

# **WHITE PAPER ON LEGAL ISSUES IN HEALTH CARE**

## **(Recommendations of 'National Convention on Medicine & Law – 2015')**

THIS WHITE PAPER documents the recommendations of the National Convention on Medicine & Law – 2015 organised by the Institute of Medicine & Law on the 6th September 2015 at Mumbai. Thought leaders amongst doctors, lawyers, editors of medical and law journals, academicians, and representatives from medical associations, hospitals, regulators and policy makers were part of the deliberations.

India is witnessing a sharp rise in cases of medical negligence in courts along with cases of violence against doctors and hospitals. These indicate a systemic failure and breakdown of trust between doctors and patients. A soft regulatory framework, unrealistically high expectations of patients, and the peculiar socio-economic character of the nation further compound the issue. And this does not augur well for a developing country like India.

Some of the key causes include lack of dialogue between the doctor community, hospitals, legal professionals, and policy makers. It is also inappropriate that courts are forced to find solutions to issues that should have been provided either by the policy makers or the medical fraternity.

This makes it imperative for doctors, medical associations, and hospitals to come together to identify and discuss the legal issues relating to medicine and to find practical and legally appropriate solutions. Policy makers need to be updated about these contentious issues and the changes required in the legal and regulatory framework.

The Convention was an attempt to identify the legal issues relating to medicine, discuss them threadbare, and suggest remedial measures. The suggestions and actions recommended by the Convention will be conveyed appropriately to the regulators and policy makers.

The Convention comprised of five joint sessions on pre-determined issues of importance to healthcare and three break-away sessions on hospitals, critical care and emergency care. The final recommendations were generally unanimous.

**Issue 1.****Providing free treatment (medicines, bed, food) to "Acid Attack Victims" – Supreme Courts direction that needs reconsideration**

Key Note Speaker: *Dr. Atulkumar Shah*

The Supreme Court in the judgment passed on 10.4.2015 (Laxmi v/s Union of India) has directed that "the private hospitals should not refuse treatment to victims of acid attack and that full treatment should be provided to such victims including medicines, food, bedding and reconstructive surgeries" and further observed that "what we understand by free medical treatment is not only provision of physical treatment to the victim of acid attack but also availability of medicines, bed and food in the concerned hospital".

No mechanism is prescribed in this judgment for reimbursement to the concerned hospital/doctor and therefore this direction becomes onerous especially for certain specialties like plastic surgeons and ophthalmologists.

**Deliberations / Opinions**

- The judgment is contrary to IMC Regulations 2002 that gives unqualified right to doctors to charge fees for rendering their professional services.
- The doctor / hospital should not be constrained to bear expenses of treatment of the acid attack victim when it is the failure of the government to protect the victim and regulate sale of acid. The State is anyway

bound to provide affordable treatment under Article 21.

- It is irrational that the victim gets fine under Cr.P.C. and also 3 lakhs as compensation and bears no expenses for treatment but the hospital is penalized to provide free treatment.
- There is lack of clarity in the judgment on some issues like:
  - Can reimbursement be claimed?
  - Free is not defined. Is it free to the victim or the government?
  - What about treatment if the victim has an MI post acid attack? Ambulance? Co-morbidities?
  - All types of hospitals are not competent to treat a victim but this is not reflected in the judgment.
  - Differentiation is not made between initial and final treatment.
  - The competency of the doctor / hospital to treat the victim is not taken into account, moreover as each hospital has its own SOPs. It was specifically pointed that 20 years back MCI had constituted a committee to prescribe and define privileges of each speciality but the report is yet not made public.
  - Whether for this good Samaritan act protection under professional indemnity (insurance) will be available to the doctors / hospitals or not?
- Dr. Suresh Vasistha, President-elect of the Association of Surgeons of India, volunteered that his association will take care of the treatment cost exceeding 3 lakhs of each and every acid attack victim in India. This was disapproved by the house. It was pointed that there was no problem in the doctor's

community contributing to treat the 370 odd victims but this will then become precedent - Today it will be acid attack tomorrow something else.

- Relying on a recent judgment of the Delhi High Court it was pointed that every hospital could spend a part of its CSR fund for such victims. This was again disapproved by the house. It was pointed that any such compulsion would create another set of problems instead of resolving the one at hand.

