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INDIAN MEDICO LEGAL & ETHICS ASSOCIATION

Aims & Objectives

- To promote, support and conduct research related to medico-legal, ethical and quality care issues in the field of medicine.
- To help, guide, co-ordinate, co-operate and provide expert opinion to the government agencies, NGO, any semi-government, voluntary, government agencies, legal bodies / institutions and judiciary in deciding settled or unsettled laws or application of laws / rules related to medico-legal or ethical issues.
- To train the medical professionals in doctor-patient relationship, communication skills, record maintenance and prevention of litigations.
- To promote and support the community members and individuals in amicable settlements of the disputes related to patient care, management and treatment.
- To provide specialized training in related issues during undergraduate or postgraduate education.
- To organize conferences, national meets, CME, updates, symposia etc related to these issues.
- To identify, establish, accreditation and promote organizations, hospitals, institutes, colleges and associations working on the related and allied issues.
- To promote goodwill, better care, quality care, professional conduct, ethical values.
- To establish and maintain educational institutes, hospitals, medical colleges, libraries, research centers, laboratories etc. for the promotion of its objects and to provide scholarships, fellowships, grants, endowments etc. in these fields.
- To print and publish the bulletins, books, official journal / newsletters or periodicals etc on related and allied subjects.
- To co-operate, co-ordinate, affiliate and work with other bodies, agencies or organizations to achieve the objects.

Legal Angle in ARSH

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Introduction:

Focusing on adolescent reproductive health is both a challenge and an opportunity for health care providers. Giving sexuality education and making ARSH services available and accessible to both married and unmarried adolescents, is the prime responsibility of not only government but also of the private practitioners, the NGOs & whosever come in contact with this vulnerable group. More than 30% young population belongs to the age group of 10-24 years. They may not recognize their basic developmental needs or illnesses. Because of this, they face countless missed opportunities for prevention of health problems.

Due to unequal power dynamics young people are at a higher risk of sexual violence as well as gender based violence. Unmarried / married adolescent and young girls are more vulnerable to violence in the form of eve-teasing, sexual coercion, child abuse, physical and emotional violence. All these result into early marriage, unwanted pregnancy often unsafe abortions and related health problems that affect day to day household work resulting in loss of work and economy and an increase in health costs. It affects their self esteem and image, education, restricts mobility, limits expression of opposite sex friendship. **'Culture of silence'** inhibits them and their families from seeking support and services. Life skill education in ARSH can be used as a preventive strategy to empower adolescents, to promote age appropriate sexual behaviors and to enhance gender sensitivity. It has also been effective in reduction of HIV/ AIDS and other reproductive and sexual health issues. Let us study in brief about the different legal issues related to delivery of services during this crucial phase of life.

Adolescents & Consent:

Consent in adolescents should be such that it serves the best interest and welfare of the child. It should never be for the benefit of parents and for social indications. Natural/Legal guardian can consent legally for medical or surgical treatment in adolescents. In their absence, district court can appoint the guardian. Judge exercising ward-ship jurisdiction can consent for particular treatment or procedure.

Professional Secrecy:

There is always an implied contract between the doctor and the patient unlike adults. No disclosure can be made about the illness of the minor without the consent of guardian even if requested by a public or statutory body, except in case of notifiable diseases. Adolescent's wish is to be respected. Therefore there is always an inevitable conflict between adolescents' rights and parents desire to know about their child. Guardians need to be informed of the nature of illness after proper counseling of the adolescent.

Examination of an adolescent child:

Privacy, confidentiality and comfort are the three key principles while examining an adolescent child. [1] Careful and detailed history is must. Physical examination with appraisal of secondary sexual characteristics, congenital anomalies, height and weight measurement & gynecological examination in sexually active or with history suggestive of, is all that is desired.

Consent in Medico-legal cases (MLCs):

Written consent from the parents/guardians is necessary before examining minor adolescent to prepare a medico-legal report. e.g. victim of rape, assault etc. The parents can refuse the examination but they must be given prior idea that the report may or may not go in their favor.

Consent in MTP:

Pregnancy & its termination pose a magnitude of serious problem medico-legally and socially. Rules of MTP Act also apply to this age group. Under MTP Act, consent of parent/legal guardian is required before MTP of a girl < 18 yrs. If there is any violation, doctor is liable for punishment. Due to fear & lack of knowledge, usually they resort to unsafe and illegal practices leading to effects on future obstetric career & social life, infertility & death. In addition to this, feeling of inadequacy, immorality, loss of virginity, promiscuity, premarital sex, multiple pregnancies, risk of STD, AIDS & Cancer is always there. [2]

Teenage & Contraception:

Teenage pregnancy is a worldwide problem (prevalence-2-25%). STI rate is also shows an increasing trend due to earlier age at puberty & early onset of sexuality in girls. It contributes to high maternal mortality and peri-natal morbidity and mortality. There is lack of knowledge about contraception despite availability of family planning methods, efforts of education department and wide advertisement through media. Compliance remains a problem. Therefore there is a need of proper advice and appropriate education.

Live in relationship:

Legal Definition: Living arrangement in which an unmarried couple lives together in a long term relationship that resembles a marriage. It is just blindly following of western style by eastern countries but number of unmarried adolescents living together is increasing.

Consequences of Live-in relationship:

Unplanned /undesirable pregnancy/ Illegal abortions rate is high. What about the legal status of the child born out of unwedded lock? There would be increase in the cases of sexual abuse, sexual violence, HIV & STIs. All this would have long term impact on educational career. Apex Court judgment regarding statement made by film actress Khushboo on premarital sex, virginity and live in relationship needs rethinking to preserve culture as well as safety of individuals.

Drug/substance abuse:

It is a global phenomenon**.** Economic instability, familial maladjustment, poor parental care, complexities of modern lifestyle, glorification by media**,** rebellion against authority, experimentation & in girls due to misconception of modern feminity, behaving/adopting male life style are the main background reasons. It definitely affects health & development & thus future life. The Cigarettes & Other Tobacco Products Act, 2003 prohibits sale of cigarette or other Tobacco products to a person < 18 yrs.

Physical/Sexual abuse/Domestic violence:

It is again a worldwide phenomenon affecting 40 million children between 0-14 yrs (WHO). It affects persons either psychologically or physically or both leading to increased morbidity and mortality. Indian Cabinet passed Domestic Violence Bill in 2005 which is a progressive piece of legislation providing relief to the victims of domestic violence. Comprehensive medico-legal examination of victim is a must for full investigation of case with high degree of suspicion & building of an effective prosecution in the court of law (star evidence).

Sexual Abuse:

It's a Criminal offence to be investigated by police. It is mandatory for all medical practitioners, government/ private to report all suspected cases of child abuse & neglect. Failure to report may result in to a penalty. Examination at the earliest after the incident & collection of biological evidence of alleged sexual abuse if occurred within preceding 72 hours & forensic technique provide corroborative evidence. Pregnancy test in sexually abused girl in reproductive age can give a clue. ***Good attention with proper management of pregnancy and infection coupled with effective investigation and prosecution of culprit does prove beneficial to victim.***

Adolescenct & Rape:

The incidence of rape on adolescent girl below 16 yrs of age accounts for more than 75% of total rape cases during last decade. Interpretation of physical findings is relatively easy in girls < 16 yrs as compared to adult. Plea of consensual rape is not valid. Rape is a cognizable offence under IPC Sec375 & Sec 376. Medical practitioner must report it. It is immaterial of penetration or ejaculation. If there is no evidence in the form of ejaculate, still there can be conviction under indecent assault, IPC Sec 354. Efforts must be made to collect all possible corroborative evidences. Resistance shown by raped victim should be recorded but occasionally she may not offer due to fear, terror, helplessness, risk to her or others life. Two finger test is not necessary as per the recent Apex Court judgment. Criminal Law Amendment Act 1983 has brought many changes in Sec 375, Sec 376 of IPC to prohibit sexual abuse of woman of any age who is in custody, care and control by authorities.

Date Rape:

It's a growing concern in metropolitan cities especially in teenagers belonging to high socio-economic class. In 25% of rape cases 'drug' is involved. Adolescent girls (16-19 yrs) are 4 times likely to get affected. The interaction of drug with alcohol may prove lethal to the life of victim apart from mental injury. The saddest part of this crime is that most of them go unnoticed, unreported, unsolved and unproven.

Incest, Molestation, Indecency, Eve-teasing:

Incest per se is not a cognizable offence. However, any sexual relationship without consent < 16 yrs (15 yrs in case of wife) amounts to rape. IPC Sec 294 applies to molestation, eve teasing and indecency. It may create psychological problems in this tender age. Careful medical examination is very useful.

Child trafficking & prostitution:

It's a most common form of sexual abuse & an ultimate denial of Human Rights. There are Legal provisions under Sec 366-A IPC, Sec.372, Sec 373 IPC & Immoral Traffic in Persons Prevention Act, 1986 but the problem is currently beyond control. Again a proper medical examination, would serve as a vital piece of evidence during trial against the accused.

Conclusion:

Adolescence is a challenge to society, medical profession & policy makers of the country. There is a growing need that all the adolescent programs must be planned in an integrated manner. Research has proved that WHO-Age appropriate sexuality education delays the age of first intercourse, increase practice of safe sex, reduces consequences. Right to health care & health protection is the basic fundamental right of every individual. To exercise this right to the fullest extent, the adolescents need scientific information about their health problems & the ways to prevent & tackle them. It is the additional duty of the health providers to make them aware about the legal provisions through ARSH programs organized on a mass level so that they can enjoy sound health and concentrate on their education and other basic needs. Let the adolescents realize their **'self worth'**.

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FAQs on MTP

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Question: What is the Legal framework of MTP Act?

Answer: MTP Act (1971)

It lays down when and where pregnancies can be terminated. It grants the central govt. power to make rules and the state govt. power to frame regulations

- MTP Rules
  - Lays down who can terminate the pregnancy, training requirements, approval process for place, etc.
- MTP Regulations
  - Lays down forms for opinion, maintenance of records
  - Custody of forms and reporting of cases

Question: What is the composition of District Level committee for MTP?

Answer: District level MTP Committee is as follows:

  - Minimum 3 & Maximum 5 members including chairperson (CMHO)
- Composition of the committee
  - One medical person (Gynecologist/Surgeon/ Anesthetist)
  - One member from local medical profession; NGO & Panchayati Raj Institution of the district.
  - At least one member shall be a woman
- Tenure: 2 calendar years - NGO members shall not have more than 2 terms

Question: Is abortion available on demand and a woman's legal right in India?

Answer: No, abortion is not a right of a woman by Indian Law. It cannot be done on just demand of woman.

But termination of pregnancy can be done, under MTP law when the authorized person (who can perform MTP by law) forms an opinion that woman has to undergo termination under one of the following indications:

1. To save the life of the woman(mother)
2. Continuation of pregnancy constitutes risk to the life or grave injury to the physical or mental health of woman
3. Substantial risk of physical or mental abnormalities in the fetus as to render it seriously handicapped
4. Pregnancy caused by rape (presumed grave injury to mental health)
5. Contraceptive failure in married couple (presumed grave injury to mental health)

Question: A married or unmarried woman, age 17 years comes with an 8 weeks pregnancy for MTP. Whose signature should be on the consent form?

Answer: Under any circumstances if the age of the patient undergoing MTP is less than 18 years then the consent should be signed by legal guardians only.

Question: An unmarried woman, age 21 years, comes with an 8 weeks pregnancy for MTP. Whose signature should be on the consent form?

Answer: Above the age of 18 yrs only the patient's (woman undergoing MTP) signature is required if she is in healthy and sound mental condition. It does not matter whether she is married or unmarried.

Question: What is form C and form 1 [one and not capital I (alphabet)]?

Answer: Form C is the consent form and Form 1 is the opinion form. Both have to be filled before the procedure.

Question: Should Gynecologists prescribing Medical Abortion by Tablets Mifepristone & Misoprostol fill up the specified Form '1', Form 'C' & make entry of such cases in MTP resister?

Answer: Medical Method of abortion is a recognized method of MTP up to 49 days so all records pertaining

to MTP Act, Rules and Regulations have to be maintained.

Question: Is it necessary to fill up the '1' and 'C' both forms for 1st & 2nd trimester MTP?

