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Vol.: 03 | Issue: 03 | Jul-Sep 2015

### CONTENTS

Aims & Objectives of IMLEA	62
Conflict of Interest: Controversy and Confusion <i>Dr. Satish Tiwari</i>	63
Emergencies: When to refer & How to transfer <i>Dr. Alka Kuthe</i>	68
Medicolegal Issues in Hospital Management <i>Dr. Gourab Maitra, Dr. Saikat Sengupta, Dr. Madhulina Nag</i>	71
Trends of Household Chemicals Poisoning Cases in Rural Hospital of Central India <i>Dr. P.N. Murkey, Dr. B.H. Tirpude, Dr. Rajesh B. Ramteke, Dr. Sachin Kumar Meena, Dr. A Salankar, Dr. T Wankhade, Dr. Vishal B. Surwade,</i>	77
Readers Ask, Experts Answer <i>Dr. (Prof.) Mahesh Baldwa, Dr. Sushila Baldwa, Dr. Namita Padvi, Dr. Varsha Gupta</i>	82
Trust the Patient <i>Dr. (Prof.) Mahesh Baldwa, Dr. Sushila Baldwa, Dr. Namita Padvi, Dr. Varsha Gupta</i>	84
Medico Legal News <i>Dr. Archana Tiwari</i>	86
Membership Form - Human Milk Banking Association	88
Professional Assistance / Welfare Scheme	89
IMLEA - Life Membership Form	91



## 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.

## Conflict of Interest: Controversy and Confusion

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The globalization and industrialization of human race has many positive and negative impacts in the society. The physical comforts and amenities, in the name of development has become the necessity of life. The technical advances and invasion by media has further increased these needs. This has resulted in the growth of many multinationals with their focused vision of monetary gains. The increasing inequalities in the community not only mean that there has been no improvement in the standard of living of the poor and that they are still living in poverty, in spite of economic growth but it is also causing a hindrance in the future economic growth. The top few people like; capitalists, government officials, highly educated salaried peoples and a few corrupt politicians have undoubtedly benefitted by economic growth but the majority of population has remained deprived of the so called developmental economic benefits. Even the middle class is under duress due to the increasing cost of livelihoods and the physical needs.

### Health needs:

All these changes have not only affected the financial status of the society but also have major impact on the health of the individual and health needs of the community. This has also resulted in the emergence of group of people or companies with “**conflict of interests**” so as to reap the benefit of these societal needs. Health sector can't remain exception to these global developments. In this era of technical advances and 'medical tourism' each and every aspect of health sector is affected by conflict of interests (COI). In many cases, these individuals do not

believe the relationship influences their medical advice, research or prescribing habits although clearly the drug industry would not continue devoting millions of dollars to this type of marketing if it did not pay off. But even prominent researchers and expert physicians are often being influenced by the industry, whether they realize it or not. *Accreditation & Standardization* of services in terms of treatment, care and registration are poor despite recommendations. Lack of explicit standards for patient safety creates gaps in licensing and accreditation and lets health care organizations function without some of the basic safety systems in place.

### The food industry:

The food and nutrition are one of the basic needs of any society. But, the misconceptions and confusions regarding diet continue to be fixed and deep rooted in the minds of people. These inadequacies are exploited by the people with conflicts of interest by projecting a specific food having magic effects, as energy boosters and as brain developers / enhancers. The food safety, human health and ethical issues are not the priority in their agenda. In fact most of such advertisements are evidences of outright dishonesty to human being. Most of the “ready to use food”, easily available and packaged artificial food are only a part of money spinning business for them. The exaggerated health claims associated with commercial food have taken the toll of many lives. They have been responsible for the continuous prevalence of nutrition related morbidity and mortality in spite of regular health programs.

Those having COI in the artificial or commercial food have come out openly in favor of market based food. According to them, the Indian market completely lacks affordable complementary foods for infants from poor families or for poor children during or recovering from illness. This is one of the main causes of acute undernutrition among children younger than 2 years, affecting their physical and cognitive development. The Indian food industry is not developing cheap complementary foods because of the marketing prohibitions and the lack of a specific mandate in the international code or IMS Act. It is also likely that because of this legal barrier, public health experts and civil society do not mobilize support on the matter. The WHO 2001 guidelines on complementary feeding must be developed to formulate an international code for the promotion and production of complementary foods. This would set the necessary standards and enable national governments and civil society in India to actively advocate production and marketing. [1]

### **The vaccination industry:**

Immunization or vaccine industry has frequently been a talking point whenever the issue of conflict of interest is discussed. One is compelled to admit that murmurs of dissent are always heard whenever a new vaccine is recommended. The situation now is such that any vaccine, news related to it, media report, press note, communication or recommendation creates flutter amongst the hyper-excitable academic experts, which hardly dies down before the next wave sets in. Perhaps, the truth evades and controversy, contradiction and confusion prevail as most of us grope in dark. Many a times there are allegations and counter allegations amongst the experts. Committee on immunization of Indian Academy of Pediatrics felt that persons qualified to serve as an expert for the Committee may have personal interests related to the subject of their expertise. At the same time, it is

imperative that situations be avoided in which such interests may unduly affect, or may be perceived to affect, an expert's impartiality or the outcome of work in which he/she was involved. Thus, all office bearers and members of IAPCOI (including its subcommittees) should disclose any financial, professional or other interests relevant to the subject of the work or meeting in which they will be involved and any interest that could significantly affect the outcome of the meeting or work. They are also asked to declare relevant interests of others who may, or may be perceived to, influence their judgment, such as immediate family members, employers, close professional associates or any others with whom they have a substantial common personal, financial or professional interest. [2]

### **Pharmaceutical industry:**

In July 2012, leading pharmaceutical major GlaxoSmithKline started issuing advertisements saying that nearly five lakh babies die in India due to Rotavirus. The aim was clearly to ensure that Rotavirus vaccines become a part of the mandatory vaccines that are given to new born babies and infants. What makes this advertisement interesting is that it did not promote a particular company but the need for the vaccine. In other words, here was a sly attempt by the pharmaceutical companies to unite and look forward to 'creating' a new market. Dr Nalini Abraham, a Delhi-based medical practitioner, objected to the advertisements featuring the Rotavirus vaccination being broadcast freely on television channels and filed an official complaint with the Advertising Standards Council of India (ASCI) alleging that the advertisement misrepresents facts as it demonstrates that vaccines are the only way to reduce incidents of infection. [3] Medical fraternity comprises of experts who have a basic instinct of realizing what is true and what is false, what is neutral opinion and what is vested interest, do we wish to take away even that from



them and consider them as a herd to be dictated by a few shepherds?

The term *Medical Device* covers a vast range of equipments from tongue depressors to Heart Lung Machine and much more. Due to innovation and rapid development of technology, it is one of the *fastest growing industries in the world*. Many countries like India lack access to high quality devices and equipments which are appropriate for their specific epidemiological needs. *Lack of standardization & regulation* puts patients' lives at risk. For this we need national regulation to implement certain policies, legislations and correlating sanctions to be an eternal part of national health system. These policies are to protect the population against unsafe and inappropriate technologies. IMA supports the Govt. in this and there is technical support of the WHO as well. In India, 80% of the medical technology is imported. There is *lack of price and quality control* despite the recommendations. The financial implication of this is reflected on the patients.

Breaking the drug industry's strong hold on the conventional medical industry will not be easy after all, the drug industry spends nearly twice as much on promotion as it does on research and development – but increasing numbers of people are now waking up to these harsh realities, and that is instrumental in getting the tide to turn.

### **Publications and research:**

It's well known that studies funded by industry or conducted by researchers with industry ties tend to favor corporate interests. That's why it probably comes as no surprise that many so-called "experts" are very much on the drug industry's payroll but they masquerade as independent medical experts or even state officials during their "day jobs." All research institutions, international organizations; international donor agencies have direct/indirect

funding from industry. The interpretation in positive terms is "corporate social responsibility" the negativity is "Bribery". To draw a line between this is very difficult because of the gray zone that exists. The conflict of interest within this practice is obvious, which is why the drug industry often keeps quiet on their actual payments, as do the medical professionals involved. Although many medical, educational and research institutions require faculty members to disclose such potential conflicts of interest, many do not actively monitor employees' activities.[4] Researchers and certainly those who sit on government panels are supposed to disclose these types of relationships with the drug industry, but they often don't and little is done about it.