### **Recommendations**

- The one year imprisonment to doctors under the relevant provisions of the Cr.P.C. and I.P.C. (recent amendments) must be deleted forthwith by bringing appropriate amendments.
- NCR Government circular dated 25.8.2015 which threatens doctors with contempt of court and cancellation of registration should be withdrawn immediately.
- A Review Petition must be filed before the Supreme Court for pointing out the clinical aspects in accepting and treating acid attack victims and seeking the requisite clarifications. This can be filed by either the Government of India / medical associations / any other public spirited citizen. It was suggested in the alternative that doctors could treat victims free, raise the bill, and send it to the Supreme Court to get it reimbursed
- Emergency treatment guidelines for acid attack victims must be formulated by professional bodies such as Association of Plastic Surgeons of India or Association of Surgeons of India and sent for approval to the Supreme Court.

- Government must identify the best centres for giving treatment to the victims. Other hospitals must only be bound to give first aid.
- Lifetime treatment to the victim must be provided by the government at the best and designated hospitals as it is the failure of the government in stopping this heinous act.
- Focus should be on training doctors and paramedics in treating such victims.
- Surgeons and reconstructive surgeons are perhaps best suited to treat victims. But MCI must clearly come out with the requisite clarifications about competency of specialities best suited to treat acid attack victims.

**Issue 2.****Emergency Medical Care – Need for a new Law**

Key Note Speaker: *Dr. Imron Subhan*

Since the Supreme Court's direction in the case of Pandit Parmanand Katara v/s Union of India in 1986, doctors and hospitals are bound to provide medical facilities to patients in need of emergency care. But many aspects of emergency care remain unidentified, undefined and unregulated. The Clinical Establishment Act has provisions in this regard but they are insufficient and the applicability of this Act across the country is another issue.

The Gujarat Emergency Medical Services Act, 2007 and the EMTALA Act (US) are two laws from which inspiration can be drawn.

A law in place, defining the role and responsibilities of the doctors will only help the patients in need of emergency care.

**Deliberations / Opinions**

- The delegates approved and lauded the following:
  - National Ambulance Service provided by dialing 108.
  - Arogyashree scheme in Andhra Pradesh that is working successfully for the past many years. Under this scheme any patient in need of emergency care below poverty line can get treatment in the best corporate hospitals designated under the scheme absolutely freely.
  - The Gujarat Emergency Medical Services Act, 2007.

- It was pointed that in US (under the EMTALA Act) and UK, the patient in need of emergency care is guaranteed that someone will take proper care of the patient.
- A start must be made in this direction at the earliest assuring the availability, uniformity and affordability of emergency care.
- The new law must take into account the following as far as emergency care is concerned:
  - A team of doctors and not an individual doctor delivers care in emergencies.
  - Role of non-doctors like police, ambulance, call centres, insurance, government is equally important.
  - Division of responsibilities at different levels, rural and urban, primary and tertiary facilities, government and private hospitals.
  - Government hospitals must be recognised as a class apart as they invariably accept emergency cases well over their capacity.
  - Emergency care during disaster like situations needs to be treated as a different class.
  - Provision for reimbursement of the expenses incurred to the doctors / hospitals in providing emergency care.
- Every State can come with its own law on emergency care depending on its unique problems.
- The right to refuse emergency patients outside expertise should be recognised and a well defined process should be there for privileging. It was also emphatically pointed that every MBBS doctor has the

basic knowledge to treat emergency cases, at least in giving the initial treatment.

- MCI must specifically permit other specialties to practice in emergencies.
- Courts must be more lenient in protecting health care workers working in threatening medical emergencies.
- Every doctor can carry an emergency kit though this is not mandatory and has other attendant problems.
- It was questioned that why are we still depending on certification of ACLS by the American Heart Association and why can't Indian professional bodies like ISSCM provide the same.
- Law must also protect other citizens (non-medicos) who provide help in emergency.

### **Recommendations**

- Every person must be assured of the best medical help in emergencies, freely.
- There is an urgent need for a new law or further fortification of The Clinical Establishment Act, 2010 for emergency care.
- Standard SOPs for emergency care must be defined.
- Emergencies across the hierarchy of hospitals must be defined.
- Health insurance of all citizens by the government especially for emergency medicine that is very expensive could be tried.
- Insurance companies can partly offload expenses
- Amend the Motor Vehicles Act making it mandatory for the insurance company to pay for the treatment, or a part thereof, in case of a motor accident victim.

