MEDICOLEGAL ISSUES IN NEUROSURGERY

Introduction

- Consent
- Duties of Medical practitioner
- Medical Negligence
- Medical records
- Brain death
- Organ transplantation
- Human experimentation

Consent in Medical practice

- Consent means voluntary agreement, compliance or permission
- To be legally valid, it must be given after understanding what it is given for and of the risks involved
- Why to obtain consent ?
  - To examine, treat or operate a patient without consent is an assault in law, even if it is beneficial and done in good faith
  - If the doctor fails to give required information to the pt prior to obtaining consent, he may be charged for negligence

Consent in Medical practice

- Consent –
  - Express – Verbal or Written
  - Implied
- Informed consent – implies understanding by the patient of
  - The nature of his condition
  - The nature of the proposed treatment or procedure
  - The alternative procedure
  - The risks and benefits involved in both
  - The potential risks of not receiving treatment
  - The relative chances of success & failure of both the procedures
  - Disclosure should be in a language the pt can understand

Consent in Medical practice

- Full disclosure-
  - The facts which a doctor must disclose depends on the normal practice in his community & on the circumstances of the case
  - In general, pt should ordinarily be told everything

Consent in Medical practice

- Therapeutic privilege-
  - Exception to the rule of “full disclosure”
  - Patient’s personality, physical and mental state, to be considered
  - Full disclosure could result in frightening a patient who is already fearful or emotionally disturbed, who may refuse treatment when there is really little risk
  - Malignancy or a unavoidable fatal lesion may not be disclosed
  - Explain the risks to the family, note in patient’s record explaining his intention and the reasons

Rules of Consent

- Consent is necessary for every medical examination
- Oral consent should be obtained in the presence of a disinterested third party e.g. nurse
- Written consent for specific procedure
- Any procedure beyond routine physical examination e.g. operation , blood transfusion etc. requires express consent prior to the procedure

Rules of Consent

- A child under 12 years and an insane person cannot give valid consent-consent should be obtained from the guardian
- For organ transplantation, pathological autopsy; consent of the guardian/legal heirs is necessary

Refusal of care

- Mentally competent adult patients
- Mentally competent parents
- Patient should sign refusal form
- Ensure that all actions and the patient's condition are well documented, particularly history and assessment findings. The patient should be encouraged to seek medical care.

Duties of Medical Practitioners

- Exercise a reasonable degree of skill & knowledge
- Attendance and examination
- Furnish proper & suitable medicines
- Give instructions, control and warn
- Inform the patient of risks
- Notification of certain diseases
- Consultation

Duties of Medical Practitioners

- Operations-
  - Explain nature & extent of operation
  - Written informed consent
  - Wrong patient, wrong side
  - Must follow current standard practice, no experimentation
  - All swabs, instrument to be removed at the end of surgery
  - Proper post-op care and appropriate advice at the time of discharge

Privileges and Rights of Patients

- Choice of doctor
- Access to healthcare
- Dignity – no discrimination
- Privacy & confidentiality
- Receive thorough information
- Consent / refusal
- Second opinion
- Continuity of care
- Complaint
- Compensation

Professional secrecy

- The doctor is obliged to keep secret all that comes he comes to know concerning the patient in the course of his professional work
- Trust & confidence
- Establishment of Physician-Patient Relationship
- The doctor can be sued for the breach of confidentiality

Principles of Confidentiality

- Legal Requirements to Maintain Confidentiality of Information
- Increase in Legal Risks if Information is Misused

Professional secrecy

- Don’t discuss the patient’s illness without the consent of the patient
- Doctors in Govt practice are also bound by code of professional secrecy even when the patient is treated free
- Publication in journal

Privileged communications

- Exception to the rule of professional secrecy
- To protect the larger interest of community/state
- Examples-
  - Infectious diseases, notifiable diseases
  - Suspected crime
  - Self interest
  - Patient's own interest

Professional Negligence (Malpraxis)

- Defined as the absence of reasonable care & skill, or willful negligence of a medical practitioner in the treatment of a patient, which causes bodily injury or death of the patient
- Acts of omission or commission
- Improper, unjustifiable deviation from accepted practices
- Duty , Dereliction, Direct causation, Damage
- Civil negligence or Criminal negligence

Standard of Care

"How a reasonable, prudent, properly trained medical practitioner at the same level of training would perform under the same or similar circumstances."