### **Health facilities (Five star hospitals):**

In the present era of modernization and urbanization, newer and newer multi specialty hospitals or private medical colleges are mushrooming for providing the so called latest medical services and facilities. But, their interests are very obvious and they are seen as money or profit making business tycoons in the name of providing medical care. The malpractices, over investigations and unjustified surgeries are some of the fields which expose their COI. These Five star hospitals are catering to the needs of classes and not the masses, which still remain unprivileged and unattended as far as their health needs are concerned. *The insurance sector* has a major role to play. The TPA's associated with these insurance companies have their own rules by which they function. General public at large is unable to avail of this facility and compensations or payouts are made with difficulty.

### **The Clinical Establishment Act:**

There are lots of controversies and conflicts of interest about the much discussed Clinical Establishment Act. The development of guidelines for medical practice is a controversial

and complicated issue. This is compounded by the emotive vocabulary used by various interest groups, "Standards" by the government to indicate enforcement, "Parameters" by the Medical Council of India (MCI) to indicate a limit or boundary. In most developed countries, the tension imposed by increasing healthcare costs, amplified by consumer forces, has led to calls for increased accountability and the identification of efficient practice patterns by the profession. Today, faced with ever increasing pressures the medical profession is working in a state of disturbed homeostasis with the consumer care organizations breathing deeply down its neck.[5]

The private sector has been brought under control of bureaucrats and politicians by formulating rules so that doctors are under constant threat of getting notice of cancellation of registration on one pretext or the other. There is clear intent to legalize corruption by levying a penalty. To avoid penalty, anybody may be forced to cough up a huge amount of money to the local regulatory authority. By making one more registration mandatory, the registration system will become more complicated. The Nursing homes are required to register themselves for pollution control, under PNMT Act, under MTP Act, Nursing Home Act and for waste management etc at different places all this results in conflict of interests of various authorities. It is believed that the much debated Clinical Establishment Bill/ Act involves conflict of interest between the corporate hospital groups and the age- old small private clinics.

### **Role of Government:**

The role of government is very vital in all these issues. But, it is unfortunate that rather than planning some long term policy to curb this from society, our politicians remain busy in mud-slinging and raising insignificant issues in parliament. Obviously there are unseen underpinnings of many vested interests behind

the policy paralysis, but our leaders should ask themselves for a minute when alone, can there be any issue more important than the future of our younger generations, who will shoulder the responsibility of nation building in the coming years?

*Health is a state concern.* However policies formulated in this regard are implemented poorly. Some states like Kerala and other states in the south have evolved well planned health concerns and they try and incorporate new modalities for public benefit. On the other hand BIMARU states of Bihar, Madhya Pradesh, Rajasthan and Uttarakhand are lagging far behind even in availability of basic facilities at few far out places.[6] Though *complementary medicine and holistic medicine* is also finding acceptance by the public, it is paving the way for *unlicensed practitioners* with no degree to compete with the highly trained professionals. The Supreme Court has set guidelines in this regard. However, different states have different policies most of which are implemented poorly. In a letter written to all health secretaries of all state governments DK Sikri (Secretary Ministry of Women & Child Development) & K Sujatha Rao (Secretary Ministry of Health & Family Welfare) have emphasized the need for proper implementation of provisions of IMS Act & to monitor that on regular basis. (Published in JIMA, journal of IMA Dec. 2010 issue page 879-880).

### **Role of judiciary:**

The law makers and judiciary have come out with many enactments to improve the deteriorating situation. But, no wonder the things happen very much under the nose of the law and law makers. Courts pass orders but neither the law enforcing agencies are strong enough to enforce the various Acts, nor they are allowed to be strong by those who are in power for the obvious reasons. In India, despite existing legislations like Consumer Protection Act



(COPRA) of 1986, Indian Medical Council Act, Criminal law and Civil law, the private medical sector remains highly unregulated due to weak implementation and enforcement of rules and regulations and also due to lack of a common policy framework for the country. Various industries have big hold on governance, often by unfair and shady clout in the corridors of power. Industry buys and influences decision making in its favor. In a PIL related to laying down of science based standardization for food articles & to regulate their manufacture, storage, distribution, etc; the Supreme Court has observed that the company representatives on the scientific panel for such products was a clear breach of mandate under section 13(1) of the Food Safety & Standards Act 2006.

### **Role of Medical councils:**

Regulations of medical councils have also been questioned with regards to conflict of interests. The "Indian Medical Council (Professional Conduct, Etiquette and Ethics) (Amendment) Regulations, 2009, clause 6.8 and its sub clauses; defines Code of conduct for doctors and professional association of doctors in their relationship with pharmaceutical and allied health sector industry. A medical practitioner shall not accept any travel facility inside the country or outside, including rail, air, ship, cruise tickets, paid vacations etc. from any pharmaceutical or allied healthcare industry or their representatives for self and family members for vacation or for attending conferences, seminars, workshops, CME program etc as a delegate. A medical practitioner shall not receive any cash or monetary grants from any pharmaceutical and allied healthcare industry for individual purpose in individual capacity under any pretext. Ensure that the source and amount of funding is publicly disclosed at the beginning itself. In dealing with pharmaceutical and allied healthcare industry a medical practitioner shall always ensure that there shall never be any

compromise either with his / her own professional autonomy and / or with the autonomy and freedom of the medical institution. A medical practitioner shall not endorse any drug or product of the industry publically. Any study conducted on the efficacy or otherwise of such products shall be presented to and / or through appropriate scientific bodies or published in appropriate scientific journals in a proper way".

### **Role of society:**

Morality and social concerns doesn't stand a chance before the greed of money. People are neither students, nor prisoners who can be fettered. The human right includes freedom of choice, and if our choice is wrong, who can be held responsible? If one desires to burn his hands in the fire, how long can one stop him? Who can put the reason into his mind that fire is for lighting, not for burning? [7] That's the way the circle runs. It is a rock solid system as old as the hills and it works with regularity and precision. As long as the pattern persists, money is generated in the system and as long as money changes hands, everyone is happy including traders, manufacturers, middleman, officers and everyone. The people should be taught the ill effects and the conflicts of interests of the stake holders. There are numerous ways to drive home the point, only if there is the vision and planning.

The need of the hour is awareness, which should go hand in hand with all legal measures or punishments. And awareness doesn't just mean ads in newspaper or warnings in media. It should start right from the school or classrooms. However, it may be easier said than done. India is supposed to be country of poor and illiterate, reasoning is often diluted, deflected and distorted. The real problem lies in the misguidance and misconceptions strengthened by those having conflict of interests. True, every effort should be made to develop the alternatives

*Contd...(70)*

## **EMERGENCIES**

### **When to refer & How to transfer?**

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#### **Introduction:**

Law mandates that every hospital and the doctor must treat an emergency. However there is always a possibility that the complaint of the patient is outside the scope of service provider or the specialists are not available at that point of time. In all such cases, the patient must be immediately referred to tertiary care centre for specific treatment. This strategy should be applied only if it is in the best interest and not as an attempt to bypass the legal duty of providing care to emergency patients.

#### **Following precautions should be taken while referring the patient:**

1. Referral is not an abandonment of the patient if it is done for a bona fide purpose. Referring the patient for ulterior motives, to cover-up a negligent act or the consequences arising thereof, is both unethical as well as illegal.<sup>1</sup>
2. Refer the patient to a qualified doctor or an authorized well equipped tertiary care centre. Otherwise it would be considered as negligence on the part of referring doctor. The referring doctor should not act, rely on reports and opinions of unqualified doctor as it would amount to negligence.
3. Take precaution while differing with opinion of other qualified doctor, although one is not bound by the opinion of another doctor, not even of the one to whom you might have referred the patient. The treating doctor can decide and judge the line of treatment which is accepted by the medical authority.
4. Referring the patient to competent person or taking advice from expert is always treated favorably by the courts. One can refer the

patient/seek further advice /take a second opinion/involve other doctors without any delay. The patient can be referred from one consultant to higher facilities when [1]

- It is indicated
  - The patient is outside your expertise/skills/qualifications.
  - The required facilities /doctors are unavailable.
  - The patient is not responding to treatment or his condition worsens and needs better/critical management in ICU.
  - If such request is made by the patient/relatives. It is good practice to specifically record the patients request and opinion of other doctors.
5. Doctor –in-charge of the patient should refer the patient to a higher centre when the patient is critical and needs better management with proper referral note.
  6. In emergencies if consultant is consulted over the telephone then the emergency along with the name and time of consultation must be duly recorded on the case paper.
  7. There should not be further delay in referring a patient to a proper consultant or facility when indicated and once it is decided. Unnecessary delay would result in damage and could be construed as negligence. If you or patient wishes to take a second opinion then it would be prudent to seek that in appropriate cases.
  8. In case of emergencies, the required consultant must be called to manage

emergencies.

