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 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 PCO2 (Arterial PCO2 of 35-45 mm Hg)

2. Preoxygenate with 100% O2 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% O2, 8 L per minute

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

6. Measure PO2, PCO2, and pH after 10 minutes and reconnect the ventilator
7. If respiratory movements are absent and arterial \( \text{PCO}_2 \) is 60 mm Hg (option: 20 mm Hg increase in \( \text{PCO}_2 \) over a baseline normal \( \text{PCO}_2 \)), 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 \( \text{PCO}_2 \) is 60 mm Hg or \( \text{PCO}_2 \) increase is > 20 mm Hg over baseline normal \( \text{PCO}_2 \), the apnea test is positive [supports the clinical diagnosis of brain death].

9. If the \( \text{PCO}_2 \) is < 60 mm Hg or \( \text{PCO}_2 \) increase is < 20 mm Hg over baseline normal \( \text{PCO}_2 \), the result is indeterminate and an additional confirmatory test can be considered.
Brain death – Confirmatory tests

- Four vessel DSA
- Radionuclide Cerebral angiography (using Tc\textsuperscript{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