Duty to Act

- Generally, a physician has a duty to act when he or she is on duty with an organization which is responsible for providing emergency care.
- “Duty” can be defined more broadly to mean an obligation to conform to a particular standard of care.

General Standards

- Provide medically correct treatment consistent with scope of practice
- Ensure equipment is in good working order
- Ensure that the ambulance is properly stocked and all instruments are in order

Typical Causes of Negligence

- Not performing required skills
- Performing skills incorrectly
- Performing unauthorized skills

Examples of Medical Negligence

- Failure to obtain informed consent
- Failure to examine the patient himself
- Failure to attend the patient in time or failure to attend altogether
- Making a wrong diagnosis due to absence of skill and care
- Failure to provide a substitute during his absence
- Giving overdose of medications and giving poisonous medicines carelessly

When is the doctor is not liable ?

- For an error of diagnosis, if he has secured all necessary data on which to base a sound judgement
- For failure to cure or for bad result that may follow, if he has exercised reasonable care & skill
- If the doctor attends on behalf of a third party to examine a patient for non-therapeutic purposes

Criminal negligence

- When a doctor shows gross absence of skill or care resulting in serious injury to or death of the patient, by acts of commission or omission
- Gross lack of competence, gross inattention or inaction, gross recklessness, gross negligence in the selection or application of remedies

Criminal negligence

- Practically limited to cases in which the patient has died
- Drunkenness or impaired efficiency due to illicit drug use by doctor
- Contributory negligence is not a defense

Criminal negligence - Examples

- Wrong patient, wrong side
- Leaving instruments, swabs, sponges or tubes in abdomen
- Grossly incompetent administration of a general anaesthetic by a doctor

Section 304 A, IPC- Whoever causes the death of any person by doing any rash or negligent act not amounting to culpable homicide shall be punished with imprisonment upto 2 years or with fine, or with both.

Doctrine of Res Ipsa Loquitur

- " The thing or fact speaks for itself "
- Professional negligence of a physician need not be proved by the patient in the court of law in such cases
- Prerequisites-
  - In the absence of negligence, the injury would not have occurred ordinarily
  - The doctor had exclusive control over injury producing instrument or treatment
  - The patient was not guilty of contributory negligence

Doctrine of Res Ipsa Loquitur

- Examples-
  - Failure to remove swabs/cottons during operation which may lead to complications or cause death
  - Prescribing an overdose of medications which may cause death
  - Blood transfusion misadventure

Medical maloccurrence

- Biological variations which cannot always be explained, expected or prepared for
- Occurs inspite of good medical attention and care
- e.g. adverse drug reactions

Criminalisation of fatal medical mistakes

- Is it sensible to use the criminal law to prosecute these doctors?
- They have no intention of injuring the patient
- They are “human beings”
- Errors are recognised mostly to be the failure of systems not individuals
- Punishing the individual may divert attention from fixing the system

Criminalisation of fatal medical mistakes

- Indeed, the first step in reducing errors is to encourage doctors to report them
- The law is working against the public interest
- Change of attitude

Defences against Negligence

- No duty owed to the plaintiff
- Duty discharged according to prevailing standards
- Medical maloccurrence
- Error of judgement
- Contributory negligence
- Limitation – within 2 years

Protection Against Litigation

- Good rapport with Patient and Family
- Good & rationale patient care
- Comprehensive and Factual Written Reports; **Complete, accurate & legible medical records.**
- Compliance with Safety Requirements
- Respect, care, concern, professionalism & humanistic approach

Requirements to Prove Negligence

- The physician had a ‘duty to act’
- The physician’s act or omission did not conform to the ‘standard of care’
- Injuries occurred to the plaintiff
- The acts or omissions were the proximate cause of the injuries
- The injuries are of a kind for which damages can be awarded

Vicarious Liability

- Also known as “respondent superior”
- Occurs when employer held responsible for negligence of employee or someone under employer’s control

Determination of Damages

- Compensatory
  - Special Damages
  - General Damages
- Punitive

If You're Involved in a Suit

- **Always** notify employer and medical director
- **Always** make sure that complaint is answered

Medical records

- Accurate, appropriate, chronological, factual, relevant & complete
- No tampering
- Confidentiality
- Good patient notes may be of greatest importance in supporting the doctor's evidence against that of the plaintiff