9. In case there is refusal or delay on the part of patient in following the advice for referral it must be specifically recorded on the case paper. It has been seen in many cases that even after getting referral note, the patient's relatives either refuse or delay in following the advice, but in court the allegation made is exactly opposite. Therefore to defend if needed in future, the service provider must note down this with date and time with reason on the case paper.
10. The treating doctor should do lot of counseling if there is no need to transfer the patient to another facility though it is requested by the patient /relatives. A great care and precaution is required at this juncture as sometimes they may draw adverse inference from the same.
11. When the patient's condition is critical or otherwise also, it is healthy practice to suggest the available alternatives to the patient and also the name of the speciality and the doctor skilled to perform the said alternative and this must be specifically recorded in the patient's medical records. The aforesaid becomes mandatory when the patient demands such consultation.
12. When a patient is referred to a specialist by the attending physician with a case summary of the patient, it is advisable that he should communicate his opinion preferably in writing to the attending physician.

### **How to transfer?**

Once the decision to refer/ transfer is taken, the doctor, nursing home must act to their earliest since delay may amount to negligence. Emergencies know no boundaries. Courts also take into account an emergency situation and appreciate the doctor/ nursing home if

reasonable time is taken to transfer the patient.

### **Following are the tips while transferring the patient:**

1. Doctor, hospital, nursing home and the other facilities providing ambulance to the patient must first ensure that the ambulance has the requisite facilities that may be required by the patient in transit (Oxygen/equipments/a nurse or a doctor/ emergency drugs/other requisite facilities). Any deficiency would be viewed as negligence by the court)
2. Proper care and caution must be taken in transferring a patient to another hospital/ facility.[2] The responsibility of the patient in transit lies with the hospital transferring the patient. In Praveen Gandhi & Ors.v/s Dr. K.N. Singla & Anr. (7MLCD a127; j333-September 2014)[2], allegation was that the patient was not shifted to another hospital with proper care. In defense the hospital (OP) stated that the patient was transferred "with all medical precautions and respiratory care (Intubation and Ambu bag)". [2]
3. The patient should be transferred with proper transfer note with brief history about the complaints, the diagnosis, investigations carried out, any intervention/surgery performed, medicines given till transfer so as to give the referral centre, an idea, what more they can do to save the life of the patient.

### **Precautions to be taken by consultants in case of referral:**

1. The advice and the referral letter given by the doctor referring the patient must be carefully preserved along with the other medical records of the patient .
2. Imaging centers and pathological laboratories must preserve the advice/referral letter sent with the patient /samples for investigation along with other records.
3. The pathologist should perform an

investigation as advised by referring doctor, according to an acceptable method/procedure. It would not amount to negligence although other procedures/methods to perform a particular investigation may also exist. In a case where there is more than one method or procedure to perform a particular investigation and there is some confusion regarding the method/procedure to be followed, it should be clarified from the referring doctor. The investigation report must specifically record the method followed.

### Transfer communication:

Good communication is an art that can be acquired, developed and improved by experience.[3] It is an essential component of overall care. When a critically ill patient is referred to another hospital/tertiary care unit for better management, the transfer communication is made with the patient/relatives, that explains the reason behind referral/transfer and removes doubts pertaining to the need of transfer in their minds. They understand the importance of referral and thus co-operate with the health facility in completing the requisite formalities

before transfer. It is prudent on the part of referring doctor/hospital to take signature of the relatives and if possible of the patient as well after transfer communication. The date and time of communication should be documented so that if there is unnecessary delay on the part of patient and relatives in following advice of treating doctor, the record itself would speak.

Thus the emergencies should be tackled if they need referral, as discussed above so that it would remove doubts and would increase the patient's compliance.

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### Conflict of Interest: Controversy and Confusion (Contd....)

and while some of them are already available, yet, something complete and comprehensive is still awaited. In essence, it will be prudent for the experts to figure out at the earliest what and how it should be resolved. In conclusion, to get back the glory of the profession of the golden past era, a drastic change in attitude by the public at large and a few black sheep in the profession will go a long way.

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## Medicolegal Issues in Hospital Management

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### Abstract

The running of a hospital requires human, technical and conceptual skills for which the hospital management is responsible and accountable. It is important to understand the basic legal and ethical principles that influence the work environment. Medical practice is guided by many laws and negligence leads to medicolegal issues. Laws govern from commissioning of hospital to qualification and conduct of the professionals and also medication and environment issues. Every hospital thus has responsibilities regarding consent, staff selection, refusal of treatment, monitoring, drug handling, hospital infection and blood bank service, medical records, euthanasia etc.

**Keywords:** Medicolegal, Hospital Management, Medical practise

The various operations of hospitals require human technical and conceptual skills like any other organization or industry. Hospital management is responsible and accountable for its functioning to owners of hospitals, employees, patients, visitors and public at large. They enter into various contractual obligations for employment, business and safety operations. All these activities are liable for legal scrutiny. There has been an increase in medicolegal cases against hospitals which has made hospital administrators to become aware of the

medicolegal aspects to minimize litigations and ensure quality of medical care. There has been also an increasing awareness of the public about duties and obligations of medical practitioners as well as the hospitals where they work. In general people feel that a doctor can get away with negligence as he has the protection of the institution. A patient suffers as he is not aware of his legal rights and nobody guarantees against a doctor's negligence which may cause him physical injury or even death.[1]

To be an effective manager, it is important to understand the basic legal and ethical principles that influence the work environment, which includes the legal relationship between the consumer and the organization – the patient and the healthcare provider. It is the responsibility of the hospital management to develop policies for maintaining a safe hospital, physical facilities and services. Safety and fire regulations, sanitation arrangements, safety from explosive and inflammable anaesthetic gasses and chemicals, machinery are some of the prime responsibility of the management. Policies for selection and appointment of a number of medical, nursing and technical staff are another responsibility of the management as most legal problems arise through the actions of the staff.

### MEDICAL NEGLIGENCES

Medicine has never been an exact science in spite of great advances in biomedical sciences. It is imperative for doctors, nurses and paramedical

personnel to exhibit utmost precaution, care, judgment and skill in dealing with and treating patients, balancing the relative risk of the disease with the risk involved in the use of drugs, surgery or diagnostic procedures.[2]

Negligence is a tort in a wrong done by one person to another. Medical negligence may be defined as a want of proper care, attention, omission to do or a commission of a mistake by medical practitioner or hospital.

#### **Negligence may be classified as -**

- i. Subtle negligence is the act of omission or commission by the medical practitioner which other prudent or reasonable doctor would not have omitted or committed in similar circumstances.
- ii. Gross negligence is negligence written on the face of case facts, requires little proof and difficult to defend. E.g. – amputation of wrong limb, leaving swab inside abdomen/wound, administration of drug to patient with known allergy to it.[3]

Civil law focuses on the wrongful acts of the individuals and organizations based on contractual violation, in the perspective of medicolegal cases in different types of health care violations. Two basic healthcare tasks are unintentional acts of omission or commission that could negatively contribute to health of the patient and intentional tasks such as assault or battery and invasion of privacy. Example of assault or battery would be performing surgery on a patient without his or her consent and example of invasion of privacy would be violation of patient's health records.

Criminal law is concerned with actions that are illegal based on court decisions. To convict someone of criminal liability, it has to be proved without a reasonable doubt or guilt.[4, 5]

It is expected that a medical practitioner should

have reasonable degree of skill and knowledge and must exercise a reasonable degree of care. The law requires neither the highest possible nor the lowest possible form of care and competence judged in the light of the particular circumstance of each case. Failure to act in accordance with the standard of reasonable competent medical person at the time is a perfectly accurate statement, as long as it is kept in mind that there may be more than one perfectly proper standard, and if a person conforms to one of those proper standards then he is not negligent.[6]

In order to bring a successful claim for compensation against a doctor and hospital in court, the patient must prove negligence and must also prove that the negligence of the doctor and hospital caused the injury, disability or death. The burden of proof is on the claimant.