Answer: Yes. Both forms are mandatory for 1st as well as 2nd trimester abortion.

In 1st trimester there should be opinion of one gynecologist or the registered medical practitioner with MBBS degree and who has taken training of MTP.

In 2nd trimester there should be opinion of two gynecologists / registered medical practitioners

Question: Is there any difference in the qualifications required for the providers for surgical MTP up to 12 weeks by MVA or EVA or medical abortion using Mifepristone-misoprostol?

Answer: No. The qualification is same. Qualification = He / She should be either a MCI recognized Degree or Diploma holder of OBGY stream i.e. DGO, MD, MS, DNB or a registered medical practitioner MBBS with training for the MTP (25 MTP assisted and 25 MTP done under observation of a teacher at recognized training center).

Question: Which Equipment are required for site approval for MTP center up to 12 weeks?

Answer: (1) Examination / labour table (2) Resuscitation and sterilization equipment (3) Drugs and emergency tray& parental fluid (4) Back up facilities for treatment of Shock (5) Facilities for Transportation.

Question: Which Equipment are required for site approval for MTP center up to 20 weeks?

Answer: (1) Operation table (2) Resuscitation and sterilization equipment (3) Drugs, emergency tray & parental fluid (4) Back up facilities for treatment of Shock (5) Instruments for performing abdominal or gynecological surgery (6) Anesthetic equipment & resuscitation equipment (7) Facilities for Transportation.

Question: What is an Approved place for MTP?

Answer: (1) A hospital established or maintained by Government (By default it is approved) (2) A place approved for the purpose of this Act by a district-level committee constituted by the government with the CMHO as Chairperson at corporation level and Civil surgeon as chairperson at non corporation level.

Question: Is it necessary to seal the forms of the patient of MTP even if owner and gynecologist is same?

Answer: Yes, and to be kept in his / her custody. If owner is different and gynecologist doing MTP is not the owner in that case he should seal the envelope and hand it over to owner. Idea is to keep the confidentiality of the patient.

Question: How much place is required for MTP centre?

Answer: Adequate place to perform MTP & tackle related complications. No such dimensions are given in law.

Question: Can any qualified gynecologist perform MTP at any recognized / approved centre?

Answer: Yes, anywhere in India.

Question: Only the Anaesthesiologists, whose name is mentioned on the MTP certificate, will give anaesthesia to the MTP patients or other Anaesthesiologists can also give anesthesia?

Answer: Any recognized Degree or Diploma holder Anesthesiologist registered with MCI or state medical council (Ultimately registered with MCI) can give anaesthesia to patients at any approved / recognized MTP center in India.

Question: Whether cases such as Incomplete Abortion, Inevitable Abortion, Missed Abortion, Blighted Ovum come under the MTP Act?

Answer: Incomplete abortion, inevitable abortion, missed abortion, blighted ovum are obstetric complications. These do not come under the purview MTP Act.

Question: Should Gynecologists terminating pregnancies in cases of Incomplete Abortion, Inevitable Abortion, Missed Abortion, Blighted Ovum, fill up the specified Form '1', Form 'C' & make entry of such cases in MTP register?

Answer: No. The complications have to be maintained in the appropriate records (Indoor case paper) but not in the MTP Register. Different consent

for procedure is required & the procedure need to be recorded in OT register as procedure is done in a regular manner.

Question: Can we prescribe medical abortion in only clinic and not a hospital or recognized MTP center?

Answer: MTP using Mifepristone (RU 486) & Misoprostol approved for up to 7 weeks termination. Only an RMP (as defined by the MTP Act) can prescribe the drugs. He/she has to follow MTP Act, Rules & Regulations. He/she can prescribe in his/her clinic, provided he/she has access to an approved place and should display a certificate from owner of approved place agreeing to provide access in emergency. He/she should fill up Form 1 & Form C at the approved place's record before 12 midnight of the same day.

Question: Who can inspect MTP records?

Answer: Civil Surgeon, First Class Judicial Magistrate or a person deputed by the Civil surgeon with written permission and Governor in union territory.

Question: Can we do MTP with Tubectomy?

Answer: Yes.

Question: In case of unmarried girl coming for MTP, is it necessary to inform the police as per law?

Answer: If her age is above 18 yrs then it is not necessary but if the age is below 18 yrs then it is necessary not by MTP law but by "Protection of children from sexual offence act" under Section 19.

Question: If I am called to perform an MTP at a place which is not registered for MTP, who shall be liable for punishment, myself or the owner or both?

Answer: Owner is unauthorized hence will be guilty. You will be guilty too as you are doing procedure in an illegal place (Not Approved). (Only exception in Emergency (To save the life of the mother) MTP at that place can be done, but should enter in an MTP center and should be noted in MTP admission register, without giving number. Moreover we have to prove the emergency if asked by authorities or the court)

"MTP Act" Good law in place.....Let us protect it and allow it to protect us !!!!!!!!!!

Rights of the Patients

Patients have certain rights. The main ones are as follows -

Right to courtesy & dignity: A patient has the right to be treated with courtesy and respect, with appreciation of his or her individual dignity, and with protection of his or her need for privacy.

Right to information:

- A patient has the right to be given by the health care provider information concerning diagnosis, planned course of treatment, alternatives, risks, and prognosis.
- A patient has the right to a prompt and reasonable response to questions and requests.
- A patient has the right to know who is providing medical services and who is responsible for his or her care.
- A patient has the right to know what patient support services are available, including whether an interpreter is available if he or she does not speak language used by the healthcare team.
- A patient has the right to know what rules and regulations apply to his or her conduct.
- A patient has the right to know if medical treatment is for purposes of experimental research and to give his or her consent or refusal to participate in such experimental research.
- A patient who is eligible for Medicare has the right to know, upon request and in advance of treatment, whether the health care provider or health care facility accepts the Medicare assignment rates.

Right to refuse treatment: A patient has the right to refuse any treatment, except as otherwise provided by law.

Right to estimate of expenses: A patient has the right to receive, upon request, prior to treatment, a reasonable estimate of charges for medical care. Patient also has the right to know what charges have been levied upon him.

Right to itemized billing: A patient has the right to receive a copy of a reasonably clear and understandable, itemized bill and, upon request, to have the charges explained.

Right to non discrimination: A patient has the right to impartial access to medical treatment or accommodations, regardless of race, national origin, religion, handicap, or source of payment.

Right to emergency care: A patient has the right to treatment for any emergency medical condition that will deteriorate from failure to provide treatment.

Right to express grievance: A patient has the right to express grievances regarding any violation of his or her rights, through the grievance procedure of the health care provider or health care facility which served him or her and to the appropriate state licensing agency.

Patient-Doctor Communication

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Patient-doctor communication is the verbal and non-verbal processes through which a doctor obtains and shares information with a patient, thereby developing a therapeutic relationship. Communication between doctor & patient starts at the very first visit. The first visit for a patient is a crucial encounter that can either result in development of a long term patient-doctor relationship or end in dissatisfaction on both sides. This results in the patient looking for another care provider.

The medical interview is meant to capture medical information in order to make a diagnosis. The interview is a means of sharing information about themselves, their health issues & concerns and for the physician to get to know the patient better. Thus, in this process, the patient becomes a person, not just a medical problem. By understanding the patient, who they are, what are their health concerns and the expectations that they have from the doctor, the doctor can formulate the appropriate medical judgments for that particular patient. This eventually results into a satisfactory doctor patient relationship.

While communication with a patient may appear straight forward, an effective patient-doctor interaction can be quite challenging. It is up to the doctor to find out about the patient and their medical issues regardless of how difficult or complex the patient's history may be. Any doctor would be able to give satisfactory medical care provided he is able to elicit proper history of the patient.

What are a patient's expectations from a doctor?

All patient-doctor interactions are influenced by the expectations of both doctor & patient. If the doctor has unfair expectations of the patient, or the interaction is affected by bias or unfair judgment, then an effective relationship will never develop. If the patient's expectations of the doctor are not met, the patient will not develop enough respect or trust for the physician to accept his/her suggestions. Doctors expectations of their patients should be fair, unbiased and without judgment. Most importantly, Doctor must respect patients' feelings.

Primary Expectations-

- Clinical Competence: confidence that the doctor would solve health related problems.

Secondary Expectations-

The qualities that a patient looks for in the treating physician include,

- Professional
- Respectful
- Polite
- Sincere
- Interested
- Effective Communication Skills-Verbal and Non-Verbal

Communication Skills- Basic Elements of doctor patient interaction

Initial Encounter-

The First Impression-the most important one that occurs! The patient, in the first few moments, will decide if he/she will feel comfortable with the doctor and most of this first impression is made not on what the doctor says, but how he/she says it and how he/she interacts with the patient.

Be Prepared- know who the patient is before you walk through the door

Make eye contact with the patient: eye contact is important to continue the communication process. It also sends positive cues.

Build rapport: very important to start a conversation. Try to get little more information about the patient, his/ her routine, family, workplace.

Have a seat: it is important to sit & converse. The patient will feel at ease and communication is better.

Let the patient tell their story Ask the patient to explain why they are here.

Conducting the interview

As the patient explains the chief complaint and the

history of the present illness, you can question the patient using the following skills.

1. Use **open-ende**d questions. This is done to obtain general information.
2. **Direct/closed-ended questions**. Used as a follow up to open-ended questions.
3. **Avoid leading questions** Leading questions may suggest to the patient the desired answer which may not be correct.
4. **Ask one question at a time** Presenting more than one question is confusing and inconsiderate. Keep the interview **organized** and use transition statements.
5. **Learn about the patient** and his/her family formally and informally, during the course of the interview when discussing social and family history but also through an ongoing conversation with the patient.
6. **Encourage the patient to ask questions** This will further develop trust and enhance your relationship with the patient. It will also solve all the queries that the patient may have in his/ her mind.
7. **Listen** Accurately to the Patient.

Responding to the Patient-

It is important for doctor to empathize with patient to understand what he/ she is going through. It helps in building trust.

Verbal communication: It is often difficult for patients to disclose personal information about themselves or problems they may be experiencing.

Non-Verbal **communication**: The patient's body language may be telling you something different from what the patient is saying. It is appropriate to point discrepancies to the patient and elicit their understanding about their causes.

Avoid judgmental language or behaviours: Being judgmental is the biggest hurdle in doctor patient communication. The doctor must put aside own beliefs & values and refrain from projecting them onto the patient. The medical problem or issue is about the patient and their beliefs system and you need to understand it from their perspective

Provide encouragement: Praising patients also strengthens the patient-doctor relationship. Encourage them to speak out to ensure better dialogue

Be aware of your non-verbal cues Being attentive, making eye contact, and providing positive cues will encourage the patient to be open with you. Your body language should show that you are engaged, do not sit back in the chair, rather lean forward and pay attention.

Educating, negotiating and collaborating with the patient

Once all the information is collected from the history, physical exam, and other testing, it is time to explain to the patient about the probable diagnosis & possible treatment modalities. This has to be done essentially in a language that the patient understands.

Avoid the use of medical jargon or abbreviations

Unexplained medical jargon can have a negative effect on the conversation.

Ascertain that the patient understands the information you have provided.

Before the patient leaves ensure that the patient has clearly understood what the problem is, & what the treatment options are. The doctor must elicit the patient's feeling or concerns about the information and respond appropriately. The physician, must be sensitive to the patient's concerns.

Closing the interview

At the end of the interview, it is important for you to establish that both you and the patient understand what occurred and what the action plan is going to be.

Summarize the conversation:

1. **Answer the patient's questions** The patient should leave knowing that all of their concerns have been addressed
2. **Confirm partnership** The patient needs to be able to depend on the fact that you will be there in the future for them.
3. **Provide your initial thoughts** In any given situation, you may need to discuss the plan with the patient and your supervising physician.
4. **Discuss next steps** This could include a discussion with your supervising physician.

Frequently Asked Questions (FAQs) on PCPNDT Act

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Question: Registration Renewal Application made in time but Appropriate Authority (AA) is not responding for renewal? Where to go?