Medical Indemnity Insurance

- Contract under which the insurance company agrees, in exchange for the payment of premiums, to indemnify the insured doctor as a result of his claimed professional negligence
- Legal opinion, professional assistance, claim settlement

Euthanasia (Mercy killing)

- Producing painless death of a person suffering from hopelessly incurable & painful disease
- Active or Passive, Voluntary or Non-voluntary
- Strict rules, another physician to be consulted and life must be ended in a medically appropriate way
- Not legalized in India

Good Samaritan Law

- Encourages people to render care by decreasing risks of liability.
- Typically does not cover those with a duty to act.
- Does not cover gross negligence or reckless or intentional misconduct

Penal provisions related to Medical practice

- **Sec.88 IPC-** provide exemption for acts not intended to cause death done by consent in good faith for the person's benefit
- **Sec.87 IPC-** a person above 18 years can give valid consent to suffer any harm, not intended to or not known to cause death/grievous hurt.

Penal provisions related to Medical practice

- The doctor is not criminally responsible for a patient's death unless his negligence is gross, disregard for life and safety is so gross as to amount to a crime.
- **Sec.304A IPC-** it is necessary that the death should have been the direct result of a rash and negligent act of the accused and that act must be proximate and efficient cause without the intervention of another's negligence.

Penal provisions related to Medical practice

- A private complaint need not be entertained unless another credible opinion to support the charge of rashness or negligence on part of the accused doctor is produced
- Serious embarrassment and harassment for the doctor.
- Loss of reputation
- Malicious proceedings against the doctors have to be guarded against.

Consumer protection act,1986 (amended in 2002)

- Provide for better protection of the interests of consumers
- Covers all private, corporate & public sector enterprises
- Consumer Disputes Redressal Agencies
- Powers of a civil court
- Speedy redressal of complaints

Brain Death

- Classical death -‘Cardiac’
- Brain or brain-stem death: A state of irreversible damage to the brain which over a period of time (12 to 36 hours) inevitably leads to cardiac arrest
- Head injury, massive stroke, brain tumors, hypoxic brain damage

Brain death – Why is it important to declare brain death ?

- Ability to support cardiorespiratory function for prolonged periods after brain death
- Organ transplantation
- Ignores the reality of situation
- Keeps family and relatives in a limbo of uncertainty and false hope
- Violates the trust placed in the physician by the family to recognize death

Brain death – Why is it important to declare brain death ?

- Requires health care workers to treat an essentially dead body
- Waste of precious & often limited resources
- Might be perceived as indignity to and abuse of the body

Brain death – Clinical criteria

- No respiratory effort (apnea)
- Absent brainstem reflexes
  - Fixed, mid-dilated pupil
  - Absent corneal reflex
  - Absent oculovestibular reflex(Cold caloric)
  - Absent oculocephalic reflex(Doll's eye movement)
  - Absent gag and cough reflex
- No response to deep central pain

Brain death – Clinical criteria

- No signs of eye opening,

  no spontaneous movement,

  no movement elicited by noise or painful stimuli to the face or trunk **other than spinal cord reflex movements**

Brain death – Clinical criteria

- **Absence of complicating conditions –**
  - Hypothermia (Core temp. < 90 deg F)
  - Shock (SBP<90 mm Hg) & anoxia
  - No e/o remediable exogenous/ endogenous intoxication
  - Immediately post-resuscitation
  - Patients coming out of pentobarbital coma (Wait until blood level < 10 mcg/ml)

APNEA TEST

1. Prerequisites:
   - Core Temperature 36.5°C or 97°F
   - Systolic blood pressure 90 mm Hg
   - Normal PCO_2 (**Arterial PCO_2 of 35-45 mm Hg**)

2. Preoxygenate with 100% O_2 for 30 minutes

3. Connect a pulse oximeter and disconnect the ventilator

4. Place a nasal cannula at the level of the carina and deliver 100% O_2, 8 L per minute

5. Look closely for respiratory movements (abdominal or chest excursions that produce adequate tidal volumes)

6. Measure PO_2, PCO_2, and pH after 10 minutes and reconnect the ventilator

APNEA TEST

7. If respiratory movements are absent and arterial **PCO2** is 60 mm Hg (option: 20 mm Hg increase in **PCO2** over a baseline normal **PCO2**), the apnea test result is positive (supports the diagnosis of brain death)

Connect the ventilator if during testing the systolic blood pressure becomes < 90 mm Hg or the pulse oximeter indicates significant desaturation and cardiac arrhythmias are present: immediately draw an arterial blood sample and analyze ABG!