#### **Laws applicable to Medical Practice and Hospitals in India [7, 8]**

##### **1. Laws governing the commissioning of hospital**

To ensure that hospital facilities are created after the process of registration and are safe for public using them with at least the minimum essential infrastructure for the type and volume of work anticipated and are subject to periodic inspection to ensure compliance.

- i. Society Registration Act 1960
- ii. Electricity Rules 1956
- iii. Fire Safety Rules 1987
- iv. Delhi Nursing Home Registration Act 1953
- v. Bombay Nursing Home Registration Act 1949
- vi. Atomic Energy Act 1962
- vii. Radiation Protection Certificate from



BARC

viii. The Clinical Establishment Bill 2010

**2. Laws governing qualification/practice and conduct of professionals**

To ensure that the staff employed in hospital for health care delivery is qualified and authorized to perform their duties within specified limits of competence and with standard code of conduct and ethics and their credentials are verified from registered council.

- i. Indian Medical Council Act 1956
- ii. Indian Medical Council/ Professional Conduct, Etiquette and Ethics Regulation 2002
- iii. Indian Medical Degree Act 1916
- iv. Registration of Medical Practitioners with State Medical Council
- v. Indian Nursing Council Act 1947
- vi. The Paramedical and Physiotherapy Central Council Bill 2007

**3. Laws governing Sale, Storage of Drugs and safe Medication**

To control the usage of drugs, chemicals, blood and blood products, prevent misuse of dangerous drugs.

- i. Drugs and Cosmetics Act 1940 and Amendment Act 1982
- ii. Blood Bank Regulation and Drugs and Cosmetics Rules 1999
- iii. Pharmacy Act 1948
- iv. Narcotics and Psychotropic Substance Act
- v. IPC sec 274 (Adulteration of drugs), sec 275 (Sale of adulterated drug), sec 276 (Sale of drug as different drug or

preparation) and sec 284 (negligent conduct with regard to poisonous substance)

**4. Laws governing management of patients**

For setting standards and norms for conduct of medical professional practice, prevention of unfair practices.

- i. Birth, Death and Marriage Registration Act 1986
- ii. Law of Contract sec 13 (for consent)
- iii. PNDT Act 1994 and Preconception and Prenatal Diagnostic Test (Prohibition of sex selection) Rules 1996 (Amendment Act 2002).
- iv. Transplantation of Human Organ Act 1994, Rules 1995
- v. Medical Termination of Pregnancy Act 1971
- vi. The Mental Health Act 1987

**5. Laws governing environment safety**

- i. Biomedical Waste Management Handling Rules 1998/ Amended in 2000
- ii. Environment Protection Act and Rule 1986, 1996
- iii. Air ( Prevention and control of pollution) Act 1981
- iv. Water (Prevention and control of pollution) Act 1974
- v. NOC from Pollution Control Board
- vi. Noise Pollution Control Rule 2000

**6. Laws governing employment and management of manpower**

- i. ESI Act 1948
- ii. Equal Remuneration Act 1976

- iii. Industrial Dispute Act 1947
- iv. Shop and Factories Act (for national holiday)
- v. Minimum Wages Act 1948
- vi. Payment of Bonus Act 1956
- vii. Payment of Gratuity Act 1972
- viii. Maternity Benefit Act 1961

## **7. Laws governing medico-legal aspects**

- i. Consumer Protection Act 1986
- ii. Indian Evidence Act
- iii. Law of Privileged Communication
- iv. Law of Torts
- v. IPC sec 52 (good faith), sec 80 (- in doing lawful act), sec 89 (for insane and children), sec 92 (consent/good faith) and sec 93 (communication/good faith)

## **8. Laws governing safety of patient, public and staff within hospital premises**

- i. Radiation Surveillance Procedure for Medical Application of Radiation 1989, Radiation Protection Rules 1971
- ii. IPC sec 336 (Act endangering life or safety of others), Sec 337 (causing hurt by act endangering life and safety of others), sec 338 (Causing grievous hurt by act endangering life and safety of others).
- iii. Prevention of Food Adulteration Act 1954
- iv. Disaster Management Act 2005

## **9. Laws governing professional training and research**

- i. MCI rules for MBBS, PG and internship training
- ii. National Board of Exam rules for DNB teaching

- iii. ICMR rules governing medical research
- iv. NCI rules for nursing training

## **10. Laws governing business aspects**

- i. Charitable and Religious Trusts Act 1920
- ii. Contracts Act 1982
- iii. Income tax Act 1961

## **HOSPITAL RESPONSIBILITIES**

### **Consent**

It is implied in case of a patient who approaches a doctor for consultation, it implies his or her willingness to be examined by the doctor. Written consent is necessary for surgical operations and special procedures. It also applies to autopsy except in medicolegal cases. Consent should be given voluntarily out of his or her free will and should be signed in presence of witness. Consent is invalid if given by a child under 12 years of age, person of unsound mind or person who is intoxicated and when given under fear of injury or under misconception or by fraud, mistake or misrepresentation.

However in cases of emergency treatment or surgery, all prerequisites for valid consent will be set aside and the doctor is legally authorized to do whatever is necessary to save the life of the patient. Consent is also necessary for patients and healthy volunteers included in clinical research and drug trials. The consent should be a written and valid consent explaining the details of the treatment, benefits, consequences and risks.[9]

### **Staff Selection And Legal Privileges**

Hospitals must exercise care in selecting doctors and nurses who are qualified and competent with valid registration with the State Medical Council or nursing council as well as paramedical and technical staff. The legal privileges and limitations should be laid in writing.

## **Refusal Of Treatment**

The Medical Council of India has pointed out that there is no provision in any law which prevents doctors from attending seriously injured patients and accident cases before arrival of police and other formalities.[10] All hospitals and medical institutions should provide immediate aid to all cases irrespective of the fact that they are medicolegal or otherwise (Parmanand Katra vs Union of India and others, Supreme Court 1989). Every doctor whether at government hospital or otherwise, has a professional obligation to extend his service with due expertise for preserving life.

## **Physical Facilities and Equipments**

A hospital is obliged to provide and maintain physical facilities, premises and equipments for diagnosing, monitoring and treatment of patients with periodic inspection and maintenance as a part of functioning of hospital. Bed rails, side rails in corridors and hand rails in bathrooms to prevent patient fall and injury are also hospital responsibility.

## **Negligent Monitoring**

Monitoring the condition of all patients admitted in the hospital is one of the most important obligations of a hospital and its failure makes hospital management responsible under doctrine of vicarious liability. Monitoring not only to require the hospital and its nursing staff to recognize complications but also to provide emergency management of the condition by the attending doctor.

## **Drug Handling**

The process of ordering, storage and distribution of drugs is the direct responsibility of hospital management and drug administration to patients is the responsibility of medical and nursing staff. Liability arises from improper labeling, drug administration to wrong patient, wrong dose and

use of expired drug.

## **Hospital Infection and Blood Bank Service**

Hospitals are obliged to follow policies and procedures that prevent patients from acquiring hospital acquired infections and also infections from personnel during course of their duty. Blood bank service carries a high potential risk for injury to patients with high risk of legal liability. Such risks include acceptance of donor, blood extraction, storage, grouping and cross matching.

## **Medical Records**

The medical records are generated in the course of patients' treatment, compiled and stored by the hospital, but the information is the property of the patient. If patient desires it should be given to patient at a reasonable charge and cannot be disclosed to anyone except with patient's consent as all communication between patient and doctor is privileged communication and confidential.

Information can be shared for referring to another doctor, if asked by court of law, in consumer protection cases and only on written request to police or insurance company.[9]

## **Withholding Life Support and Euthanasia**

Prolonging life with the help of machines and other heroic measures in case of terminally ill is now being questioned. When the brain is dead, there is no point keeping the heart and circulation going with expensive medical technology. Supreme court verdict in 2011 in Aruna Ramchandra Shanbaug vs Union of India and others case has legalized passive euthanasia (withdrawing life support in patients in permanent vegetative state). Active euthanasia or medically assisted suicide at patient's wish because of terminal pain or suffering is not legalized in India. It is legalized in Belgium, Netherlands and some states of the USA.

