

Medicolegal issues in Neurosurgery

Presented by - **Dr Sachin A Borkar**

Moderators- Dr S S Kale

Dr G D Satyarthee

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 patient 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 patient 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, patient 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 government 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 wilful 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 judgment
 - 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 defence
-

Criminal negligence - Examples

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

Number of British doctors charged with and convicted of manslaughter as a result of the death of a patient, 1972 to 2002



Defences against Negligence

- No duty owed to the plaintiff
 - Duty discharged according to prevailing standards
 - Medical maloccurrence
 - Error of judgment
 - 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

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 Tc⁹⁹ 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