- Focus should also be on quality and training of other healthcare workers like ambulance workers, paramedics, nurses who deal with emergency patient

**Issue 3.****The Clinical Establishment Act, 2010 – Compliments, Comments, Complaints**

Key Note Speaker: ***Dr. Anil Kumar, CMO, Ministry of Health & Family Welfare & Dr. Shiva Utture***

The first statute in India to regulate all the medical establishments unfortunately is stuck up in controversies. There is an urgent need for all stakeholders in healthcare to discuss, deliberate and understand each others concerns and position. The Convention acted as a platform bringing both the sides together.

**Governments viewpoint**

- There was need for this enactment as majority of the States in India do not have any legislation to regulate clinical establishments or have outdated laws.
- This Act will result into a comprehensive health registry that will help in policy formulation.
- The aim is not to regulate the establishments but to provide proper healthcare.
- The salient features of the Act are:
  - Laboratories will be regulated for the first time in India.
  - All the systems of medicine including AYUSH will be regulated for the first time in India.
  - Both government and private establishments are covered.
  - Clinical establishments run by the armed forces are exempted.

- Emergency patients have to be stabilized within the staff and facilities available. State governments "can" reimburse the actual expenses.
  - Objections before registering are invited from the public only because physical inspection of the premises is not mandatory for granting registration.
  - Fees have to be displayed.
  - Fees charged will have to be within the defined range of rates decided by the authority. It will be for procedures only and is basically intended for laboratories. It was pointed that this provision was introduced in the Rules and "can be changed".
  - Minimum records have to be maintained.
  - Compulsion to maintain electronic health records.
  - Implementation of this Act will be by the State government.
  - List of registered clinical establishments will be published.
  - Flexibility given to State government to exempt solo doctors from the ambit of the Act.
- It was pointed that the maximum penalty of 5 lakhs prescribed by this Act was found less by Rajasthan government and they want it to be increased.
  - It was pointed that in Himachal Pradesh the practice of electrohomeopathy has stopped, a clear indication of the effect of this Act in containing quackery in India.
  - One major handicap in its implementation is that health is a State subject and hence the Union

government can only request the States to adopt this Act and not force them to do so.

### **Objections**

- This Act was rejected by the Planning Commission in 2007 as the Commission was of the view that the investments required for complying with the various provisions of this Act will spiral healthcare cost and setting up of paraphernalia for inspection needs to be discouraged
- This is an additional law and the other laws regulating medicine will still exist. On the contrary there is a need for a single law to govern practice of medicine. There is too much of conflict of law.
- It was pointed that the Preamble of the Act is factually incorrect when it states that the "medical profession is unregulated". Today, 70 laws are applicable in opening a new hospital.
- The Preamble of the Act states about reimbursement but the body of the Act does not have any such provision.
- This Act will neither help the society nor upgrade the facilities but only increase cost of healthcare.
- Stabilization cannot be defined precisely and therefore its implementation will also be a big problem.
- The competent authority inviting objections from public before granting registration could result in doctors getting blackmailed. Once the prescribed conditions have been met to the satisfaction of the authority, grant of registration must be an automatic process.

- No provisions for hospitals registered under the existing acts, some of which would be more than 40 - 50 years old.
- Penalty of 5 lakh is too much. There is no such huge penalties for other professionals.
- The Act is cumbersome for a 'solo practising' doctor.
- This Act does not stop the courts from holding a doctor negligent for treating a patient outside expertise in emergencies.
- Money spent by the government on a patient in AIIMS and a municipal hospital is not the same as the quality of service is different. Then how can the rates charged by the doctor / hospital be fixed? Other factors like experience of the doctor, place of practice (rural/urban) and so on also impact the fees. A suggestion was made that the government should disclose in a transparent manner the cost incurred per patient in government hospital and the same could then be made applicable even to private players.
- Who will pay for treatment provided to an emergency patient especially by a superspeciality hospital? It is an admitted fact that today in India 70% of patients go to private hospitals and about 40 to 50% amongst them are emergency patients. Today half of the 'less than 50 bedded hospitals' are on the verge of closure. This Act will ensure that this closure happens quickly. Ultimately, the common man will get affected.
- The Act must instead prescribe minimum standards.
- Quackery will not get abolished by the Act.

### **Maharashtra Draft Bill**

Dr. Shivkumar Utture, a member of the drafting committee pointed out the salient features of the draft Bill.

This Bill was unanimously approved by all stake-holders and sent to the government and may become a law in near future.