## Dying Declaration

From the judgment in Charipalli Shankarrao vs public prosecutor, High Court of Andhra Pradesh 1995, it is clear that if the presence of magistrate or legally authorized person of law cannot be ensured in time, a doctor can be called by the patient himself to record his dying declaration. The doctor should read the declaration in presence of one witness.

## Ethical Concepts in Healthcare

Ethical standards are considered one level above the legal standards as individuals make choice on what is the right thing to do or what one ought to do, not what the minimal actions are required by law. A healthcare dilemma is a problem or a situation that requires a healthcare provider to choose an action between two obligations. The dilemma is the conflict of the ethical reasoning of the decision maker. Dilemmas are resolved by the guidelines provided by the code of ethics of medical association or healthcare institution.[11]

Role of ethics in healthcare industry is based on fine basic values[12] –

- *Respect for autonomy* –  
Healthcare providers must respect their patient's decisions.
- *Beneficence* –  
Healthcare provider should have patient's best interests in mind.
- *No malfeasance* –  
Healthcare provider should do no harm while taking action
- *Justice* –  
Healthcare provider should take fair decisions
- *Dignity* –  
Patients should be treated with dignity

Ethics in the work place must be governed by

organizational ethics, so developing code of ethics, creating decision model for healthcare dilemmas and providing ongoing ethical training are tools that both human resource and arrangement can use to create ethical culture. The code of ethics should be a user friendly resource for the organization, should be updated to the current law and regulations and the language should be specific as to what the organization should expect from its employees.

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# Trends of Household Chemicals Poisoning Cases in Rural Hospital of Central India

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## Abstract

In present years, due to advancement of synthetic chemistry and the fast changing scenario placed an ever increasing number of highly poisonous substances within the reach of modern man. Thousands of man-made chemicals are currently in common use throughout the World, and one to two thousand new chemicals appear in the market each year. In industrialized countries, there are at least one million commercial products that are mixture of chemicals, and the formulations of up to one third of these may change every year. A similar situation exists in the rapidly industrializing developing countries like India, where population is increasing & in that proportion, households are also increasing. The increased use of household chemicals has become the cause of deaths in Modern India.

**Key Words:** Household chemicals, poisoning, mortality, developing Countries.

## Introduction

During the past few decades, there is massive expansion in the settlement due to rapid urbanisation in India. There has been a steep rise in number of new households especially in urban

setup. As the number of households increased the use of household chemicals also got increased. Eventually it was noted over the period of years that, it has become one of the leading causes of poisoning related morbidity & mortality.

In present years, due to advancement of synthetic chemistry and the fast changing scenario placed an ever increasing number of highly poisonous substances within the reach of modern man. Thousands of man-made chemicals are currently in common use throughout the World, and one to two thousand new chemicals appear in the market each year.

## Aims and Objectives

Present study entitled for the "Trends of household chemicals poisoning cases in rural hospital of Central India" with following aims and objectives:

1. To study household chemicals poisoning cases admitted in our Hospital and poisoning cases brought for post-mortem in mortuary of our Hospital in Department of Forensic Medicine and Toxicology, situated in rural part of Central India during the period from August 2012 to October, 2014.
2. To study the type of poisons consumed and

mode of poisoning.

3. To study incidence of poisoning in different age groups.
4. To study incidence of poisoning according to sex.

## **MATERIAL AND METHODS**

Cases of poisoning were studied in 1038 cases of poisoning reported in our Hospital situated in rural area of Central India during the period from August 2012 to October 2014. 804 cases were admitted in hospital out of which 588 cases were admitted with history of consumption of poison and 216 cases were admitted with history of snake bite. Out of them 147 expired during treatment of which 135 were of poisoning and 12 with history of snake bite. Total 234 cases including 6 Snake bite cases were directly brought dead to the mortuary, in our Hospital for post-mortem examination. Approval of local institutional ethical committee has been taken.

History of incidence of poisoning was taken from patient or their relatives whenever possible. When patient was unconscious, history was taken from relatives. Analysis of gastric contents, blood, and urine was done in Toxicology laboratory of Forensic Medicine Department by T.L.C. (Thin Layer Chromatography) method.

### **Material and methods used were as follows:**

- History and examination of living poisoning cases admitted in hospital.
- Post-mortem findings in cases of death due to poisoning.
- Analysis of gastric content, blood and urine in Toxicology laboratory in Department of Forensic Medicine & Toxicology and Regional Forensic Science Laboratory.

## **Post-mortem Cases**

Total 381 post mortem cases of poisoning were studied for the period from August 2012 to October 2014, in the mortuary of Department of Forensic Medicine and Toxicology, in our Hospital.

Out of 381 cases 147 cases died in the hospital on which post-mortem were done. Total 234 cases were directly brought dead from spot or died while bringing to hospital.

Out of total 147 cases died in hospital, 135 were due to various poisoning and 12 were due to snake bites.

Careful post-mortem examination was done in the mortuary of the Department of Forensic Medicine in our Hospital. Main features observed during post-mortem examination were for evidence of poisoning like:-

- Cyanosis
- Frothing from mouth & nostrils and its nature
- Congestion of lungs, liver, spleen, kidneys and other organs
- Congestion of stomach mucosa and state and nature of stomach contents
- Conditions of pupils
- Conditions of heart
- Post-mortem lividity
- In case of snake bite fang marks and swelling around fang marks
- Smell if any
- Rigor mortis

Study of incidence, age, sex, occupation, education, and religion, and socioeconomic status, suicidal, homicidal or accidental, period



of survival after consuming poison was done.

Samples of blood, urine and gastric contents of poisoning cases admitted in hospital and cases brought for post-mortem were analysed in Toxicology Laboratory in Department of Forensic Medicine, in our Hospital and sent to Regional Forensic Science Laboratory for chemical analysis.

### Techniques used for preservation of samples for chemical analysis in Departmental Clinical Toxicology Laboratory:

The common materials preserved for chemical analysis in cases of suspected poisoning, was stomach wash, vomitus, blood and urine. The sample were collected in thoroughly cleaned glass bottles of 100ml capacity which were properly closed with rubber cock and labelled containing details as name, age, sex, poison suspected date and time of sample collected. Preservative used, treatment being given at the time of sample collection, name and signature with designation of treating physician, were properly noted.

### Preservative used for material preservation:

Type of material	Type of preservative used
Stomach wash fluid/vomitus	Saturated solution of common salt. (Sodium chloride)
Blood	Mixture of sodium fluoride and potassium oxalate
Urine	Thymol

A parted form required preservative each and every careful step was used to ensure that the samples were send to Toxicology Laboratory without undue delay, for minimizing the time gap between sample collection, preservation and chemical analysis.

### COMMON HOUSEHOLD CHEMICAL POISONS & MORTALITY\*

Types	Cases	Mortality	Survival
Boric acid	4	1	3
Benzene hexa chlorides	2	1	1
Carbamates (Baygon)	27	2	25
Chloroxylonol (Dettol)	1	0	1
Fenitrothion (Tick-20)	13	0	13
Gamma benzene hexa chlorides	2	0	2
Kerosene	42	5	37
Naphthalene	4	0	4
Phenyl ( Carbolic acid)	4	0	4
Potassium Permanganate	2	0	2
Savlon (chlorhexidine & Cetrimide)	1	0	1
<b>Total</b>	<b>102</b>	<b>9</b>	<b>93</b>

### Discussion

Poisoning was more in rural area than urban area. Common poisons in rural area were Insecticides, Alcohol and Snake bite. Common poisons in urban area were rodenticides, alcohol, and various drugs like ferrous sulphate, Phenobarbitone, diazepam etc.

Poisoning was more common in people having low socio-economic status, poisoning was rare in people having higher socio-economic status.

Poisoning was common in uneducated and poor people. Poisoning was rare among educated people.

Period of survival was 0-6 hours in most of the cases. Poisoning was suicidal in most of the cases followed by accidental while homicidal

poisoning was rare.

Food poisoning was reported due to consumption of poisonous food in marriage ceremony and different social programmes.

Kerosene poisoning was reported in children of 0-10 year age group, it was mainly accidental in manner. All cases were reported from urban area. Phenol poisoning was reported from urban area and manner of poisoning was suicidal. Phenobarbitone poisoning was reported in 3 cases of epileptic patients and it was due to their suicidal tendency.