Answer: Sub Rule 5 of Rule 6: Grant or rejection of application for registration shall be communicated to the applicant as specified in forms B or form C, as the case may be within a period or 90 days from the receipt of application for registration,

Under Sub Rule 3 of Rule 8, AA is duty bound to communicate the reasons recorded in writing to the center applying for renewal. Sub rule 6 of rule 8 says that in the event of failure of AA to renew the certificate of registration or to communicate rejection of application within 90 days of receipt (Inward record wise) - then certificate is deemed to have been renewed (Sub Rule 6 of Rule 8)

Question: When and why AA (Appropriate Authority) will cancel the registration of Genetic Counseling Center, Genetic Clinic, Genetic Laboratory?

Answer: *Section 17(A)*– confers powers to AA to summon any person who is in possession of any information relating to violation of any provisions of this act or rules made thereunder.

Section 17 (4)– The Appropriate Authority shall have the following functions:

- To grant, suspend or cancel registration of Genetic Counseling Centre (GCC), Genetic Laboratory (GL) or Genetic Clinic (GC)
- To enforce standards prescribed for GCC,GL and GC
- To investigate complains of breach of provisions of this Act or the rules made thereunder & take immediate actions
- To take appropriate legal action against the use of sex selection technique by any person at any place, suo moto or brought to its notice and also to initiate an independent investigation in such matter.

Procedure adopted by AA for cancellation or suspension of registration-

Section 20 (1)– The A.A. may suo moto or on complaint issue show cause asking why registration should not be cancelled or suspended for the reasons mentioned in the notice.

Section 20 (2)– If after giving a reasonable opportunity of being heard to the Genetic Counseling Center, Genetic Clinic, Genetic Laboratory and having regard to the advice of the advisory committee, the A.A. is satisfied that there has been a breach of the provisions of this Act or the rules, it may, without prejudice to any criminal action that it may take against such center, Lab, or clinic, suspend its registration for such period as it may think fit or cancel its registration, as the case may be.

Section 20 (3)– Notwithstanding anything contained in above sub-sections, if the A.A. is of the opinion that it is necessary or expedient so to do in the public interest, it may, for reason to recorded in writing, suspend the registration of any Genetic counseling center, Genetic clinic, Genetic Laboratory without issuing any such show cause notice.

Question: What are the requisites of certificates, display Boards & other specifications in the USG centre?

Answer: Requisites of certificate of Registration: Refer the compliance of Rule 3 of the Act, & then AA will act in accordance of Rule 6 of PC& PNDT Act regarding availability of place, equipment and qualified employees, and standards maintained by such laboratory or clinic

1) Registration certificate in Original
2) Code of conduct
3) Copy of PCPNDT law in English and local language
4) Helpline numbers
5) PCPNDT Board suggesting provisions of

punishment for breach of law in English and local language at patient's waiting and USG room

Earlier Rule 3 of the Principal Act specified the minimum requirements as in Schedules I, II and III. Schedule I mentioned requirements for registration of a genetic counseling centre as a place with room with an area of seven (7) square meters. Schedule II mentioned requirements for registration of a genetic laboratory as a place or room with adequate space for carrying out tests. Schedule I mentioned requirements for registration of a genetic counseling centre as a place with room. Schedule III mentioned requirements for registration of a genetic clinic as a place with room with an area of twenty (20) square metres with appropriate aseptic arrangements.

However via Amendment in 2003, for rule 3 the following rule was substituted, namely:

3. The qualifications of the employees, the requirement of equipment etc. for a Genetic Counseling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre shall be as under: (1) Any person being or employing (i) a gynaecologist or a paediatrician having six months experience or four weeks training in genetic counseling or (ii) a medical geneticists, **having adequate space** and educational charts/models/ equipments for carrying out genetic counselling may set up a genetic counseling center and get it registered as a genetic counselling center. (2)(a) Any person **having adequate space** and being or employing(i) a Medical Geneticist and (ii) a laboratory technician, having a B.Sc. degree in Biological Sciences or a degree or diploma in medical laboratory course with at least one year experience in conducting appropriate prenatal diagnostic techniques, tests or procedures may set up a genetic laboratory. (3) (1) Any person **having adequate space** and being or employing (a) Gynaecologist having experience of performing at least 20 procedures in chorionic villi aspirations per vagina or per abdomen, chorionic villi biopsy, amniocentesis, cordocentesis, foetoscopy, foetal skin or organ biopsy or foetal blood sampling etc. under supervision of an experienced gynaecologist in these fields, or (b) a Sonologist, Imaging Specialist, Radiologist or Registered Medical Practitioner having Post Graduate degree or diploma or six months training or one year experience in sonography or image scanning, or (c) A medical geneticist may set up a genetic clinic/ultrasound clinic/imaging centre. Section 2 (D) further explains that Genetic clinic includes a vehicle, so an ordinary size of vehicle may suffice for the purpose)

Question: For how much time the records should be preserved?

Answer: People are often confused with & they limit it to preservation of Form F only. All records should be kept properly for at least two years as per section 29 of the act, Rule 9 provides for maintenance and preservation of records and sub rule (6) provides for particulars of manner in which the records are to be maintained and also provides that ALL CASE RELATED RECORDS, FORMS OF CONSENT, LAB RESULTS, MICROSCOPIC PICTURES, SONOGRAPHIC PLATES OR SLIDES, DOCOTR REFERRAL / RECOMMENDATIONS AND LETTERS be preserved for 2 years from the date of completion of & in event of any legal proceeding till the final disposal of the legal proceeding. (Except: In case of any legal proceeding pending in the court of law, then these records should not be destroyed till the proceedings have been disposed off)

Question: If a consultant wishes to change his/her USG machine, shall they inform AA in advance? What is the actual procedure?

Answer: Every change of 1) Sonologist / Radiologist 2) Place 3) Address and 4) Equipment shall be intimated to the Appropriate Authority at least 30 days in advance of the expected date of such change and seek re-issuance of certificate of registration from the Appropriate Authority, with the changes duly incorporated.

The Notification was concurrently challenged in the High Court of Delhi in the case of Indian Radiological and Imaging Association Vs Union of India, W.P (C) 4009 of 2012 wherein the petitioner challenged the constitutional validity of all the provisions namely Rule 3(3), Rule 5(1) and Rule 13 of the Gazette notification as being unconstitutional, arbitrary and beyond the scope of the Parent Act. On the issue of Rule 13 the bench opined that the condition of an advance of 30 days is onerous particularly qua

employee. Therefore it directed that an interim arrangement qua Rule 13 be made wherein for every change in place, equipment and address an advance notice of seven days be given to the Appropriate Authority and for every change in employee intimation can be given within 7 days of such change. The Court also held that a delay on the part of the Appropriate Authority in incorporating the change and re-issuing the certificate would not prevent the concerned clinics from effecting the change in place/ address/ equipment after a lapse of seven days and to continue with their activities.

Question: How many centers can be registered by the name of a Sonologist / Radiologist?

Answer: At present each medical practitioner qualified under the Act to conduct ultrasonography in a genetic clinic ultrasound clinic/ imaging centre shall be permitted to be register with a maximum of two such clinics/centers within a district (and outside too….Act is silent on this)

The constitutional validity of the Rule 3(3) which regulates each medical practitioner to conduct ultrasonography in a genetic clinic/ultrasound clinic/imaging centre with a maximum of two clinics/centres was challenged before the Hon'ble High Court of Bombay in the case of Dr Rajeev Vasant Zankar Vs Union of India and Ors W.P (Lodg.) No 1829 of 2012 wherein the petition was admitted and the Division Bench through its Order dated2 0.07.2012 issued an ad-interim stay on the operation of Rule 3(3). To defend its case, the Union of India has filed a detailed Affidavit-in-reply in the case placing on record the Objective and the circumstances leading to the amendment of Rule 3. The Notification was concurrently challenged in the High Court of Delhi in the case of Indian Radiological and Imaging Association Vs Union of India, W.P (C) 4009 of 2012 wherein the petitioner challenged the constitutional validity of all the provisions namely Rule 3(3), Rule 5 (1) and Rule 13 of the Gazette notification as being unconstitutional, arbitrary and beyond the scope of the Parent Act. The Ministry of Health and Family Welfare has filed a detailed reply in the instant matter. However based on the premise of the Bombay High Court, the Division bench in Delhi also issued an ad interim stay on the application of Rule 3(3).

Case in court pending (Stay granted by court)…..so as on today there is no restriction on number of centers

Question: Can we move our USG machine in the same hospital premises for indoor patients?

Answer: Yes! The USG machine can be used and moved within the premises of the registered place for providing services to the indoor patient. For example, a multistoried building of a hospital.

Question: Is special training required for OBGYN doctors to do ultrasonography? Have MCI / Govt. given some guidelines regarding this?

Answer: MCI in its Meeting held on 26-12-2011, decided that OBGYN having postgraduate Qualification in OBGYN as specified in the schedule I/II/III of the MCI Act of 1956 are eligible to do Ultrasonography. They require NO additional training. Please refer The PC & PNDT (Prohibition of Sex Selection) (Six Months Training) Rules, 2014

Question: Is there any requirement that the ultrasound clinic / room should have a particular size?

Answer: As explained earlier, the only requirement in terms of Rule 3(3) (1) is that the space should be adequate. This does not amount to laying down strict rules regarding the actual or minimum or optimum size of the premises. The space should be adequate. As already mentioned that even a vehicle may be registered for Genetic Clinic where size of vehicle is not defined.

Question: Is there any requirement that the ultrasound clinic should have an attached bath room or urinal?

Answer: There is no such requirement laid down anywhere in the PC&PNDT Act/Rules.

Question: Is it permissible to keep two ultrasound machines in the same room?

Answer: There is no prohibition regarding this as per the PC&PNDT Act/Rules. It is natural that the size of the room would have to be correspondingly larger. (Registration centre will be having one registration number but the both machines should be registered / mentioned on the registration certificate)

Question: If the same doctor is carrying out both functions (examining Gynae-obstetrics cases and doing ultrasound) is it permissible to have a combined room for both types of examinations?

Answer: This is a matter of individual discretion of the physician concerned. No provision of the PC&PNDT Act/Rules would be violated by doing so. All criteria of USG room should be fulfilled in consulting room. He / she can use same room for both purposes but the space should be adequate enough.

Question: No suit, prosecution or other legal proceeding shall lie against government officer for anything which is in good faith, done or intended to be done in pursuance of the provisions of this Act. Is it correct?

Answer: "Good faith": Nothing is said to be done or believed in good faith which is done or believed without due care and attention (IPC Section 52) Special provision in Section 31 of the PC PNDT Act exists for this. Unnecessary comments or action is objectionable during the inspection by inspectors. Recently conduct rules have also been framed in the gazette notification for AAs

Question: Whether the Appropriate Authority of PCPNDT are authorized to inspect MTP records?

Answer: No, not at all. AA are not authorized to inspect MTP centers where the Civil Surgeons are Chairperson of the Advisory Committee but in corporation areas where CMHO is Chairperson, he/she can inspect or can authorize any person in written (unless & until they are prior permitted by Civil Surgeon/ First Class Magistrate/ Governor of union territory in their respective areas.)

Question: Can MCI give guidelines to Govt./Court to decide PCPNDT cases within a stipulated time? (To protect doctors from harassment?)

Answer: We don't know about MCI guidelines. But Judiciary is quite ahead to protect. Please also see Supreme court decision by Hon'ble Justice Deepak Misra and Radhakrishanan. Example: WP.No. 7896 of 2010. Dated 6th June2011. High Court issued clear guidelines as - "We are also distressed by the fact that a number of cases for trial of offences registered under the Act are pending in Courts of the JM(I) Class for a long period, sometimes up to 6 years and in few cases as long as 6 to 8 years. It is therefore, directed that all cases under the Act shall be taken up on top priority basis and the Metropolitan Magistrates and the JMFCs in other Districts shall try and decide such cases with utmost priority and preferably within one year. Criminal cases instituted in the year 2010 and prior thereto shall be tried and decided by 31 December 2011.

Question: How to sell the ultrasound machine? Can we sell our machine directly to a doctor or any nonmedical person?

Answer: Machine should be sold to registered centre only. Amendment of 2003, Nobody can sale, distribute, supply, rent, allow or authorize the use of USG machine or equipment in any manner, whether on payment or otherwise, to any center which is not registered under the Act. Once in three months a list of those to whom the machine/equipment has been provided is to be provided to the AA. An affidavit from the center is to be taken.