- The word stabilization has been replaced with - "to provide basic emergency care within the facilities available."
- Single window registration will be ensured in lieu of the 40 odd regulations that have to be complied with for starting a hospital. Statutory bodies like pollution control board have been included in the authority.
- Provisions for deemed registration incorporated. If within 30/60 days the fate of the application is not intimated to the applicant, it will be deemed to have been registered.
- Provisions regarding objections from the public removed.
- Appellate authority will have doctors also.
- Penalty brought down drastically.
- In case of emergency care provided to an unidentified or unaccompanied person, the government will reimburse the expenses.
- Booklet of charges will always be there at the reception of each and every hospital and will be made freely available to the patients.

### **Recommendations / Consensus**

- The 'spirit' of the Act is good.
- It is laudable in the sense that some standards are laid down.
- Efforts must be made to take into account the concerns of the healthcare providers.
- The government is ready to reconsider the provisions regarding fixing of fees.

#### **Issue 4.**

#### **Unrealistic compensation in medical negligence cases – Where does the solution lie?**

Key Note Speaker: ***Dr. Alexander Thomas***

Two years back, the Supreme Court granted an astronomical sum of 11 crores as compensation in a case of medical negligence. This judgment not only resulted in a sudden rise in compensation granted by courts but also in a corresponding increase in the cost of healthcare, doctor-patient distrust and apprehension amongst doctors and hospitals.

Two important questions need to be answered in this context. Can a developing nations' healthcare delivery mechanism afford such huge compensation? If not, what is the best possible solution?

#### **Deliberations / Opinions**

- First world regulatory structure is being enforced in a third world infrastructure.
- 'Restitution integrum' is the reason behind compensation but it seems to have been violated by the Kunal Sahas judgment granting 11 crore compensation.
- Compensation cannot be looked in isolation.
- The ill-effects of higher compensation were pointed as follows:
  - The insurance premium has increased four folds – from 7 crore to 25 crore in case of a hospital in Mumbai. This is bound to increase the healthcare cost.

- 30 – 50 bedded hospitals where the majority of children are born in this country will close. A simple compensation of 1 crore can ruin the doctor and make him sell his house, clinic and farmland.
- Shutting shops by doctors will ultimately harm the patients, who may in some cases have to travel a long distance to get quality healthcare.
- Migration of doctors from smaller towns to bigger cities and to bigger hospitals that have a legal team is being observed.
- These concerns are a drain on the doctors skills.
- It will result in the practice of defensive medicine that will ultimately push the cost of healthcare. A study in UK pointed that 60% of the referrals / investigations were unnecessary.
- Medical profession will cease to be an appealing profession for the future generations. Shortage of specialists in litigation-prone specialities in an already doctor deficient system will be disastrous.
- Even In US certain States have capped compensation to 1.5 crores. Challenges to such laws in courts have failed. Australia also has capped compensation.

### **Recommendations**

- The government must act and that too fast.
- There should be only one forum to sue doctors. Constituting medical tribunals to exclusively try cases of medical negligence is a better option.

- All courts trying cases of medical negligence must be staffed with at least one medical professional as judge.
- Capping compensation to realistic amount is a sensible option by bringing an Act to quantify the amount (minimum / maximum) of compensation.
- Cap on interest granted by courts.
- Compulsory referral of all cases of medical negligence to alternative disputes redressal mechanism (ADR). Mediation as a tool to contain this abnormal rise in litigation should be statutorily promoted in cases of medical negligence. Civil courts are today pushing litigants towards ADR.
- Amend Consumer Protection Act.
- Heavy penalty must be prescribed for false litigation.
- Minor relatives of the deceased patient must get pension from the government till they attain majority but no compensation.
- Doctors must be made to disclose the compensation cap / indemnity insurance to the patient.

**Issue 5.****Role of law in controlling the healthcare cost – Reuse of equipments / disposables, a case in hand**

Key Note Speaker: *Dr. Barun Nayak*

Rising cost of healthcare is one of the principal reasons of the increasing trust deficit between patients and doctors. Law and regulations can play an important role in controlling costs

Certain equipments are often declared as 'single-use' or 'disposable' by the manufacturer though they can be safely reused by employing scientifically proven means. Reusing will obviously mean reduced expenses for the patient. But the doctor/hospital desist from reusing simply because the inserts or instructions from the manufacturers are otherwise and the law clearly states that acting contrary to such inserts or instructions is negligence. In fact, in the landmark case where compensation of 11 crore was granted, one of the reasons for holding the doctor negligent was that the dose prescribed by the doctor was exceeding the one prescribed in the literature accompanying the said drug.