Allethrin poisoning was reported in 3 cases which were from urban area and due to consumption of a packet of "kachhuwa chhaap agarbatti" by young males.

It was observed that, though the number of household chemical poisoning was high, the mortality was very low as compared to other type of chemical poisons. Out of 102 cases reported to the hospital, only 9 died & 93 survived.

### **Summary & Conclusion:**

One of the most common household poison viz. Zinc phosphide tablets can be confused with some medicinal tablets, hence proper labelling of bottles of poison should be done. Substances like Kerosene, phenyl, petroleum products, medicines, are accidentally consumed by children, hence they should be kept out of their reach. Any poisonous substance like insecticides, rodenticides which are common household poisons should be kept out of reach of children. Accidental snake bites can be avoided by using gum boots and proper care should be taken while wandering or doing work in the field.

### **Prevention of Accidental poisoning:**

Preventive measures can be tried to control

accidental insecticide poisoning as given below:

1. Pesticide will be used only if it needs after all other simple means of pest controls like Neem tree extract, dusting of ash, etc. are useless.
2. Before opening the bottle read label carefully, study all warning and follow directions given strictly.
3. Using protective clothing (gowns), masks, gloves, shoes while handling pesticides to prevent inhalation and skin absorption of poison.
4. Discard pesticides or its container or equipment used, by deeply burying under the earth.
5. Keep away remaining pesticides away from the reach of children and pets.
6. Never use household utensils to measure or mix pesticides.
7. Clean spraying equipment by rinsing it with at least three changes of water.
8. Wash hands and other exposed area of the body immediately after spraying pesticides and before eating and eatables.
9. Spraying in fields should not be done for more than two hours a day and not more than six days per week. The edible commodities particularly fruits and vegetables should not be made available to consumers by the producers at least within one week after spraying as they are loaded with substantial quantities of pesticides.
10. Persons suffering from lung, liver and kidney diseases should not be engaged in spraying pesticides.
11. No smoking, drinking or eating should be

allowed during spraying.

12. Spraying should be done towards the current of wind.
13. Proper storage of pesticides to avoid contamination and leakage of these chemical to edible commodities.
14. Government should take necessary steps to prevent poisoning by educating people by various modes of propaganda and practical demonstration to use the pesticides.
15. Exporting firms and manufacturing countries should provide detailed information on the labels of these chemicals.
16. International organisations like WHO, FAO (Food and Agriculture Organization) should form a uniform code of practice towards strict control on imports and exports as well as distribution and use of hazardous pesticides and chemicals.

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## Readers Ask... Experts Answer

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### Question:

**Should doctors encourage patients to record consultations?**

### Answer:

#### Introduction:

Indian patients are not so illegally inclined in recording Doctors consultations as compared to western countries. In fact Indian doctors have fitted CCTV camera's in clinic and hospitals displaying signs boards that the areas are under CCTV surveillance.

#### Indian scenario recording doctors talk

In India rarely when a mishap occurs some patients use their smart phones / pen recorders to record talk with doctor as piece of evidence to be produced in court, without permission of doctor.

#### Doctors in west cannot record doctor patient talk consultation:

In western countries legally doctors are not permitted to record consultations without the consent of Patient party. In India some doctors install CCTV camera's in their consulting rooms but not in examination rooms/area. In the United States, recording is subject to the laws developed for wire-tapping. In western countries because of legal restriction on doctors to record consultation, doctors should encourage patients to record consultations.

### Compulsory or mandatory recording of consultation should be done for

1. When both parties agree that they wish to record the consultation.
2. when a patient is unable to write or read notes written by doctors, which is the case in India more often than usual
3. The recording consultations for training purposes and review purpose. In the case of training, there are strict rules governing who may play the recording and when and how it must be destroyed so the identity of patient is not revealed to strangers.

### General negative effects of encouraging patients to record consultations:

- a. It is presumed that the doctor does not know everything on first consultation/ occasion . it requires series of consultations before arriving as justifiable diagnosis.
- b. It is wrong for either doctor or patient to record consultations with the intention of deliberately entrapping or tripping up the other party, and this implies that ending of doctor-patient relationship .
- c. usually recording of consultation is becomes sham, with one party intending to catch the other out. It does not matter whether there is litigation in prospect. This is not what doctors or patients should do to each other to outwit each other.

### **Consultations Recording may change in behavior of patient as well as doctor:**

1. The act of recording becomes like measuring of performance, alters the way the doctor-patient discussion goes on.
2. Medical consultation/advise alters if recorded. When doctor speaks, he is slower and with half an eye to posterity, even though consent from the patient is received or tacit. Patients are also inhibited, even if they say they are content to be recorded, and they speak and act in a more guarded way.
3. Consultations may take longer and both parties are more circumspect in what they say.
4. The interference with the consultation goes beyond the professional relationship.
5. Recording interferes with the precious doctor-patient relationship making doctors react defensively

### **Misuse of recording**

1. With any recording comes a risk of misuse.
2. The recording can be given to third parties without both parties' permission; it can be used as evidence about the doctor, the patient, or other people who are being discussed in some way by the patient, or rarely, by the doctor during the consultation; it can be published as "entertainment" on social media; or it can be (mis)used by the media.
3. The only way to mitigate these risks is for the doctor and patient to have a copy of the recording so that both know what truly transpired.

### **Situation in western countries versus India**

1. Although doctors should usually permit recording by patients (because it is the patient's consultation and a legal right), they

should not encourage it.

2. Any recording should be done with mutual consent and copies given to both parties.
3. Recording, if done it will lead to better practice and shared decision making. What concerns doctors in India that if recording is given to patient routinely it may lead to defensive medical practice and also put doctor-patient relationship in jeopardy.
4. In western countries doctors encourage patients to record their meetings openly to help improve patient care, encourage more evidence based medicine and shared decision making, and increase trust and openness.

### **Will to recording all consultations lead to improved patient care**

1. By far the strongest argument for encouraging patients to record Consultations is that it is likely to improve the quality and safety of patient care. No studies have shown improved patient, but it would be odd, if clinicians did not adhere to good practice if recording is done.
2. There may be some negative effects on doctors if consultation recording given to patient became Routine thing in India. Doctors might order more tests and generate more referrals and more follow-up visits. This kind of defensiveness may well lead to over-diagnosis, over-treatment, and increased costs to patient party.
3. Routine consultation recording will lead to better practice, greater reliance on evidence, and greater patient engagement, which Prevents unwanted medical treatments.

### **Will to recording all consultations lead to Shared decision making**

1. Routine consultation recording can not only be reviewed by patient party, other doctors as

*Contd...(85)*



## Trust the Patient

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### Introduction

Interpersonal trust is a key feature of the doctor-patient relationship that resonates with both patients and doctors. Trust in another person refers to an expectation that the other person will behave in a way that is beneficial, or at least not harmful, and allows for risks to be taken based on this expectation. For example, patient trust in the doctor provides a basis for taking the risk of sharing personal information. Similarly doctor should also risk understanding value system, knowledge, attitude and practice followed by patient party with respect to hygiene and health.

### Mutual trust

Usually it is the trust the patient party reposes in doctor. Mutual trust is an important aspect of the patient-doctor relationship with positive consequences for both parties. Doctor should develop trust in the patient. Doctor's trust in the patient will be useful in investigating the antecedents and consequences of mutual trust, and the relationship between mutual trust and processes of medical care, which can help improve the delivery of clinical medical care.

### Patients are the more vulnerable

Given that patients are the more vulnerable party in the relationship, it is not surprising that virtually all investigation of trust in the patient-doctor relationship has been limited to patient

trust in the doctor; however, patient and doctor trust are closely linked in that both refer to expectations of future behavior with respect to complementary roles. For example, a doctor needs to trust a patient to provide information or to commit to a course of care. Doctor trust in the patient appears to enhance patient trust in the doctor; conversely, lack of doctor trust is perceived quite negatively by patients and likely affects patient behavior. Mutual trust improves cooperation and reduces the need for monitoring relationship between doctor and patient. Successful and sustainable cooperation must be built on a foundation of trust and reciprocity."

### Trust in patient by doctors

Trust in patient allows for the characterization of mutual (reciprocal) trust in the patient-doctor relationship and could potentially provide a better understanding of the relationship between mutual trust and processes and outcomes of care leading to improvements in quality care and both patient and doctor satisfaction.