Question: Are there some guidelines for access to unauthorized persons – (viz media etc)—during PCPNDT inspections or raids or stings?

Answer: Actually it's a confidential drive, hence it will be an unlawful action which can be challenged in the Court of law.

Question: Can an obstetrician perform and report an ultrasound including a level II targeted anomaly scan? Is training at a recognized center mandatory?

Answer: Yes. An obstetrician can perform and report an ultrasound including a level II targeted anomaly scan. They do not require additional training. Eligibility criteria are same as laid down by PCPNDT Act. Please refer to Training Rules 2014 on PC PNDT Act

Question: Which will be the perfect remedy to stop sex determination practices at doctor-patient level? Sting operation? Graded punishment? Sealing of USG machines?

Answer: It is the doctor's will and patient's will both!!! Book the culprits and help the law enforcing agencies for better implementation.

Landmark Judgement

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A case for calculation of the claim made by the Hon. Supreme Court

Background

Appeals were filed by the doctors and AMRI against the judgment of National Consumer Forum and also by claimant – appellant Dr Kunal Saha. Whereas the doctors felt that the quantum of compensation awarded was unjust and should be set aside, AMRI hospital felt that the compensation should be reasonable and therefore reduced. The claimant –appellant Dr Kunal Saha felt that the compensation is inadequate and should be enhanced.

The Honorable supreme court of India had remanded the case to National consumer forum Malay Kumar Ganguly Vs. Dr. Sukumar Mukherjee[1] for calculation of just compensation. Dr Kunal Saha had claimed a compensation of Rs. 77,07,45,000/-.

Argument of Doctors and Hospital

In support of his claim, claimant has produced only a computer generated sheet, which does not explain whether the deceased had a stable job and income, whether it is a onetime payment or regular income and the type of job for which said emolument was received. The document produced in support of the income of deceased is of June 1988 where as she came to India in 1998, therefore it is vague and unreliable document.

It was further contended that cognizance should have been taken of the tax liability and life style related expenses as was laid down by honorable Supreme Court. Deduction towards tax should be 25% although it may be much more as is evident from another case[3]. The foreign expert examined to assess the lifetime income of the deceased stated that the deceased was not employed at the time of her death and that he was not aware of the annual income as filed in income tax returns of the deceased.

Compensation for loss of consortium awarded to the tune of Rs 10 Lacs was considered inappropriate as in previous pronouncements has been to a maximum of Rs 25,000/-. The claim that the compensation is to be calculated was also considered inappropriate as in two previous judgments [2,4] court has not allowed the same.

Word "reasonable" implies that the AMRI and doctors cannot be saddled with an exorbitant amount as damages. Also it was claimed that "loss of dependency" cannot be applied in this case unlike a case against Nizam Institute [5] where the victim was paralyzed. It was also contended that the enhanced claim of Rs 20 crores was rightly rejected by the national commission as every adverse event in the life of claimant cannot be attributed to the death of his wife.

On calculation of pecuniary damage, it was contended that in some previous cases [3,6] loss to dependents is calculated by multiplier method and that a lesser multiplier needs to be applied as the deceased had no dependents. It was also contended that multiplier method were used in other cases other than motor vehicle act [7, 8, 9]. It was also claimed that the commission should have deducted 25% of the compensation due to contributory negligence.

The court has observed that the death may be the result of cumulative effect of negligence and other factors like (i) Disease TEN itself is a fatal disease which has very high mortality rate. (ii) TEN itself produces septicemic shock and deceased Anuradha died because of such consequence. (iii) No direct treatment or treatment protocol for TEN. (iv) Negligence of many in treating deceased Anuradha. (v) Contributory negligence on the part of Dr. Kunal Saha and his brother.

Additional arguments of AMRI hospital

The patient was treated initially by Dr. Sukumar Mukherjee and wrong medication (overdose) of steroid was used by him whereas after admission to

the hospital appropriate treatment was provided. Therefore apportioning 25% of award on AMRI is incorrect.

Additional arguments of Dr Sukumar Mukherjee

It was contended that nowhere in the judgment Hon. Supreme Court has observed that Dr. Sukumar Mukherjee and AMRI hospital is primarily responsible for the death. In fact it is stated that death may be result of cumulative effect of several factors as stated above. Therefore National commission has erred in apportioning equal liability on Dr. S. Mukherjee and AMRI (25%) of total compensation. The diagnosis of Septicemia as the cause of death was questioned and also that transport in a chartered flight may have contributed to infection of skin and not the treatment at AMRI hospital.

Additional arguments of Dr Balram Prasad

He was the junior most physician who carried out the orders of the Senior with diligence. The main complaint of the claimant was that he never suggested that the AMRI is not equipped to handle the TEN patients and stood as second fiddle. In this situation, apportioning equal compensation is not justified.

Additional arguments of Dr Baidyanath Haldar

That Dr Baidyanath Haldar is elderly about 80 years and is ailing with a heart disease. He is not in active practice and therefore the liability should be set aside.

Argument of Claimant Dr Kunal Saha

Dr Kunal Saha claimed that the National commission has erred in disallowing more than 98% of the original compensation claimed. The National Commission has failed to consider the pecuniary, non-pecuniary and special damages. The use of multiplier method is not appropriate. National commission has erroneously used multiplier method for the first time in the Indian Medico-legal history. National commission reinvestigated the whole case and did not rely on the judgment of Hon. Supreme Court. The national commission failed to grant interest on the compensation. The national commission failed to consider devaluation of money since 1998 when the case was filed. The claimant also requested to expunge the comments that he was trying to "make a fortune out of a misfortune" which must be expunged.

The appellant doctors and AMRI claimed that the compensation claimed is enormously fabulous and should not be granted. Here a case [10] was referred where in Hon. Supreme Court had observed that to deny a legitimate claim or to restrict the size of the claim arbitrarily amounts to substantial injustice. Principle of compensation is "restitutio in integrum" (which means the original condition must be restored to the extent possible). It was claimed that the National commission rejected the entire claim as the additional claim was not made initially, therefore none of the claims can be considered. This is contrary to the judgments of Honorable Supreme Court [5].

While referring the case to National Commission for calculation of compensation, it should be based on the "educational qualification, her own upbringing, status and husband's income". The deceased was a recent graduate in Psychology and had a bright future ahead. Therefore calculation of compensation on the basis of the income of $30,000/annum was not appropriate. National commission did not take into account the loss of income calculation by Prof John F Burke, a financial expert who had concluded that the financial income of the deceased Anuradha to be about 5 million dollar after deducting for her personal expenses and income tax.

The claims of the senior doctors that they cannot be penalized as they did not charge their professional fee cannot be upheld in view of the judgment of the Honorable Supreme Court in another case[11]. It was further contended that if this principal of "no liability for free treatment" is established than the poor patients in many charitable hospitals would be killed with impunity by the reckless doctors. Punitive damages should be awarded for acts of negligence as a means of deterrent for future.

The Verdict of the Honorable Supreme Court of India

The Hon. Supreme Court considered the claim of the claimant for enhancing the claim arising out of inflation over 15 years as valid. Court agreed that it was not initially possible for him to claim "just compensation" for the pain that claimant suffered

over a period of 15 years of trial. The Honorable Supreme Court of India stated "Therefore, we are of the view that the claimant is entitled for enhanced compensation".

The court observed that "Loss of wife to a husband may always be truly compensated by way of mandatory compensation. How one would do it has been baffling the court for a long time. For compensating a husband for loss of his wife, therefore, the courts consider the loss of income to the family. It may not be difficult to do when she had been earning. It is capable of being measured on monetary terms although emotional aspect of it cannot be. It depends upon her educational qualification, her own upbringing, status, husband's income etc."

The National commission committed grave error in taking existing income of the deceased for calculation of compensation under the 'Loss of dependency' by not taking into account the current educational qualification and future prospects. Hon. Supreme court disagreed with the counsel of AMRI and doctors "the claimant is not entitled to seek the additional claims by way of affidavit, the claim is barred by limitation and the same has not been rightfully agreed by the national commission".

On multiplier method - Hon'able Supreme court quoted another judgment[5] "The kind of damage that the complainant has suffered, the expenditure that he has incurred and is likely to incur in the future and the possibility that his rise in his chosen field would now be restricted, are matters which cannot be taken care of under the multiplier method." Based on this and other judgments court agreed in favor of the claimant and disallowed use of multiplier method in this case.

On cost of litigation Hon'able Supreme court disallowed the claims on loss of income and reduced the claims on travel expenses etc considerably to realistic levels. The court also observed that the claimant has not produced evidence of his expenditure but agreed that he has been travelling from USA for the purpose of this case. Honorable Supreme Court observed that the National commission did not grant interest on claim from the date of appeal and found it unreasonable and therefore awarded an interest of 6%.

The court also held that the AMRI hospital has the vicarious responsibility for ensuring the quality of care and is therefore liable for payment of total amount due after deducting the amount payable by the appellant doctors.

On Liability of Dr Sukumar Mukherjee

The court observed that he 1. Did not refer the case to dermatologist initially, 2. Prescribed steroids, which is not commonly used in such cases and in dosage that exceed all limits of prescribed dose regimens, 3. When charged with liability he tried to shirk the responsibility to others. Therefore he is liable to pay the compensation.

On Liability of Dr Baidyanath Haldar

Prescribed steroids which is not commonly used in such cases and in dosage that exceed all limits of prescribed dose. When charged with liability he tried to shirk the responsibility to others. Therefore he is liable to pay the compensation.

On Liability of Dr Baidyanath Prasad

Hon'able Court recognized that he is a junior doctor. However, Hon. Court also observed that he is an independent practitioner, he did not use his brains and contributed to negligence by standing second fiddle. Therefore his liability was reduced.

On Liability of Kunal Saha

Hon'able Court recognized that Dr Kunal Saha may have been overanxious and may have administered antibiotics on own, however, the same were considered necessary later on. Therefore Hon. Court did not agree with the allegation of contributory negligence.

Based on the abovementioned facts which are detailed in the judgment, Hon'able Supreme Court calculated compensation under following heads.

1. Pecuniary Damages (Which essentially deal with loss of income or direct expenses incurred)

   1a. Loss of income of the diseased

   1b. For Medical treatment at Kolkata and Mumbai

   1c. Travel and Hotel Expenses at Mumbai

   1d. Cost of litigation

2. Non pecuniary damages

   1a. Loss of consortium

   1b. Pain and suffering to the deceased

In addition to the claim, interest of 6% was granted from the date of application to the date of payment.

However, Hon'able Supreme Court declined to award any claim under the head emotional distress, pain and suffering to the claimant on the ground that "this claim bears no direct link with the negligence caused by the appellant-doctors and the Hospital."

Learning from the Case

1. Institutions are primarily responsible for Quality of Care being provided by the staff working with them.
2. Doctors working in Institutions will not get the total cover of Institution if they are found negligent. Cost of negligence will have to be borne personally.
3. An effort to shift the blame to your colleagues and subordinates is deemed as "shirking the responsibility" and is viewed very seriously by the court.
4. There is absolutely no defense against use of drug in dosage beyond the therapeutic limits. Though it is not a part of the judgment, it may be prudent to add that even for research purpose prior sanction of Ethics committee of the institution must be sought as a means of legal protection.
5. Doctors should be aware of current standard of care in dealing with diseases that they do not commonly treat.
6. Compensation for foreign resident will be calculated on the basis of their place of residence.
7. Compensation will include loss of potential income based on the educational background and status, even if the deceased was not in current employment.
8. Interest is payable from the date of application and not from the date of judgment. Therefore, delaying tactics in the court of Law will be counterproductive.
9. Even if you are a junior doctor, Court does expect you to take a considered view of the case while handling one and not merely follow the orders of the seniors. This defense is considered inadequate by Hon. Supreme Court.
10. Not charging consultation fee is not a defense against charges of negligence in the eyes of Court of Law.