8. If PCO2 is 60 mm Hg or PCO2 increase is > 20 mm Hg over baseline normal PCO2, the apnea test is positive [supports the clinical diagnosis of brain death]

9. If the **PCO2** is < 60 mm Hg or **PCO2** increase is < 20 mm Hg over baseline normal **PCO2**, the result is indeterminate and an additional confirmatory test can be considered.

Brain death – Confirmatory tests

- Four vessel DSA
- Radionuclide Cerebral angiography (using Tc^{99} HMPAO) – "Hollow skull" phenomenon

- TCD –
  - Loss of flow in a vessel previously insonated
  - Disappearance of systolic spike
  - Flow reversal during diastole
- PET
- EEG-Electrocerebral silence(No electrical activity > 2μV)
- BERA- Preservation of Wave I (arising from VIII nv) and no other waves on BERA is useful in confirmation of Brain death

Brain death

- Recommended observation periods to pronounce “Death” in brain dead patient-
  - If an irreversible condition is well-established – repeat clinical tests after 6 hours and declare
  - At any time, if there is no flow on four vessel DSA- declare
  - During initial 6 hours – if no flow on Radionuclide angiography, declare

Brain death

- Recommended observation periods to pronounce “Death” in brain dead patient-
  - EEG- Electrocerebral silence at least 6 hours after loss of neurological activity + Clinical tests
  - If the anoxic injury is the cause of brain death – 24 hours

Brain death – Ethical & Moral aspects

- When a patient is declared brain dead, support could be terminated legally
- Continuation/ Withdrawal of life-sustaining measures – Doctor or Family ??

Suggested approach to the family of Severely Brain-injured patients-

- Poor prognosis to be explained
- Inform ORBO as soon as possible
- Brain death declaration
- Discussion regarding organ donation should be a "Team approach"
- The family should be told clearly and unequivocally that the person is "Dead" when neurological criteria have been confirmed

Organ transplantation

- What is truly distinctive about transplantation is not technology but ethics. Transplantation is the only area in all health care **that cannot exist without the participation of the public**. It is the individual citizen who while alive or after death makes organs and tissues available for transplantation. If there were no gifts of organs or tissues, transplantation would come to a grinding halt.

Arthur Caplan, Bioethicist.

Human organ transplantation act, 1994 (amended in 2002)

- Aims at putting a stop to live unrelated transplants
- It accepts brain death criterion
- Certification of death by a panel of experts
- Authorization by donor/family
- In case of unclaimed bodies, organs can be removed after 48 hours

Human organ transplantation act, 1994

- Removal of organs only for therapeutic purposes
- Compulsary registration of hospitals engaged in the removal, storage or transplantation of human organs
- Punishments for unauthorized removal of human organs or for commercial dealings
- Imprisonment 2-5 yrs, Fine based on the nature and degree of offence, removal of name from Indian Medical Register

Human experimentation

- Declaration of Helsinki, 1964
- Must conform to the moral and scientific principles that justify medical research, should be based upon scientifically established facts and animal & laboratory experiments
- Risk benefit assessment
- Written informed consent from patient or his legal guardian
- Right to withdraw from the investigations whenever the patient likes

Human experimentation

- Therapeutic experimentation, Research experiments, Innovative experiments
- Should not vary too radically from accepted methods
- Extensive animal research is an absolute pre-requisite to the use of an innovative technique in the treatment of human beings

Human experimentation

- Experiments on human volunteers can only be justified if they do no significant harm to the subject & the results are likely to be beneficial
- It would be unethical to do something merely by way of experimentation i.e. which is not strictly related to the cure of the patient's illness
- There must also be no great risk in the proposed experimentation, even if the patient consents to run the great risk

Human experimentation

- A new experiment should not be undertaken merely to find out its efficacy, if there is already a treatment which is equally efficient
- The experimentation should be stopped as soon as ill-effect is noted which should be immediately remedied

Take home message

- Consent is an important legal document
- Establish a good rapport with the patient & family, exercise a reasonable degree of care
- Medical record keeping helps a lot in putting your case in issue of claimed professional negligence
- Brain death is an accepted criteria for organ transplantation in India

THANK YOU