings are very necessary to avoid litigations. The basic screening is mostly done by USG. Other examinations like CVS, amniocentesis or some biochemical investigations may be necessary depending on the individual case. Patient's counselling is very necessary regarding false positive and negative test thereby avoiding legal problems.

Intrauterine growth retardation

- Apart from clinical suspicion of IUGR modern gadgets like ultrasonography, CTG and ultrasonic Doppler study to detect the end diastolic flow volume- are important. Failure of timely detection of IUGR may cause intrauterine fetal death and the doctor may have to the court for this reason.

Multiple pregnancy

- It is a high risk pregnancy involving two fetal lives. Management problem is such a case may cause fetal complication which will invite legal problems.

Intrauterine fetal death

- The cause of IUFD must be explored. As routine autopsy in India is not performed and unexplained fetal death; may impose problems of medical litigation

Sex selection and PNDT act

- In view of the falling sex ratio the Indian government promulgated Prenatal Diagnostic Technique Act in 1994. This test by this act was evolved to identify genetic and congenital abnormalities in relation t sex. Unfortunately this test was misused. Prenatal sex determination and selective female feticide became widespread allover in India inspite of the amendment of PNDT act in 2002, the amended act prohibits unnecessary sex determination without any disease problem and aims at preventing selective abortions of female foetuses. However, still unethical practice of selective abortions is going allover India.

Intrapartum care

- Proper intrapartum management during labor is essential for a healthy mother and a healthy child. In majority of the mothers there is spontaneous onset of labor. Injudicious administration of oxytocics was the primary reason disciplinary action in 33 percent of cases. Randomised controlled trial of EFM and auscultation of fetal heart rate found that an increased incidence of caesarean delivery and decreased neonatal seizures in the EFM group but no effect on cerebral palsy or perinatal death. Newer methods like pulse oximeter or fetal electrocardiogram analysis can prevent birth asphyxia and thereby minimize litigations.

Caesarean section:

- With the advent of CPA; there is an increased incidence of caesarean section. The WHO global study 2005 revealed that high rate of caesarean section does not contribute to an improved pregnancy outcome, rather is associated with increased maternal morbidity and mortality with higher incidence of newborn illness due to low birth weight.
- Delayed decision of CS must be avoided as this may lead to undesirable situations like obstructed labor causing maternal and fetal morbidity and mortality.

- *Difficult vaginal delivery:*

Shoulder dystocia

- Various clinical risk factors like diabetes leading to big baby etc; must be identified to predict and prevent this condtion and associated injuries like erb's palsy. But if we afce such situations in emergency obstetric care it must be tackled by experienced obstetrician otherwise litigation problem are there.

Breech

- Timely decision to be taken whether to deliver the breech by vaginal route or CS so as to avoid legal problems.

Multiple pregnancy

- Involves enormous risk and modern concept is to be delivered by CS.

Instrumental delivery-forceps/vaccum

- High forceps must be avoided; only low forceps can be indicated in special circumstances to expedite the labor process. Ventouse must be avoided in premature baby and fetal distress. Concerned personnel may be sued due to untoward effects like facial palsy or visceral injury of mother and baby.

Emergency obstetric care:

- Every year more than 500000 women die during child birth in the world; out of which 1/5 th, ie 100000 women die in india alone. With present situation when there is no improvement of infrastructure yet doctors have the risk of facing medicolegal problems regarding EmOc.

Postpartum care:

- **Postnatal complete perineal tear,**
  Obstetric anal sphincter injuries[OASIS]

Significant perineal pain, dyspareunia, maternal morbidity and mortality and anal incontinence are problem areas. Forceps delivery is associated with increased perineal injury. Patients must be counselled about the risk of anal sphincter injury when operative delivery is contemplated thus avoiding litigations.

Perinatal morbidity

- ***Brain damage:***
- Any neurological and psychological deficiencies is the major litigation issue where compensations are claimed. A health professional will be sued if it can be proved in the court that brain damage has occurred during intrapartum period due to negligence of the health professional.

- ***Damage to bones and visceras***
- This may occur specially during breech delivery. Health professional must be very conscious during face, legs and arm delivery in breech.
- ***Analgesia and anaesthesia:***
- Expert anaesthetist is required; to prevent medical litigations.