References

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2. Oriental Insurance Company Ltd.Vs. Jashuben. (2008) 4 SCC 162.
3. United India Insurance Co. Ltd. Vs. Patricia Jean Mahajan (2002) 6 SCC 281.
4. R.K. Malik Vs. Kiran Pal (2009) 14 SCC 1
5.
6. Nizam Institute of Medical Sciences Vs. Prasanth S.Dhananka (2009) 6 SCC
7. Sarla Verma v. Delhi Transport Corporation, (2009) 6 SCC 121
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9. M.S. Grewal. Vs. Deep Chand Sood (2001) 8 SCC 151
10. Municipal Corporation of Delhi Vs. UphaarTragedy Victims Association (2011) 14 SCC 481.
11. Indian Medical Association Vs. V.P.Shantha. (1995) 6 SCC 651
12. Savita Garg Vs. Director, National Heart Institute. (2004) 8 SCC 56

Request for contributing articles

All the members, reviewers, well wishers are requested to contribute articles, case reports, happenings, original studies, research publications as per the guidelines for the authors published in this journal.

Wrong Diagnosis: Is It Medical Negligence?

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The practice of medicine has been an art since ancient times. In recent years, it has become increasingly difficult to practice medicine. The availability of medical information on internet has resulted in a radical change in the way in which patients approached their doctors. The prerequisite for acquiring perfection in the art of medical science includes a proper diagnosis, related necessary investigations and a rational therapeutic approach. Proper diagnosis of an illness to differentiate it from other diseases with almost identical presentation is a must for treating any patient effectively. Delayed or missed diagnosis may result in delayed or wrong treatment which may ultimately result in injury or damage to the patient. A wrong diagnosis unless its genesis is in negligence or incompetence, can't be considered as deficiency in service [1].

Once a doctor decides to undertake the treatment of any patient, he has to provide care which must be of average skill, knowledge and experience that a prudent doctor with equivalent qualification in a similar situations would have done. The carelessness in such management may result in damage to the patient. This carelessness may amount to negligence if a direct nexus (*causa causans*) is proved between the deficiency & the damage [2]. In a case *Mrs. Bhanupal v. Dr. P. Padode*, an MBBS doctor running a nursing home, called Surgeon & Anesthetist for operating his hernia patient. The patient died in OT. Post mortem showed that there was aspiration pneumonia, stomach was full. Patient was also asthmatic. In this case all the three doctors were held liable for the negligence. The carelessness resulting in damage may be co-related with the wrong diagnosis. In, *M Bhagat v. Bhandari Hospital I (12) CPJ 59*, there was allegation that after an injection, foot drop developed due to injury to the sciatic nerve of right lower limb. The medical board finding suggested that the muscles which were weak were not supplied by sciatic nerve. It was also observed that the involvement of right as well as left leg was probably due to polio. Negligence was not held.

History taking & Examination

The duty or care starts with proper listening to patient's history. The doctor shouldn't only carefully listen to the complaints but he should also ask for significant positive or negative history related to those complaints in order to arrive at a proper diagnosis & to rule out important common differential diagnosis [3]. While recording history it is important to note down any previous drug sensitivity. In, *B Kaur v. C Malhotra I (2008) CPJ 265*; pre-operative sensitivity test didn't show any reaction. But patient succumbed on table due to cardiac arrest. The allegation of drug reaction was also negated in Postmortem report and hence negligence was not held. As against this, in *Noorjahan v. Dr. Smita Bangal III (2000) CPJ 132*, the doctor was held liable for prescribing medicine without checking for pregnancy as it resulted in severe reaction & ultimately abortion. It is patient's responsibility that he/she should give proper history without hiding or misrepresenting any facts. A missed or wrong history may lead to missed or wrong diagnosis.

Once the history is over the attending doctor must carefully examine the patient for various signs related to the suspected diagnosis. Missing of important signs may itself result in wrong or missed diagnosis ultimately resulting in improper treatment. In a case *SK Sharma v. Dr. P Desai III (2000) CPJ 407*, a patient of Ca. Breast right side was treated with chemotherapy & radiotherapy. Later on malignancy was found in left breast also. It was alleged that left side was not examined. In defense it was held that every doctor checks both sides where paired organs are concerned. The treatment given in this case was also one of the accepted methods. Negligence was not held in this case. In *Nivedita v. Dr Asha I (2010) CPJ 281,* there was allegation that gangrene of the toes developed due to prolonged lithotomy position during the delivery. The first and 2nd toe of the right foot has to be amputated. It was defended that there was no other complications and lithotomy is a normal position during delivery. The important finding which went in favor of doctor was bed head ticket which

proved that there was a wound prior to her admission.

Investigations

If it is not possible to diagnose the illness clinically, help of investigations should be taken. In *Ms Sujatha v. Dr. Suryaprakash I (1999) CPJ* 560, patient presented with red eye & irritation, corneal scrapping was negative for the fungus but patient didn't improve. The second scrapping turned out to be positive & patient was treated accordingly. The patient lost vision but the case was dismissed on the ground that the treatment was appropriate. Those investigations which are necessary according to the presenting symptoms & signs must be advised. In a case, *Rani Devi v Dr. S R Agrawal III (2002) CPJ 136*, where a patient with fever & swelling in the neck was investigated (FNAC) & treated for tuberculosis. There was no relief, patient went to other doctor who did biopsy & diagnosed malignancy. In this case also negligence was not held, because the practice followed in this case was one of the accepted methods. Failure to advice investigations may amount to negligence. Don't advice unnecessary investigations. If patient doesn't do the suggested investigations, this becomes a contributory negligence on the part of the patient or relatives. In *P Gupta v. AV Nursing home*, a patient of fever who was being treated for typhoid, developed bleeding. Blood report was ? Leukemia, Bone marrow biopsy was advised but not done. Patient was given many blood transfusions but ultimately died. Negligence was not held.

The National Commission in a case; *Bombay Hospital v. Sharifabai Ismail I (2008) CPJ 432 (NC)* held that consultant is liable for errors in interpreting report. Senior consultant is not expected to sign whatever junior staff suggests, without reading the same. The consultant radiologist who signed the report is responsible for misreading / non-reading of MRI films correctly. The duty of consultant begins and ends with correct interpretation of reports of film/scan.

Some of the very basic instruments like ECG machine, glucometer, phototherapy units, fetal monitor etc. should be available in the hospital, depending upon the specialty in which the doctor is practicing. These instruments may help in timely diagnosis & treatment of some of the very common complications which may occur during the course of illness. In the absence of these routine instruments, we may miss very simple diagnosis or complications ultimately resulting in unfavorable outcome. In *DK Sharma v. PGI Medical Education & Research I (2002) CPJ 211* doctors were held negligent as operation couldn't be completed due to non-availability of drill machine. Compensation was granted to the applicant & it was held that a valid consent can't be a defense for the non-availability of instruments.

Diagnosis of the Complications

Some of the illnesses are self limiting, while others are progressive. Some of the illnesses have mild progression while others have fulminant course irrespective of treatment. Hence in any illness treating doctor must be able to foresee common complications, diagnose & treat them at proper time. This principle was applied in *Sumitra Biswas v. Dr. I Ahmad II (2002) CPJ 275*, in this case patient was taken for eye surgery after proper check-ups. During the surgery expulsive hemorrhage (one of the rare but known complication) was detected, surgery was abandoned & the patient was referred to a better center. No negligence was proved on the part of operating doctor. If the doctor misses this it may amount to negligence. Negligence was held & compensation was granted to the complainant in *Padma v. Sudha nursing home*, where a patient was treated for enteric fever & discharged but was re-admitted. There was delay in diagnosing and treating enteric perforation. The postoperative care was given by unqualified doctors. Patient was re-operated at Apollo hospital. If the complications are too remote then it is not negligence. In one of the cases, *Study Circle society v. Chithiram hospital*, a child went into coma after operation, doctors contended that it is an unforeseen complication. The relatives couldn't produce any contrary or expert evidence. The case was dismissed.

If the complications are developing or if the doctor feels that the particular case is beyond his skill or competence, a referral to a higher, better equipped center is always preferable. In *Sayed Mohammad Owais Quadri v. Dr. Neena Desai III (2002) CPJ 52*, full term woman with twins and PIH was taken for LSCS. Postoperatively Amniotic fluid embolism developed. Patient was treated with blood, FFP, Fibrinogen and was shifted to ICU Apollo hospital. After the death of the patient, negligence was alleged

in performing surgery and postoperative care. The case was dismissed on the ground that deficiency in service couldn't be proved, the complication is known, treatment was proper and referral was also in time. Timely referral after explaining the reasons for getting expert opinion may prevent many cases of negligence in day-to-day practice. Similar view was taken in *Goswami v. Dr. Deepak II(2001) CPJ 374*, in which patient became unconscious after appendicectomy. There was cerebral stroke, cardiologist was called and patient was shifted to other hospital. It was alleged that the doctor was only MBBS. The court held that in this case doctor was competent and there is no evidence of wrong treatment. As against this in *S Krishan Rao v. Sudha nursing home*, a patient of breast cancer was operated twice before referring to a cancer hospital. It was held that the referral was too late and doctor is liable.

Mistaken or Delayed Diagnosis

Sometimes the symptoms and signs of the illness may be so overlapping that it is very difficult to clinically diagnose the disease [4]. In the case *Dr. V J Patel v. K Thakkar* I (12) CPJ 69 (NC) it was alleged that there was mis-diagnosis of cerebral malaria, IV Quinine was given without taking due care and ruling out adverse reaction. In this case negligence was established in investigating and treating a patient. Sometimes, diagnosis may be mistaken or delayed inspite of diligence and due care by the treating doctor. In *Vinitha Ashok v. Lakshmi hospital SC I (2002) CPJ 4*, the patient had excessive vaginal bleeding, hysterectomy was done for cervical ectopic pregnancy. There was no evidence of malignancy hence histopathology was not done. Negligence was not held on the ground that the diagnosis and the mode of treatment were according to expected line. Negligence may not be held in such cases if proper examination and related investigations were done. Reports are not always conclusive and doctor may not be held negligent for this was the decision in *Rajkumar v. Dr. Ajay I (2001) CPJ 495*, where a patient after sonography/scan was diagnosed as a case of gall stone with ascites. There were no malignant cells in ascitic fluid, but on operation table secondaries were detected in mesentery. In *M Parimanam v. Dr. Jaganathan I (1999) CPJ 243*, where the patient died due to Rabies, it was alleged that there was wrong diagnosis and treatment. The defense in this case was that clinical tests were conducted and a pediatrician was called. The case was dismissed. But in *J Padia v. Dr. Trivedi I (1997) CPJ 11*, a child was under treatment for fever, diagnosed as measles, did not improve. A pediatrician was called, admitted and treated as measles for 36 hours then diagnosed as Stevens Johnson Syndrome, referred to eye surgeon ultimately lost vision. In this case the pediatrician was held liable.

Diagnosis in Emergency Situation

In the practice of medicine, many times we have to tackle the emergency situation. In such situation the clinical features may not be very obvious to suggest a particular diagnosis. Proper history may not be available especially if the patient is unconscious or distressed. At the same time, sufficient time may not be there to go in for investigations. In *Babu Kople v. Dr. M. Bhatambre III (2000) CPJ 366*, it was alleged that there was wrong diagnosis, no investigations and delay in blood transfusion. The doctor explained that the child was referred to him in serious condition (septicemia), antibiotics were started, blood culture would have taken long time, Lariago was continued as started earlier. Blood transfusion takes at least three hours as certain tests are to be carried out as per Govt. notification. The civil surgeon also certified that the treatment was proper. The doctor was not held liable and the case was dismissed.

In such situation immediate aim is to save the human life. It is not negligence if there is error in diagnosis or judgment while managing an emergency case. Similar view was taken in *Lekhraj v. Bharaj nursing home II* (1998) CPJ 335, where a patient with multiple accidental fractures was taken to the hospital. X-rays were taken next day and referred to a higher center. By this time gangrene has developed and the leg had to be amputated. It was alleged that there was delay in taking x-ray and referral of the patient. According to attending doctor, the patient was in shock, with hematoma and fracture so treatment was started to stabilize the patient and was referred next day when he could travel. The expert testified that the treatment given was proper and as the patient was in shock he couldn't have reached within time to the higher center. The case was dismissed. Once the emergency is over, the patient's life is saved then the detailed investigations may be done to confirm the diagnosis and provide further treatment.