### Trust patient is new dimension

This new dimension of clinician trust in patient shall lead to further boosting and bonding of mutual trust leading to ideal doctor-patient relationship. Low trust by doctors in patient party adversely affected the quality of services provided to patient. It is possible that low trust by patient party similarly can lead to differences in



clinician behavior that adversely affect patients. Studies in social psychology have found that trust is generally lower between individuals with fewer shared characteristics e.g. there is stark difference between characteristics of doctors and patient party. It may be that differences in sex, age, race, or culture, knowledge, skill, attitude and hygienic standards between doctors and patients can result, even unconsciously, in lower levels of clinician trust that in turn may contribute to health disparities. In India infections are ubiquitous result of low hygienic standards amongst patient party. Post-operative infections and complications are most of the times because of low hygienic standards of patient party. Identifying circumstances that lead to inappropriately low trust in patients may help doctors avoid or mitigate adverse consequences. How does continuity of care by same doctor

affect mutual trust? What are the effects of restructuring practices around the Patient-Centered Medical OPD/IPD model on levels of trust between doctors and patients? What is the relationship between mutual trust and shared decision making? Has Indian doctor emancipated to realize that one has to descend down to level of values and beliefs of patient party to earn the trust? Before one wins trust one must also repose full faith and trust in values system of patient party.

### Conclusion

doctor-patient relationship is fiduciary relationship both clinician trust in the patient as well as patient trust in the clinician will facilitate mutual trust in the doctor-patient relationship that can help protect and improve the quality of the doctor-patient interaction without bias.

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### Readers Ask... Experts Answer (Contd...)

well as treating doctor himself for self-assessment. Treating doctor if forgot to mention alternative approaches, he can rectify the situation.

2. Treating doctor may share more information to help compare alternatives in next visits.
3. Treating doctor may indicate about probabilities of harm as well as the likelihood of benefit o treatment proposed.
4. Treating doctor may can look for evidence sources and see where such medical references are cited.
5. Treating doctor may look for national or local guidelines when he reviews his recorded consultation.
6. Treating doctor may use recorded consultation as tool to help the patient party to make informed decision.
7. Treating doctor will automatically become

patient centric and help patient to achieve his health preferences.

8. Treating doctor can practice evidence based medicine and shared decision With patient party
9. Treating doctor should keep in mind the possibility of medico-legal use by him or patient party both.
10. Recordings of recording all consultations considered as admissible evidence in law courts in western countries as well in india.

### Conclusions:

Recording all consultations can lead to Trust and openness. Doctors who are willing to be recorded will be viewed as having nothing to hide. A similar development is the Open Notes concept in the United States, which enables patients to comment on the accuracy of their electronic medical record.

## Medicolegal News

Contributed by:

**Dr. Archana Tiwari**

Consultant Obstetrician & Gynecologist

Executive Member, JIMLEA

Apex Hospital, Gwalior

### **PIL for extension of MTP rules**

*Source: dailymail.co.uk. 28.07.2015*

Kindling hope for lakhs of women forced to give birth to abnormal or stillborn babies each year thanks to the obsolete MTP Act, the Supreme Court is also separately hearing a plea seeking an extension of the legal limit for abortion from the existing 20 weeks to 28. Two women victims of the law, and Dr Nikhil Datar - who had in 2008 unsuccessfully challenged in the Bombay High Court the archaic MTP Act - have in their public interest litigation termed the rule "irrational, outdated, unconstitutional and a violation of women's rights to equality, health and life". The National Commission for Women, Federation of Obstetricians and Gynaecologists of India (FOGSI), the international community and several women's groups are backing the PIL, saying the Act violates women's rights to physical integrity. Armed with views of several doctors, they argue that with advanced technology now available to conduct abortion safely at any stage, the rules need to be drafted in a way that suits the changing times.

### **Now Surveillance suggested to prove or disprove Medical Negligence Cases**

*Source: The Hindu. 19.09.2015*

The Karnataka State Health Department is planning to get surgeries videographed, free of cost, and share the footage with patient's relatives if they demand it. The reason cited is that many times, doctors are blamed unnecessarily for the death of a patient even if the person would have died of co-morbidities or other complications. A video of the surgery will help find out if the doctors conducting the surgery are

actually at fault. It is for this reason that the department is also planning to amend the Karnataka Private Medical Establishments (KPME) Act, 2007 to permit a patient's relative to enter a hospital's intensive care unit (ICU) during treatment. Presently, hospitals do not allow family members once a patient is taken into the ICU. The reason for this cited that there are complaints by relatives about treatment in the ICU. Relatives are not sure whether the patient is being given proper treatment or not. If the patient dies, the doctors and hospitals are blamed even if they are not at fault. So it is better to allow them in the ICU, with precautions to avoid infections. The government is also planning to recommend changes in laws pertaining to compulsory post-mortem in cases of unnatural death, as stipulated by the Code of Criminal Procedure. The Health Department would shortly send a proposal in this regard to the Union Health and Home Ministers.

### **NHRC to conduct inquiries into people's rights violations due to medical negligence**

*Source: indiamedicaltimes.com. 09.09.2015*

Mumbai: The National Human Rights Commission (NHRC) is planning to conduct a series of public hearings to inquire into the people's rights violations in the health sector. The move is aimed at providing relief to patients "who suffer at the hands of doctors and hospitals". Jan Swasthya Abhiyan, a national network of civil society groups working on health rights, is assisting NHRC in conducting Jan Sunvaidis, which will aid patients to put forth problems they suffer at the hands of doctors, reports DNA. Representatives of the union health ministry, state health officials, and officials from

Brihanmumbai Municipal Corporation (BMC) as well as Maharashtra Medical Council (MMC) will be present at the hearings. The first hearing will happen in Mumbai at the Tata Institute of Social Sciences (TISS) on November 18 and 19. Following the western region hearings for Gujarat, Maharashtra, Goa and Rajasthan in Mumbai, five more hearings will occur at Chennai, Raipur, Guwahati, Lucknow and Chandigarh up to March-end. "Issues like destruction of medical records, life threatening complications in surgeries, not taking informed consent of patient before the surgeries and using patients as guinea pigs in clinical trials, exorbitant billing of patients by private hospitals, will be discussed, the secretary said.

### **Five sentenced to life for doctor's murder**

*Source: indiamedicaltimes.com. 07.09.2015*

Madurai: The Mahila court in Tuticorin has sentenced five people to life imprisonment for murdering Dr T R Sethulakshmi, an anaesthetist, two years ago. The court sentenced five persons to life imprisonment, reports ToI. Dr Sethulakshmi, 55, of Kamarajar in Tuticorin was hacked to death in her clinic on January 2, 2012. Investigations revealed that auto rickshaw driver Mahesh had murdered the doctor, as his pregnant wife Nithya and their baby died during delivery at the doctor's clinic. Mahesh believed the doctor was responsible for the death of his pregnant wife and their baby. He and his friends conspired and murdered her.

### **Lawyer directed to pay Rs 75,000 as compensation for filing unnecessary complaint against a doctor**

*Source: indiamedicaltimes.com. 29.07.2015*

Mumbai: Maharashtra State Consumer Disputes Redressal Commission has ordered a practising advocate, to pay a total compensation of Rs

75,000 to Dr Prashant K Pattnaik, a urologist, for filing an unnecessary complaint against the doctor that was eventually dismissed. The order said "We are of the view that it cannot be believed that he does not know the consequences of unnecessarily dragging a person into a litigation for years together. Without there being any proof of facts, the complainant tried to claim a huge compensation of Rs 20 lakh," (Source: ToI)

### **Attitude and law remain the same despite Savita's death**

*Source: dailymail.co.uk. 30.07.2015*

A recently-released report by Amnesty International points to how little has changed in Ireland's attitude towards abortion despite the outrage over Savita Halappanavar's death in 2012. Savita, an Indian-origin dentist had died in October 2012 after doctors in Ireland refused to perform an abortion. The 31-year-old's death had sparked widespread outrage and renewed calls for reforms to Irish law to allow termination of pregnancy if the life of the mother is at risk. The report, titled "She is Not a Criminal: The Impact of Ireland's Abortion Law", said pregnant women and girls risk putting their health and life in danger if they remain in Ireland. Savita, who was a dentist, was 17 weeks pregnant when she died from septicaemia, according to an autopsy conducted two days after her death on October 28. Savita had feared the foetus was dead and was likely to give her sepsis. According to her family, she asked several times for a termination as she had severe back pain and was miscarrying, but doctors at University Hospital Galway refused a medical termination of pregnancy on the grounds that abortion was illegal in Ireland. "The interpretation of the law related to lawful termination in Ireland is considered to have been a material contributory factor," found a report into Savita's death by Ireland's health service.