There is a need to identify such arenas where appropriate legal or regulatory mechanism can help in bringing down the cost of healthcare.

**Deliberations / Opinions**

- The current trend is to shift to single use.

- The basic flaw is that manufacturers don't have to take approval / permission to prescribe single use from statutory authorities.
- Certain devices can be reused after reesterilization without compromising on functionality.
- Costly ones are generally reused.
- US FDA has a stringent reuse law. India can have a watered down version of the same.
- Patients consent is irrelevant for permitting reuse and also unethical as far as poor patients are concerned.
- NABH says that hospitals can have a policy on reuse. But this is legally untenable.
- One must accept that the manufacturer is there to make money and will run away from the liability arising out of reuse, especially in case of devices that are imported.

### **Recommendations**

- Statutory guidelines are needed to promote reuse. It can result in national saving and will also be environment friendly. Cost-reducing and not profiteering should be the only motive.
- Professional bodies could come out with guidelines. An example is the reuse of coronary catheters in angioplasty following the guidelines issued by the Indian Cardiac Association in this regard.
- Companies can be directed to cut rates drastically if it is single use or they can be directed to reesterilize and give back.

# Hospitals

## (Break-away session - I)

Moderated By: *Dr. Suganthi Iyer*

### **General Issues**

- Violence against doctors is a big concern. Even lady doctors are slapped and doctors disrobed.
- Unique number must be given to each patient waiting for transplantation by a central authority and not with hospital.
- Patient of sexual assaults are a big cause of concern for private hospitals.

### **Emergency patients**

- Hospitals not having the requisite infrastructure / facilities at times have to accept patients even if they are not qualified to stabilize / accept such patients. Obstetrics cases are the best examples.
- Emergency care is yet not defined.
- Emergency care is expensive and the hospital has to provide it freely to a non-affording patient. If transporting the patient to another hospital about 100 kms away is required what should be done? Especially as there is no reimbursement.
- Emergency patient who refuses to go even after the emergency is over.
- One-man hospitals are the worst hit.

### **Patients right to buy medicines from outside**

- Who will assure the quality?

- Such right is not given at other places. Can one bring food from outside in a hotel?

### **Pollution**

- Pollution Board not giving licenses without STP.
- Maintaining STP instead of having a central plant is a waste.
- The issue in some urban hospitals is where to put this effluent.

### **Fees**

- If the patient is not willing to buy medicine hospital is forced to buy medicines as it cannot neglect the patient.
- Non-payment of fees by patient, the only remedy is civil courts which is not prudent.
- Caucus of non-paying patients must be penalized
- Doctors must take strict legal action for non-payment of fees and publicize the same in newspapers.

### **Attendants**

- Different set of attendants during different stages.
- Doctors must ask who will pay and explain everything and take consent from such attendant.
- Last minute relatives who come to claim dead body are the biggest problem.
- Whom should the medical records of a deceased patient be given? Who is the authorised attendant?

### **Shortage of nurses and junior doctors**

- MBBS students are busy preparing for PG exams and hence not joining as residents. Increasing number of PG seats is an option.

- For staffing there are no guidelines except nurses.

### **Post mortem**

- Patients forcefully taking away the body and police refuses to intervene.
- Call 100, a good option.
- Duty is only to inform the police even by email.
- 15 – 35 year dead patient is the most problematic one.

### **Medical Records**

- Law relating to discarding medical records not clear.
- Validity of digital records not clear.

# Emergency Medicine

## (Break-away session - II)

Moderated By: *Dr. Imron Subhan*

### **1. INCORPORATION OF THE EMTALA ACT OF USA, IN INDIA**

An Indian law similar to the EMTALA (Emergency Medical Treatment and Active Labor Act) of the United States, which ensures all citizens to be provided emergency treatment whenever required, must be enacted. The EMTALA Regulations must be revised to suit the Indian healthcare system extending from the urban corporate hospitals to the government PHCs.

An alternative recommendation is that the EMTALA Act can be inserted, as a new amendment, into the Clinical Establishment Act which already exists.

### **2. LAW TO PREVENT VIOLENCE IN EMERGENCY ROOMS**

A law already exists protecting doctors working in hospitals. However the awareness of this law is extremely poor. Many police stations do not know about this.

It is recommended that widespread awareness be done on the existence of this law, so that both doctors and other staff are protected from violence.