Error in Diagnosis

Sometimes the diseases (metabolic, genetic) are so uncommon or their manifestations are so atypical that it is really very difficult to diagnose them with routinely available facilities or investigations. In such cases there is every chance that error may be made inspite of diligence and care. In *P Roychoudhury v. Dr. CS Darwan I (2002) CPJ 504*, a child specialist was not consulted, there were no any signs at the time of discharge. The baby subsequently developed jaundice and it turned out to be a case of G6PD deficiency. It was alleged that the pediatrician should have been consulted immediately and exchange transfusion should have been done. The doctors explained that the persons with G6PD deficiency are born with it and the baby was normal at the time of discharge. No relief was granted as no negligence was established in this case. It is always better to refer cases to higher center where the rare and latest investigations may be done to confirm the diagnosis. In *Krishna Dey v. Dr. TK Roy,* a girl with difficulty in walking was examined, investigated and advised operation. It was alleged that after operation the girl became totally disabled. The doctors contended that it was a case of Muscular dystrophy (a non-curable genetic disorder) and the surgery was only a palliative one. The experts confirmed this and hence the case was dismissed. Such illnesses may not be treatable, but a proper diagnosis is important to explain the progress and the prognosis of the disease to the patient or relatives. In a detailed, well reasoned and analyzed discussion *Shailesh Munjal v. AIIMS, 2004 CTJ 940 (CP) (NCDRC);* National commission observed that the process of pre-natal diagnosis is a complex one and the genetic technologies have not developed to the extent that the same are free from all errors. *It is further submitted that no scientific technology can be 100% perfect. The error is inherent in nature of test itself and can occur due to various independent and contributory factors*. Even though error or imperfection has crept in while bifurcating the fetal tissue from the mother's tissue, it is difficult to arrive at the conclusion that it amounts to medical negligence. No doubt, in such cases, there is a thin difference between the error, imperfection or fault and negligence.

Now-a-days we are in the era of telecommunication and telemedicine where we can take an expert's opinion who may be sitting several miles away from the patient. The doctors can collaborate with colleagues nationally and internationally. Computer based technologies may prove to be a double-edged weapon. There is every possibility of wrong diagnosis and subsequently wrong treatment in such situations. There is also possibility of misuse of this evolution if strict access controls are not maintained. Computer aided diagnosis has become a reality in areas such as mammography, bone densimetry and electrocardiography. In the future, these methods will be used to screen the healthy population, relieving the physician to oversee suspect cases [5].

Conclusion

The availability of technically advanced instruments, better diagnostic modalities, and advance treatment facilities has resulted in soaring expectations of patients or relatives [6]. The different financial avenues, insurance facilities have also forced the patient to go for advanced diagnostic investigations and therapeutic measures, even though not necessary in many cases. In such situation when the patient is willing to pay any amount (at least verbally), he expects more and more benefits. The skill and competence of the doctor may be overlooked in the presence of well furnished, equipped hospital. [7] But as a good doctor we must understand that basically it is the doctor's competence, knowledge and skill that are important for proper diagnosis and treatment. Accurate diagnosis along with rational drug therapy will always bring good reputation in today's competitive atmosphere.

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Medico-legal News

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Doctor not guilty of negligence if he takes reasonable care, rules court

A doctor who has taken reasonable care of a patient cannot be held guilty of negligence, a consumer court has ruled. Sixteen years after the complainant, a police officer lost his pregnant young wife to complications of jaundice the additional consumer disputes redressal forum at Bandra held that there was no negligence on the part of two doctors and Wadia hospital. "While considering the aspect of negligence on the part of a treating doctor, what we have to see is whether he took reasonable expected care of the patient which any other medical practitioner (would have done)," said the forum. "A medical practitioner would be liable only when his conduct fell below the standard of a reasonable competent practitioner in the field," the forum added, while dismissing the application.

The bench said the complainant's wife had died due to sudden complications in her health due to infective hepatitis. "One thing is seen from the record that the medical complications that occurred to the wife of the complainant were within a short time and the nature of the medical problem was so serious wherein the percentage of cure is rare," said the bench, adding that the complainant was expected to produce expert opinion to discharge the burden of proof, which he had not done.

The doctors claimed that there was no specific treatment for hepatic encephalopathy, which the deceased contracted, and that her condition deteriorated despite their best efforts. The complainant said his wife was six months pregnant with the couple's first child when she approached a doctor of a private maternity home in Chembur. She was admitted to the hospital on July 30, 1998, and the next day was referred to Wadia hospital. From Wadia hospital, she was taken to Kasturbha hospital, where she died. It was alleged that his wife died due to negligence as her health problem was not detected in time and no proper and timely care and treatment was given to her.

(Mar 1, 2014. The Times of India, Mumbai)

Indian Medical Association wants medical tribunal for negligence cases

Considering the amount of expertise required to determine whether a doctor has been negligent, the state branch of Indian Medical Association (IMA) wants a separate Doctors' Redressal Forum or a medical tribunal formed under the Consumer Protection Act. Doctors from the state unit of IMA, who visited the city for the installation of the new team of IMA, Nagpur, raised some other important issues too.

"There have been several cases in the recent years where the punishment or compensation to be borne by doctors has been unfair. The bodies making these decisions have no doctors on board. We are not against punishments being meted out to those who do wrong, but unfairly punishing the innocent, too, must be avoided," said Maharashtra president of IMA.

"Agreed", a past president of National IMA said, "A very thin line separates death caused by illness, medical negligence and medical accident. There are actually very few genuine cases where negligence actually happens. This difference is not easy to understand, especially by people with little or working knowledge of medicine." He believes that there must be a cap on the compensation to be paid by doctors in such cases.

(Apr 28, 2014, Times Of India, Nagpur)

Research Briefs

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Ethics and Medico Legal Aspects of "Not for Resuscitation".

Naveen Sulakshan Salins, Sachin Gopalakrishna Pai, MS Vidyasagar, and Manikkath Sobhana

(Indian J Palliat Care. 2010 May-Aug; 16(2): 66–69.)

AProviding a good end of life care to all is a social obligation which needs to be provided to all citizens. Indian Law is lacking in this area and there are no guidelines for withholding and withdrawing life support. There are certain barriers which act as an obstacle in taking these decisions. The study found that these barriers were not due to ethical or cultural issues but primarily due to legal issues, administrative issues and lack of hospital polices. There is ambiguity in the Indian legal system in taking a stance towards resuscitation, limiting life support, withholding or withdrawing treatment.

In 1994, the Supreme Court ruled that an attempt to hasten death in terminal illness might be viewed as a natural process. "A person cannot be forced to enjoy the right of life to his detriment, disadvantage or dislike". The above judgment of the Supreme Court was overruled by the Constitution bench which ruled that permitting termination of life in the dying or vegetative state is not compatible with Article 21 of the Constitution which states that "No person shall be deprived of his life or personal liberty except according to procedure established by law". The interpretation of Gian Kaur case disallows the concept of Euthanasia as it violates Article 21 of the Indian Constitution. As withholding and withdrawing life support amounts to abetment of suicide and abetment of suicide is a punishable offence according to Indian Penal Code. These issues are addressed by the Law commission of India and until such laws come into effect patient autonomy, family wishes and medical decision making at end of life will still remain guided by the Indian Penal Code.

Indian Society of Critical Care Medicine in 2005 put forth a position paper outlining guidelines for "not for resuscitation" in an Indian setting.

The recommendations were

a) It is the duty of the physician to discuss with honesty and clarity regarding prognosis and treatment options.

b) When the fully informed capable patient or family desires to consider palliative care, the physician should offer the available modalities of limiting life-prolonging interventions

c) Physician must discuss the implications of forgoing aggressive interventions through formal conferences with the capable patient or family, and work toward a shared decision-making process.

d) If there is a conflict then pending consensus all active treatment should continue

e) Responsibility, initiation and implementation of decision of "not for resuscitation" rests with the treating physician.

f) Clear documentation of the decision, directives and end of life wishes.

g) Withdrawal of life support should be consistent with good practice, ethically right and within the limits of existing law.

h) Physician is obliged to provide compassionate and effective palliative care to the patient and family.

Using death certificates to characterize sudden infant death syndrome (SIDS): opportunities and limitations.

(J Pediatr. 2010 Jan;156(1):38-43. doi: 10.1016/ j.jpeds. 2009.07.017.)

A study was done to determine ccause-of-death terminology written on death certificates for sudden infant death syndrome (SIDS) and to determine the adequacy of this text data in more fully describing circumstances potentially contributing to SIDS deaths. Year 2003 and 2004 US mortality files were used for this purpose .Study analyzed all deaths that were assigned the underlying cause-of-death code for SIDS (R95). With the terminology written on the death certificates, study ggrouped cases into SIDS-related cause-of-death subcategories and then assessed the percentage of cases in each subcategory with contributory or possibly causal factors described on the certificate.Of the 4408 SIDS-coded deaths, study subcategorized 67.2% as "SIDS" and 11.0% as "sudden unexplained (or unexpected) infant death." The terms "probable SIDS" (2.8%) and "consistent with SIDS" (4.6%) were found less frequently. Of those death certificates that described additional factors, "bedsharing or unsafe sleep environment" was mentioned approximately 80% of the time. Most records (79.4%) did not mention any additional factors. The study provided a unique opportunity to more accurately characterize SIDS-coded deaths. However, the death certificate was still limited in its ability to more fully describe the circumstances leading to SIDS death, indicating the need for a more comprehensive source of SIDS data, such as a case registry.

Readers Ask, Experts Answer

Question: *(by Dr Rajinder Gulati, Ludhiana, e-mail: rajinder_gulati@hotmail.com)*

A rape victim becomes pregnant and delivers the baby in a hospital. As a routine, while informing the birth to Municipal authorities, we have to inform the name of the father. Here in this case, should we leave the column blank or should we write the name of the person i.e. the accused as told by the mother? What should be the course of action especially when the case is subjudice and pending in the court of Law and the accused may not be the actual criminal or may be declared innocent by the Court and acquitted?

Answer : *(Dr Mahesh Baldwa, MD, PhD in law, Mumbai, e-mail: drbaldwa@gmail.com)*

There's a lot of confusion surrounding the issue of rape victims giving birth to child and birth certificates. As per registration of birth one can give only one parent's (only mother's) or guardian's name. Best way is to name mother and keep fathers name blank since he is not available to sign the required form / documents and only the mother delivering the baby is available for signing. Doctor or hospital where the delivery has taken place can send explanation for not naming father and the court case related circumstances to medical officer of area (if asked for). Name of the father as per rape victim statement with prejudice in the subjudice case is not mandatory. Hence let the court decide who is the father of the child in future and a judgment to that effect may be given.

A Birth or Death has to be reported for registration, within 21 days of occurrence. As per law of Registration of Births and Deaths such information is compulsory throughout the states and as per the 'Registration of Births and Deaths Act 1969' - Central Act 18 of 1969, father's name is not compulsory or mandatory.

Registration of name of child.-

Where the birth of any child has been registered without a name, the parent or guardian of such child shall within the prescribed period give information regarding the name of the child to the Registrar either orally or in writing and there upon the Registrar shall enter such name in the register and initial and date the entry.

Birth and Death registration is to be done at the place of occurrence. If, the person making the entry or accepting the birth information is not accepting the birth information document, higher authorities can be approached.

Question: *(by Dr. Balraj Yadav, Consultant Paediatrician ,Gurgaon)*

What precautions should be taken while writing a prescription?

Answer : *(Dr Mukul Tiwari, Chief Editor, JIMLEA)*

Prescription/medication errors account for approximately 20% of all clinical negligence claims against doctors in the western world but the data for India is not clearly available. The problem is colossal ; costs associated with adverse events and inappropriate prescribing has been estimated at more than £750 million per year in the UK .

Precautions while prescribing

- You should prescribe any drugs or treatment only when you have adequate knowledge of the patient's health and you are satisfied they serve the patient's needs.
- You must not allow any personal interests to affect the way you prescribe for patients.
- You should avoid prescribing for yourself or for anyone you have a close relationship with, wherever possible.
- Doctors with full registration may prescribe all medicines, except those which are “Scheduled medicines”. Scheduled medicines are those which have a potential for abuse. Also ,It is expected that you will write medicines related to your specialty .