# HUMAN MILK BANKING ASSOCIATION MEMBERSHIP FORM

Photograph

Name of the Applicant \_\_\_\_\_

Date of Birth \_\_\_\_\_ Sex \_\_\_\_\_

Communication Address \_\_\_\_\_

State \_\_\_\_\_ Nationality: \_\_\_\_\_

Telephone (STD Code) \_\_\_\_\_ Other \_\_\_\_\_

Mobile \_\_\_\_\_ e-mail \_\_\_\_\_

Medical Qualification	Name of the University	Qualifying Year

Registration No. & Registering Authority (e.g. MCI or State Medical Council):-

\_\_\_\_\_  
Name, Membership No. & Signature of Proposer

\_\_\_\_\_  
Name, Membership No. & Signature of Secunder

Short Curriculum Vitte with experience of working in human milk banking (within 8-10 lines):-

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Place:

Date:

(Signature of Applicant)

Enclosures: True Copy of Degree, Council Registration Certificate & photograph.

Life Membership fee (individual Rs.2000/-, couple Rs.3000/-) by CBS (At Par, Multicity Cheque) or DD, in the name of : Human Milk Banking Association (HMBA) payable at Amravati. Send to Dr.Satish Tiwari, Yashodanagar No.2, Amravati-444606, Maharashtra.  
Phone: 0721-2541252, 09422857204 e mail - drsatishtiwari@gmail.com , drtiwarisk@hotmail.com

## Professional Assistance / Welfare Scheme

- The scheme shall be known as PAS “**Professional Assistance Scheme**”.
- 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.
- This scheme shall be assisting the members by:
  - 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.
  - Expert opinion** if there are cases in court of law.
  - 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.
  - Support of crisis management committee** at the city/district level.
  - Financial assistance** as per the terms of agreement.
- 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.
- A trust / committee / company/ society shall look after the management of the collected fund.
- 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 companies or any other similar private company.

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
2	Physician / doctors with Indoor Practice	Rs. 115 / lakh	+ Rs. 5 / IPD Pt
3	Physician / doctors with Indoor Practice of Surgeon	Rs. 230 / lakh	+ 7.5 % of basic premium
4	Physician / doctors with superspecialty, Anesthetist etc	Rs. 340 / lakh	+ Service Tax 10.3 % on the Total
5	<ul style="list-style-type: none"> <li><b>Rs/- 1000 (One thousand) per year</b> shall be collected to develop the fund of the IMLEA towards emergency assistance, risk management and conducting trainings, CME, workshops etc.</li> <li>Physician / doctors visiting other hospitals shall have to pay 5% extra.</li> <li>For unqualified staff extra charges of 8% shall be collected.</li> <li>The additional charges 15 % for those working with radioactive treatment.</li> <li>The additional charges can be included for other benefits like OPD/ indoor attendance, instruments, fire, personnel injuries etc.</li> </ul>		

- 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

<b>Name</b>	<b>Place</b>	<b>Speciality</b>
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. Prabhat Goel	Gurgaon	Physician
Dr. Sunil Mahajan	Wardha	Pathologist
Dr. Ashish Jain	Gurgaon	Pediatrician
Dr. Neetu Jain	Gurgaon	Pulmonologist
Dr. V P Goswami	Indore	Pediatrician
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. Ashish Satav	Dharni	Physician
Dr. Kavita Satav	Dharni	Ophthalmologist
Dr. D P Gosavi	Amravati	Pediatrician
Dr. Narendra Gandhi	Rajnandgaon	Pediatrician
Dr. Apurva Kale	Amravati	Pediatrician
Dr. Asit Guin	Jabalpur	Physician
Dr. Sanjeev Borade	Amravati	Ob & Gyn
Dr. Prashant Gahukar	Amravati	Pathologist
Dr. Satish Agrawal	Amravati	Pediatrician
Dr. Ashwin Deshmukh	Amravati	Ob & Gyn
Dr. Anupama Deshmukh	Amravati	Ob & Gyn
Dr. Ramesh Tannirwar	Wardha	Ob & Gyn
Dr. Sameer Agrawal	Jabalpur	Pediatrician
Dr. Sheojee Prasad	Gwalior	Pediatrician
Dr. V K Gandhi	Satna	Pediatrician
Dr. Shyam Sidana	Ranchi	Pediatrician
Dr. Umesh Khanapurkar	Bhusawal	Pediatrician
Dr. (Mrs.) Khanapurkar	Bhusawal	Gen Practitioner
Dr. Sanjay Ghuse	Amravati	Gen Practitioner
Dr. Kausthubh Deshmukh	Amravati	Pediatrician
Dr. Pratibha Kale	Amravati	Pediatrician
Dr. Milind Jagtap	Amravati	Pathologist
Dr. Varsha Jagtap	Amravati	Pathologist
Dr. Rajendra Dhore	Amravati	Physician
Dr. Veena Dhore	Amravati	Dentistry
Dr. Nilesh Toshniwal	Washim	Orthopedic
Dr. Swati Toshniwal	Washim	Dentistry
Dr. Subhendu Dey	Purulia	Pediatrician
Dr. Dinakara P	Bengaluru	Pediatrician
Dr. Laxmi Bhond	Amravati	Pediatrician
Dr. Sangeeta Bhamburkar	Akola	Dermatologist
Dr. Aniruddh Bhamburkar	Akola	Physician





## Indian Medico Legal And Ethics Association LIFE MEMBERSHIP FORM

Photograph

Name of the Applicant \_\_\_\_\_  
Surname First Name Middle Name

Date of Birth \_\_\_\_\_ Sex \_\_\_\_\_

Address of Correspondence \_\_\_\_\_

Telephone Residence \_\_\_\_\_ Hospital \_\_\_\_\_ Other \_\_\_\_\_

Mobile \_\_\_\_\_ Fax \_\_\_\_\_ e-mail \_\_\_\_\_

Name of the Council (MCI/Dental/Homeopathy/Ayurved /Other) \_\_\_\_\_

Registration No. \_\_\_\_\_ Date of Reg. \_\_\_\_\_

Medical / Legal Qualification	University	Year of Passing

Name, Membership No. & Signature of Proposer

Name, Membership No. & Signature of Seconder

A. Experience in legal field (if any) : \_\_\_\_\_

B. Was / Is there any med-legal case against you /your Hospital (Yes / No) : \_\_\_\_\_ If Yes, Give details

C. Do you have a Professional Indemnity Policy (Yes / No) : \_\_\_\_\_ If Yes, Give details

Name of the Company \_\_\_\_\_ Amount \_\_\_\_\_

E. Do you have Risk Management Policy (Yes / No) : \_\_\_\_\_ If Yes, Give details

Name of the Company \_\_\_\_\_ Amount \_\_\_\_\_

F. Is your relative / friend practicing Law (Yes / No) : \_\_\_\_\_ If Yes, Give details

Name \_\_\_\_\_ Qualification \_\_\_\_\_ Place of Practice \_\_\_\_\_

Specialized field of practice (Civil/Criminal/Consumer/I-Tax/other) \_\_\_\_\_

G. Any other information you would like to share (Yes / No) : \_\_\_\_\_ If Yes, please attach the details

I hereby declare that above information is correct. I shall be responsible for any incorrect / fraudulent declarations.

Place:

Date: \_\_\_\_\_ (Signature of Applicant)

Enclosures: True Copy of Degree, Council Registration Certificate & photograph.

Life Membership fee (individual Rs.2500/-, couple Rs.4000/-) by CBS (At Par, Multicity Cheque) or DD, in the name of Indian Medico-legal & Ethics Association (IMLEA) payable at Amravati. Send to Dr.Satish Tiwari, Yashodanagar No.2, Amravati-444606, Maharashtra.

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**Dr. Satish Tiwari**  
**07212541252**  
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