Drugs in pregnancy and lactation

- Though only a small group of drugs are known to be harmful to the fetus; but it is a wise precaution to avoid vast majority of drugs; if not genuinely indicated, ie if there is less evidence of fetal safety. FDA recommendation of drug should be followed. The health professional must not use off-license drugs. If damage occurs; he will be blamed of negligence when a licensed alternative drug is used.

Ethical issues in surrogacy:

- Surrogacy is possible by AID and IVF, where a child is borne in another mother's womb. A lady without uterus but functioning ovaries can have a child with the help of a surrogate mother. According to fertilization act 1990, the carrying mother is the mother in law. Genetic mother can get legal parenthood by legal procedures only. Surrogacy for convenience only; when the women is physically capable of bearing a child is ethically unacceptable.

HIV- positive women and pregnancy

- In an overwhelming number of cases, children of HIV positive women acquire the infection before or around the time of birth or through breast milk. The risk of vertical transmission can be potentially reduced to less than 2% by the judicious use of combination anti retro viral therapy during pregnancy and labour, delivery by caesarean section and avoidance of breastfeeding.
- The legal standard of care in prenatal care and child birth is entitled to an HIV positive women if she decides to continue the pregnancy. Neither the woman nor her child should suffer any discrimination on their HIV status.

POTENTIAL AREAS OF LITIGATION IN GYNAECOLOGY

- Failure of diagnosis or delay in diagnosis-17%
- Failure to recognize complications - 7%
- Intraoperative problems - 32%
- Failed sterilization - 6%
- Failure to warn or inadequate consent- 3%

Examination of gyaecological patient

- **Professional and personal conduct**
- Not infrequently, the midwife has to face the charge of physical and sexual assault. prior to examination consent must be taken and she must be informed about the nature of examination. Examination should be done in a closed space in comfortable position maintaining the privacy in presence of a female attendant. The attendant should not be the relative of the patient.

Forensic gynaecology

- Sexual assault and rape must be handled in a sensitive manner while complying with forensic procedure. Domestic violence and sexual violence in areas of conflict are now recognized as major factors in women's health as studied by the united-nations and by human rights groups.

- **Consent**

The consent form is the single most important document, created in the presence of the patient, which removes obstacles to effective communication concerning choice. The key to effective communication is:

- Engaging with the patientEmpathizing with her needs
- Educating her as to the available options.
- Enlisting her approval for the appropriate choice

- Only after engagement, empathy, and education is it appropriate for a clinician to ask for the approval of the patient. It will always be appropriate to record the decision. It will sometimes be appropriate for the patient to append her signature to an appropriate form. Valid consent must be taken from the patient.

Diagnosis of gynaecologic diseases

- No step should be omitted in history collection and clinical examination. Investigative procedures should be suggested as needed. Opinion of other speciality is sought in doubtful diagnosis before instituting definitive therapy.

Medical termination of pregnancy

Complications of abortion sometimes leads to complaints and litigation. The act was legally enacted in 1971 and implemented in April 1972 and amended from time to time. The basic principle is that pregnancy can be terminated when there are some maternal or fetal indications and in India it is done before 20 weeks.

Legal problems occur in certain conditions as follows:

- Continuation of pregnancy after the procedure.
- Excessive or continued bleeding due to incomplete evacuation.
- Injury to the organs either to the uterus or to the other organs.
- Failure to diagnosis ectopic pregnancy while performing MTP.

- Death following any procedure.
- MTP done by a not authorized person.
- MTP without proper counselling and informed consent.
- Termination knowingly after 20 weeks of pregnancy.

Conditions under which pregnancy can be terminated

- Continuation of pregnancy would never involve a risk to the life of the pregnant woman or grave injury to her physical or mental health.
- There is a substantial risk for the child born to suffer from such physical or mental abnormalities as to be seriously handicapped.
- Pregnancy resulting from rape and from failure of contraceptive methods constitutes grave injury to mental health of the woman. Actually a woman's foreseeable environment should also be taken into account in determining the risk to her health.