- Ensure you are familiar with current recommendations of the formulary, including the use, side effects and contraindications of the medicines you are intending to prescribe.
- You should be aware of the guidance relating to the clinical and cost-effectiveness of the medicines you are prescribing.
- You should check that you are prescribing the correct dose of the medicine; this includes checking the strength, frequency and route. This holds especially important in prescribing for children.
- You need to ensure that the patient is not allergic to the proposed medication, is not taking any medication (prescription, over-the-counter or alternative medicine) which may interact with the proposed medication, and does not have an illness that may be exacerbated by the medication.
- It may be appropriate to warn the patient of potential adverse effects and possible drug interactions if the patient is already taking other drugs. For example, after prescribing antihistamins or anti anxiety drugs ,which may cause sedation, the patient should avoid or should be cautious with driving and/or handling dangerous machinery.
- You should make appropriate arrangements for follow-up and monitoring. Patients need to know under what circumstances they need to come back, and what the consequences of failing to attend for review could be.
- Try to give a Computer-generated prescriptions. However, if you are writing a prescription, you should use indelible ink ,do not abbreviate drug names, do not use decimal places if it is not necessary, clearly state the drug, dose, strength, route and frequency, if amending the prescription, draw a line through the incorrect part and initial the change. Prescriptions should be dated, and should include the full name and address of the patient. For patients under 12 years old, you are required to include the patient's age or date of birth.

It is desirable that a clear record be maintained in your office of all the prescriptions.

Question: *(by Alka Kuthe, Consultant Obstetrician, Amravati. em: alkakuthe@yahoo.com)*

What to do with the equipment being used on the patient in case of SUD (sudden unexpected death)

Answer : *(Dr Mukul Tiwari, Chief Editor, JIMLEA)*

If a patient dies and the death is reportable to the police, you should leave all equipment in place until you have discussed the case with the police. The guidelines are as follows –

If the patient has been connected to equipment that is needed urgently for other patients – for example, a ventilator – you should take a photograph or make a sketch diagram before it is disconnected from the patient. The sketch or photograph may preserve forensic evidence that could be crucial to the police investigations.

The equipment should not be disconnected or used again if it is possibly faulty or could be the subject of an investigation into a possible complaint or adverse event.

Other equipment- Equipment such as intravenous lines, drains, catheters etc should be left undisturbed. This is to preserve any forensic evidence, and to give the police pathologist the best opportunity for independent inspection and assessment of the case. The equipment may be relevant not only in cases of possible crime, but also in cases where the clinical management may be called into question. Examples of items that should be left undisturbed include: Endotracheal tubes, Intravascular lines, Drains, Cannulae, Catheters, Feeding tubes, Defibrillator pads, Cardiac pacing, devices, Sutures.

Faulty equipment- If you think that any piece of equipment might be at fault, it must be left untouched and, if possible, sealed and stored in a locked room or cupboard. It can be then be examined by the police.

The clothing should be left undisturbed. Any item (eg. a knife, needle or syringe) should not be touched. It should be left for forensic examination. If it is necessary to remove clothing or equipment, you should make a careful note of this.

Cremations- It is essential that pacemakers and/or radioactive implants are removed before the body is taken away for cremation in order to avoid the risk of causing an explosion during cremation.

Everything a Doctor Should Know About
Consumer Protection Act

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CONSUMER PROTECTION ACT (CPA)

Consumer protection Act-1986 was enacted by Indian parliament for the protection of the interests of consumer. This was undertaken in pursuance of initiatives by United Nations to protect consumer and a report of Secretary General, International Organization Consumer Union (IOCU). It was implemented in 1986. Medical services were brought into the purview of it since 1995.

WHAT IS CPA

All of us are consumers of health service given by doctors. In past medical negligence cases were filed under civil law and criminal law from time immemorial. Usual law courts took usually more than 20 years for settlement of disputes. Both litigants got frustrated. Following case will make it amply clear.

Dr. J. N. Shrivastava operated upon Rambiharilal's wife on 27.9.1958, on opening abdomen found appendix normal, hastily diagnosed inflamed gall-bladder and removed it. No consent taken from Rambiharilal waiting outside the OT. Patient was administered chloroform anesthesia. Few hours later the patient died of hepato-renal failure. Hospital lacked basic facilities, e.g., oxygen, blood-transfusion, life-saving drugs, staff and anesthetist. Dr. J. N. Shrivastava Should not have undertaken such a major operation under such circumstances. Nothing would have happened if the operation was postponed, since same was not a lifesaving operation. Therefore, court held Dr. J. N. Shrivastava Negligent in 1985 after 27 long years and asked him to pay Rs. 3000/- to Mr Rambhirailal.

Consumer protection Act has put the legal remedy on fast tract of justice.

STIFF RESISTANCE BY IMA & MEDICAL PROFESSION

Application of Consumer Protection Act took a lot of time before it was made applicable to the medical professionals. The application of Consumer protection Act started with decision given by justice Eradi of National Consumer Disputes Redressal Commission on April 21, 1992 by which he brought all medical practitioners who charged fees under the net of consumer Protection Act. As a result of that judgment and some other subsequent judgments, the medical fraternity went into a shivers. Immediately Cosmopolitan Hospital and Dr. K. Venugopalan Nair challenged the validity of the provisions of the Consumer Protection Act in 1994 as being violative of Article 14 (Equality before law) and Article 19 (1)(g) (freedom to practice any profession, or to carry on any occupation, trade or business). There followed a spate of Writ Petitions in High Courts all over the country, some even challenging the constitutional validity of the Act. Supreme Court heard all cases to give judgment in I.M.A. v. V.P. Shantha and stressed importance of better inter-personal relationship between doctor and patient, the need to look at patients with a more caring attitude and not as "poor beggars"....., but to see them as suffering fellow humans, ...

The scenario of “justice delayed” is “justice denied” quickly changed to “justice accelerated” is “justice buried”.

Thus the new scenario has changed the equation for both patient and the doctor by putting justice on fast tract. Doctors did not like the idea of fast tract justice. This is because of many false and frivolous cases may have been be lodged out of over enthusiasm of patients and consumer NGO's against doctors, which damaged the much-cherished professional reputation by publicity in print and electronic media even though case was sub-judice. Trial by media became every day affair. Media also added fuel to fire to the woes of litigant doctor out of sensationalizing the issue to sell the newspaper.

THE LATEST VERDICT

In a latest Judgment given **by** Supreme Court Of India **on 10 February, 2010 with Bench of Justices** H S Bedi & D Bhandari is as below

The brief facts of the case are: Kusum Lata Sharma appealed to Supreme Court alleging medical negligence from doctors of Batra Hospital. Her husband with great difficulty was diagnosed to have hypertension due to malignant tumor of left adrenal gland, which was operated and removed. Postoperatively since pancreas was damaged during surgery her husband was admitted multiple times to multiple hospital till finally he died due to "pyogenic meningitis",which was unconnected with adrenal gland operation done earlier . Supreme Court of India gave eleven point guidelines for the courts to adjudicate complaints against doctors.

They are:

i. Negligence is a breach of duty or an act which a prudent and reasonable man will not do

ii. Negligence to be established by the prosecution must be culpable or gross and not the negligence merely based upon an error of judgment

iii. Medical professional is expected to bring a reasonable degree of skill and knowledge along with a reasonable degree of care but neither the highest nor the lowest degree of care and competence

iv. A doctor would be liable only where his conduct fell below that of the standard of a reasonably competent practitioner in the field.

v. Difference of opinion cannot be cited as negligence.

vi. Just because a professional looking at the gravity of illness had taken a higher element of risk to redeem the patient out of his suffering which did not yield the desired result, it may not amount to negligence.

vii. Merely because a doctor chooses one course of action in preference to the other one available, he would not be liable if the action chosen by him was acceptable to the medical profession.

viii. It would not be conducive to the efficiency of the medical profession if no doctor could administer medicine without a halter round his neck.

ix. It is our duty not to harass or humiliate medical professionals unnecessarily so as to allow them to perform their duties without fear and apprehension.

x. Doctors at times have to be saved from such class complaints who use criminal process as a tool for pressurizing them or hospitals and clinics for extracting uncalled for compensation

xi. Doctors are entitled to get protection so long as they perform their duties with reasonable skill and competence and in the interest of the patients.

WHAT SHOULD A DOCTOR DO?

First and foremost doctor should not avoid answering to legal notice or case. Send a reply to legal notice or case without delay. There should be no tendency to avoid or underestimate the importance answering to legal notice or case. Always explain mis-understandings, mis-representation and all the relevant discrepancies or wrong allegations made while answering to legal notice or case. The answers should be brief, clear and comprehensive. Attend personally all the dates in court/forum/tribunal/ commission with or without your lawyer and/ or medico-legal consultant. Produce affidavits of eye witness and affidavits of expert witness professional colleagues. Give scientific reference to support your explanation. Demand for cross-examination of complainant / litigants to support truth. Quote relevant legal case laws reported in law journals. Ask for counter compensation or file a counter suit or suit for defamation.

DON'TS IN CPA

Do not show antagonistic or negative attitude towards lawyers/judges. Do not presume court/forum/ tribunal/commission are on the side of the complainant/litigant. Don't show your disrespect towards court/forum/tribunal/commission by verbal or non-verbal means. Don't hand over unnecessary/ irrelevant documents. Don't speak unnecessary/ irrelevant details about case. Don't be panicky or frightened because you have received legal notice from court/forum/tribunal/commission related to a case.

DUTIES OF A DOCTOR

As per the directions of medical council of India vide

regulation 2.1 to 2.5 a Registered medical practitioner has some basic things to do as he approaches a patient. Patience and delicacy should characterize the physician. He must listen attentively complaints of a patient. He should take relevant and proper history and examine him carefully. A doctor has to attend to the patient and give dedicated care, once he has decided to treat the patient. He must explain the relevant facts related to the illness and take informed consent. He must prescribe only necessary and rational medicines. The doctors must have an average knowledge of the subject including recent advances. He must have a proper knowledge of use of medical equipments in his possession. The physician should neither exaggerate nor minimize the gravity of a patient's condition. The practitioners must be able to foresee the complications and refer the patient at proper time. A physician advising a patient to seek service of another physician is acceptable, however, in case of emergency a physician must treat the patient. No physician shall arbitrarily refuse treatment to a patient. However for good reason, when a patient is suffering from an ailment which is not within the range of experience of the treating physician, the physician may refuse treatment and refer the patient to another physician. Regulation 3.1.1 says, however, in case of serious illness and in doubtful or difficult conditions, the physician should request consultation, but under any circumstances such consultation should be justifiable and in the interest of the patient only and not for any other consideration. Doctors must also maintain a proper record of their patients.

Duties to Patient

These are : Standard Care, Providing Information to the Patient /Attendant , Consent for Treatment, and Emergency Care.

(A) Standard Care

This means application of the principles of standard care which an average person takes while doing similar job in a similar situation :

1. Due care and diligence of a prudent Doctor.
2. Standard, suitable, equipment in good repair. e.g. stethoscope, BP instrument, thermometer, weighing machine, torch etc
3. Standard assistants : Where a doctor delegates a task to compounder / assistant or paramedical staff, he must assure himself that the assistant is sufficiently competent and experienced to do the job, and fulfills the prescribed qualifications.
4. Standard indicated treatment.
5. Standard premises, e.g. clinic, must comply with all laws applicable as imposed by the State and these must be registered wherever required. e.g. shop and establishment act, biomedical waste etc.
6. Standard proper reference to appropriate specialist.
7. Standard proper record keeping for treatment given, X-ray and pathological reports.
8. Standard of not to experiment with patient.
9. Anticipation of standard risks of complications and preventive actions taken in time.
10. Observe punctuality in emergency.

(B) Duty to provide information to patient / attendant

1. Regarding necessity of treatment.
2. Alternative modalities of treatment.
3. Risks of pursuing the treatment, including inherent complications of drugs, investigations, procedure, surgery etc.
4. Regarding duration of treatment.
5. Regarding prognosis. Do not exaggerate nor minimize the gravity of patient's condition.
6. Regarding expenses and break-up thereof.

(C) Consent for treatment

Usual consent is implied consent. Written consent is necessary if doctor anticipated problems

(D) Emergency Care

A doctor is bound to provide emergency care on humanitarian grounds. It may be noted that prior consent is not necessary for giving emergency / first-aid treatment.

Duties to the Public

1. Health Education
2. Medical help when natural calamities like drought, flood, earth-quakes, etc. occur.
3. Medical help during train accidents.
4. Compulsory notification of births, deaths, infectious diseases, food poisoning etc.
5. To help victims of house collapse, road accidents, fire, etc.

Duty towards Law Enforcers, Police, Courts, etc.

1. To inform the police all cases of poisoning, burns, injury, illegal abortion, suicide, homicide, manslaughter, grievous hurt and its natural complications like tetanus, gas-gangrene , etc. This includes vehicular accidents, fractures, etc.
2. To call a Magistrate for recording dying declaration.
3. To inform about bride burning and battered child cases.

Duty not to violate Professional Ethics (Only important few given)

1. Not to associate with unregistered medical practitioner and not allow him to practice what he is not qualified for.
2. Not to indulge in self-advertisement except such as is expressly authorized by the M.C.I. Code of Medical Ethics-2002.
3. Not to issue false certificates and bills.
4. Not to run a medical store / open shop for sale of medical and surgical instruments.
5. Not to write secret formulations.
6. Not to refuse professional service on grounds of religion, nationality, race, party politics or social status.
7. Not to attend patient when under the effect of alcohol
8. No fee sharing (Dichotomy).
9. Not to talk loose about colleagues.
10. Information given by patient /attendant to be kept as secret. Not to be divulged to employer, insurance company, parents of major son/daughter without consent of patient. Even in court this information is given only if ordered by the Court.
11. Recovering any money (in cash or kind) in connection with services rendered to a patient other than a proper professional fee, even with the knowledge of the patient.
12. Display fees/ charges in waiting room of doctor.
13. Not to accept gifts, financial or such assistance from pharmaceutical companies

Duty not to do anything illegal or hide illegal acts

1. Perform illegal abortions
2. Issue death certificates where cause of death is not known.
3. Not informing police a case of accident, burns, poisoning, suicide, grievous hurt, gas gangrene.
4. Not calling Magistrate for recording dying declaration.
5. Unauthorized, unnecessary, uninformed treatment or procedure.
6. Sex determination.

Duty to each other

1. A doctor must give to his teachers respect and gratitude.
2. A doctor ought to behave to his colleagues as he would like them to behave to him.
3. A doctor must not entice patients from his colleagues
4. When a patient is referred to another doctor, a statement of the case should be given.
5. Differences of opinion between doctors should not be divulged in public.

DUTIES OF THE PATIENT / ATTENDANT

When a patient (consumer) hires or avails of services of a doctor for treatment, he has the following duties :-

1. He must disclose all information that may be

necessary for proper diagnosis and treatment.

2. He must co-operate with the doctor for any relevant investigations required to diagnose and treat him.
3. He must carry out all the instructions as regards drugs, food, rest, exercise or any other relevant/ necessary aspect.
4. In the case of a private medical practitioner he must compensate the doctor in terms of money and money alone. Moral considerations apart, failure on the part of the patient / attendant to do his duty : (a) will enable the doctor to terminate patient -physician contract and that would free him from his legal responsibilities, (b) will be construed as contributory negligence, and weaken the case of the patient for compensation.

RIGHTS OF A DOCTOR:

Doctors don't just have duties, they also have some rights. As per the directions of medical council of India vide regulation 2.1.1 and 2.4, a Registered medical practitioner is not bound to treat each and every person asking his services, he should not only be ever ready to respond to the calls of the sick and the injured. A physician is free to choose whom he will serve. He should, however, respond to any request for his assistance in an emergency. Once having undertaken a case, the physician should not neglect the patient, nor should he withdraw from the case without giving adequate notice to the patient and his family. He has a right to select the drugs from wide range of options available, supported by standard medical practice. A doctor can also select the investigations and method of treatment depending upon various factors related to disease, financial capacity of his patient. Regulation 3.1.2 says consulting pathologists/radiologists or asking for any other diagnostic Lab investigation should be done judiciously and not in a routine manner. He/she should obtain a written refusal in case the patient does not want to do as advised. He/she can delegate the powers to properly trained personnels or colleagues, usually with the willingness of patient. A doctor can decide regarding visits, fees to be charged and to maintain the patient's record including its secrecy in certain specific situations.

CPA IS NOT APPLICABLE TO:

The medical practitioners, Government hospitals/nursing homes and private hospitals/ nursing homes services rendered "free of charge". Such "free of charge" Patients fall into four categories. CPA is not applicable only to category number one type of "free of charge" patients treated by medical practitioners. Medical practitioners are liable under CPA for other three categories of "free of charge" patients :-

i. The medical practitioners who render medical services free of charge to each and every patient availing medical services.
ii. The medical practitioners who render medical services by charging fee to everybody.
iii. Where charges are required to be paid by some patients availing medical services but certain categories of persons who cannot afford to pay, are rendered service free of charges.
iv. The medical practitioners who render medical services and because some complication causes death or disability and therefore they do not charge such patients.

References

i. The Consumer Protection Act, 1986(Act No. 68 of 1986) first Published in the Gazette of India, Extra., Part II, Section 1, dated 26th December, 1986 Pp. 1-12,
ii. Report of Secretary General, IOCU, International seminar on Law and the consumer-30 (Hong Kong), January 6-10,1980 and United nations initiatives to protect consumer.
iii. Rambiharilal v. Dr. J.N. Shrivastav, AIR 1985 MP-HC 150 (DB)
iv. Cosmopolitan Hospital v. K Vasantha Nair 1992 CPJ 302 (NC)
v. Writ Petition no 16 of 1994 in SLP(C) Nos. 6885 and 6950/92
vi. AIR 1996 SC 550
vii. Civil Appeal No.1385 OF 2001 filed by Kusum Sharma Versus Batra Hospital & Medical Research Centre.
viii. Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002(Published in Part III, Section 4 of the Gazette of India, dated 6th April, 2002)

Professional Assistance / Welfare Scheme

1. The scheme shall be known as PAS **"Professional Assistance Scheme"**.
2. **ONLY the life member of IMLEA** shall be the beneficiary of this scheme on yearly basis. The member can renew to remain continuous beneficiary of this scheme by paying renewal fees every year. The scheme shall assist the member ONLY as far as the medical negligence is concerned.
3. This scheme shall be assisting the members by:
   i. **Medico-legal guidance** in hours of crisis. A committee of subject experts shall be formed which will guide the members in the hours of crisis.
   ii. **Expert opinion** if there are cases in court of law.
   iii. **Guidance of legal experts.** A team of Legal & med-legal experts shall be formed which will help in guiding the involved members in the hours of crisis.
   iv. **Support of crisis management committee** at the city / district level.
   v. **Financial assistance** as per the terms of agreement.
4. The fund contribution towards the scheme shall be decided in consultation with the indemnity experts. The same will depend on the type & extent of practice, number of bed in case of indoor facilities & depending upon the other liabilities.
5. A trust / committee / company/ society shall look after the management of the collected fund.
6. The Financial assistance will be like Medical Indemnity welfare scheme, where indemnity part shall be covered by government / IRDA approved companies or any other private company. The association shall be responsible only for the financial assistance. Any compensation/cost/ damages awarded by judicial trial shall be looked after by government / IRDA approved insurance

Admission Fee (One Time, non-refundable)		
1	Physician with Bachelor degree	Rs. 1000
2	Physician with Post graduate diploma	Rs. 2000
3	Physician with Post graduate degree	Rs. 3000
4	Super specialist	Rs. 4000
5	Surgeons, Anesthetist etc	Rs. 5000
6	Surgeons with Super specialist qualification	Rs. 6000

		Annual Fee for Individual	**Annual Fee for Hospitals Establishment**
1	Physician / doctors with OPD Practice	Rs. 60 / lakh	Rs. 340 / lakh + Re. 1 / OPD Pt + Rs. 5 / IPD Pt + 7.5 % of basic premium + Service Tax 10.3 % on the Total
2	Physician / doctors with Indoor Practice	Rs. 115 / lakh	
3	Physician / doctors with Indoor Practice of Surgeon	Rs. 230 / lakh	
4	Physician / doctors with superspecialty, Anesthetist etc	Rs. 340 / lakh	
5	• **Rs/- 1000 (One thousand) per year** shall be collected to develop the fund of the IMLEA towards emergency assistance, risk management and conducting trainings, CME, workshops etc. • Physician / doctors visiting other hospitals shall have to pay 5% extra. • For unqualified staff extra charges of 8% shall be collected. • The additional charges 15 % for those working with radioactive treatment. • The additional charges can be included for other benefits like OPD/ indoor attendance, instruments, fire, personnel injuries etc.		

companies or any other similar private company.

7. Experts will be involved so that we have better vision & outcome of the scheme.
8. The payment to the experts, Legal & med-legal experts shall be done as per the pre-decided remuneration. Payment issues discussed, agreed and processes shall be laid down by the members of these scheme.
9. If legal notice / case are received by member he should forward the necessary documents to the concerned person.
10. Reply to the notice/case should be made only after discussing with the expert committee.
11. A discontinued member if he wants to join the scheme again will be treated as a new member.
12. Most of the negligence litigations related to medical practice EXCEPT the criminal negligence cases shall be covered under this scheme. The scheme will also NOT COVER the damages arising out of fire, malicious intension, natural calamity or similar incidences.
13. All the doctors working in the hospital (Junior, Senior, Temporary, Permanent etc) shall be the members of the IMLEA, if the hospital wants to avail the benefits of this scheme.
14. The scheme can cover untrained hospital staff by paying extra amount as per the decision of expert committee.
15. A district/ State/ Regional level committee can be established for the scheme.
16. There will be involvement of electronic group of IMLEA for electronic data protection.
17. Flow Chart shall be established on what happens when a member approaches with a complaint made against him or her [Doctors in Distress (DnD) processes].
18. Telephone Help Line: setting up and manning will be done.
19. Planning will be done to start the Certificate/ Diploma/ Fellowship Course on med-leg issues to create a pool of experts.
20. Efforts will be made to spread preventive medico-legal aspects with respect to record keeping, consent and patient communication and this shall be integral and continuous process under taken for beneficiary of scheme by suitable medium.

List of Members
Professional Assistance Scheme
(PAS) IMLEA

Name	*Place*	*Speciality*
Dr. Dinesh B Thakare	Amravati	Pathologist
Dr. Satish K Tiwari	Amravati	Pediatrician
Dr. Rajendra W. Baitule	Amravati	Orthopedic
Dr. Usha S tiwari	Amravati	Hospi/ N Home
Dr. Yogesh R Zanwar	Amravati	Dermatologist
Dr. Ramawatar R. Soni	Amravati	Pathologist
Dr. Rajendra R. Borkar	Wardha	Pediatrician
Dr. Alka V. Kuthe	Amravati	Ob.&Gyn.
Dr. Vijay M Kuthe	Amravati	Orthopedic
Dr. Neelima M Ardak	Amravati	Ob.&Gyn.
Dr. Vinita B Yadav	Gurgaon	Ob.&Gyn.
Dr. Balraj Yadav	Gurgaon	Pediatrician
Dr. Kiran Borkar	Wardha	Ob & Gyn
Dr. Bhupesh Bhond	Amravati	Pediatrician
Dr. R K Maheshwari	Barmer	Pediatrician
Dr. Jayant Shah	Nandurbar	Pediatrician
Dr. Kesavulu	Hindupur AP	Pediatrician
Dr. Ashim Kr Ghosh	Burdwan WB	Pediatrician
Dr. Apurva Kale	Amravati	Pediatrician
Dr. Asit Guin	Jabalpur	Physician
Dr. Sanjeev Borade	Amravati	Ob & Gyn
Dr. Prashant Gahukar	Amravati	Pathologist
Dr. Ashwin Deshmukh	Amravati	Ob & Gyn
Dr. Anupama Deshmukh	Amravati	Ob & Gyn

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Reference from electronic media: 3) National Statistics Online—Trends in suicide by method in England and Wales, 1979-2001. www.statistics.gov.uk/downloads/ theme_health/ HSQ 20.pdf (accessed Jan 24, 2005): 7-18.

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