Experience or training required for MTP

- For medical practitioners registered in a state medical register immediately before commencement of the act, minimum experience of 3 yr in the practice of OBG.
- For practitioners registered on or after the date of commencement of act, 6 months of house job in OBG or one year of experience in the practice of OBG at a hospital or if the person has assisted a registered medical practitioner in performing 25 cases of MTP in an institution approved for training by the government.
- Postgraduate degree or diploma holder in OBG.

Female sterilization

Failed sterilization and the consequent wrongful pregnancy is historically the single operation most likely to give rise to litigation.

Two aspects of sterilization failure attract litigation:

- Inadequate consent
- Defective surgery.

Failure:

- Spontaneous recanalization is rare. In cases of male sterilization if contraceptive support is not advocated immediate after vasectomy, conception may occur. Incomplete occlusion or traumatic occlusion may give rise to failure. Sterilization when performed without diagnosing an existing pregnancy or done in the secretory phase with an existing preclinical pregnancy where implantation has just taken place may result in a pregnancy. Ligation of wrong structures[eg. Round ligament] can lead to failure an in such cases legal threat is high.

Ectopic pregnancy:

- There is always a less chance of ectopic pregnancy after sterilization operation.

Injuries:

- Though not very common, injuries to bladder, bowel or large blood vessel may complicate the procedure.

- **Sterilization in emergency condition:**

- Risk of legal problem is more when sterilization is done in an emergency condition without adequate counselling prior to sterilization.

Contraception IUCD

- Perforation of uterus
- Expulsion of device- confirmatory proof should be obtained
- Complications of IUCD
- IUCD failure.

Oral pill:

- Pill failure or missed pill is an usual factor behind contraceptive failure; proper demonstration is needed. Equally important to inform the user about the minor-short term and major- long term side effects.

Injectable contraceptive

- High incidence of amenorrhoea and irregular menstruation is poorly accepted by the women. Pros and cons to be informed. It should be remembered that a free- choice should be adopted for selection of the method of contraception provided the acceptor has no contraindications.

Endoscopic surgery

- Diagnostic laparoscopy remains a common cause of complaint. Possible risks should be explained.

Infertility and ART

- Assisted conception is replete with ethical and legal problems involving statutory and case law. There is increasing litigation following the adverse outcome of multiple pregnancy, with criticism of poor counselling and overoptimistic forecasts, especially in the financial driven private sector. The replacement of more than 2 embryos is not recommended by the Human Fertilization and Embryology Authority.

In management of infertility various investigative procedures may be needed. The patients may be needed. The patient's may need maximum physical, mental and financial contribution. The couple should be informed about these things and they should be explained about the different methods of treatment applicable to them with the success rates and possible hazards

WAYS TO MINIMIZE MEDICOLEGAL PROBLEMS IN OBSTETRICS AND GYNAECOLOGY

- **Awareness of medico legal problems:**

Health practitioners should be aware about the changes in laws that may influence the practice.

- **Code of ethics:**

The code of ethics for the midwife should be followed.

- **Good interpersonal relationship and clear communication:**

The patient must not be given false guarantees and needs to understand what to expect from the treatment. The health professionals must be polite and courteous showing sympathy towards patient.

- **Proper counselling:**

Good counselling instills enormous confidence and faith. It helps to remove fear and misconceptions that may exist in the mind of the patient.

- **Informed consent:**

After proper counselling informed consent should be taken.

- **Standard health services:**
- ***Improving infrastructure:***

Facilities available in the institution should be displayed. Health authorities should set norms for the health sector as a whole.

Quality of care:

- A good consultant is needed. Also active pre and post operative care needed.
- **Adequate training:**

Nursing education:

Improve the standard of nursing education as they come in direct contact with patients.

- ***Continuing education:***

Regular CME and workshops should be attended.

- ***Audits:***

Morbidity and mortality audits should be regularly done. Regular meeting of the staffs.

- ***Second opinion/ referral***

Timely referral should be kept in mind.

Documentation and record keeping:

- History, physical examination, drug allergies, chronic medications, plan of management, date and time of investigations done, operative and investigative notes, record of discussions with patient and relative, note to kept of patients not following instruction etc should be documented.

- **Risk management:**

Risk management involves limiting health risk to the patient and also reduce legal risks to the care provider. It does not primarily about avoiding or mitigating claims but rather a tool for improving the quality of care.

- **Public awareness program and health education:**

Public awareness include health awareness by professional bodies and media.

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