### **3. ADOPTION OF THE GUJARAT EMERGENCY MEDICAL SERVICES ACT 2007**

The Gujarat Emergency Medical Services Act 2007, which provides clear responsibilities for ambulances,

emergency rooms, base hospitals, and so on, must be adopted and implemented by all states in India.

Revision of this Act is required even in Gujarat to ensure maximum participating hospitals from both private and Govt sector.

#### **4. GOOD SAMARITAN LAW TO PROTECT CITIZENS**

A Good Samaritan Law must be introduced to protect non-healthcare professionals and common citizens who assist in the first aid of accident victims and other emergencies. This law has to be widely circulated to the general public to create a wide community of 'First Responders'.

Involvement of the police must be made minimum. Statement from witnesses (of an accident) must be taken only once and recorded, without further harassment.

#### **5. DO-NOT-RESUSCITATE ORDERS IN THE EMERGENCY ROOMS**

Many patients brought to the emergency rooms have long standing/ irreversible illnesses and are unlikely to benefit from any medical treatment. However the decision to withhold resuscitative care touches the domain of passive euthanasia.

Indian Critical Care Society has drafted detailed policies on DNR orders. These can be taken and adopted across all emergency rooms.

#### **6. LEGAL VALIDITY OF EMERGENCY DOCTORS PRACTICING OUTSIDE THEIR SKILL EXPERTISE DURING EMERGENCIES.**

Specialist doctors are not available uniformly across India. Most specialists are only available in urban areas. MBBS doctors, especially those working in rural areas, are required to perform emergency medical and surgical procedures (thrombolysis, burr-hole craniotomy, emergency c-section delivery, lateral thoracotomy in severe trauma, etc) in order to treat or stabilize an emergency patient. These doctors must be protected in case of the death of the patient.

Doctors must be allowed to perform procedures outside their skill expertise during emergencies.

# Critical Care

## (Break-away session - III)

Moderated By: *Dr. R. K. Mani*

- Contemporary challenges on 'End of Life Care' in India vis-a-vis the western world
- Issues discussed
  - Barriers to discussion regarding End of Life Care in India within medical fraternity, with patient, their families and care givers and with legal community
  - India lags behind in the ethics and legal laws developed to address End of Life Care Issues
  - Confusion prevails when discussing the terms euthanasia, end of life care, withdrawal and withholding of treatment in the medical and legal community
  - ISCCM (Indian Society for Critical Care Medicine) does not endorse euthanasia in any terms

### **Legal issues to be addressed**

- Need to define laws related to
  - Compassionate Care
  - Quality
- Patient rights during the process of dying need clarity
  - Right to palliative care
  - Right to refuse unnecessary treatment
  - Right to pain free life

- Article 19 -21 – laws exist but need more clarity and additional clauses
  - Redefine personal liberty during dying
  - Right to protect privacy
  - Right to mitigation of pain and dignified death
- The Law Commission of India draft bills 176 and 241 on “Medical treatment of terminally ill patients (for the protection of patients and medical practitioners)” in 2006 – key observations
  - Euthanasia and physician-assisted suicide remain criminal offences, but are clearly distinct from withholding and withdrawal of life support
  - Adult patients’ right to self determination and right to refuse treatment is binding on doctors if based on informed choice
  - The State's interest in protecting life is not absolute
  - The obligation of the physician is to act in the “best interests” of the patient
  - Refusal to accept medical treatment does not amount to “attempt to commit suicide” and endorsement of FLST by the physician does not constitute “abetment of suicide”
  - Withholding & withdrawal is viewed as an “omission to struggle” on the part of the physician that will not be unlawful unless there is a breach of duty towards the patient
  - Applying invasive therapies contrary to patient's will amounts to battery or in some cases to culpable homicide

- Clear definitions of competence, informed decision and best interests
- Recognize patient's Right to refuse treatment
- If a competent patient makes an informed decision, it is binding on the doctor
- In case the decision is not an informed one, or in cases of minors or incompetent patients doctors can take decisions in the “best interests”( include medical, emotional, ethical, social and welfare considerations)
- Statutory body to constitute a panel of experts to authorize withdrawal and withholding of life support (FLST) decisions Three experts to be consulted for FLST decisions for incompetent persons - needs further discussions between the Law Commission, ISCCM & IAPC.
- The physician will consult the family but their views are not binding on him/her
- Advance directives, and legal powers of attorney shall be deemed invalid for decision making
  - as it may “create complications”
- Provides for Court declarations: Family / physician / hospital can move court on the question of
  - lawfulness of withdrawal of life support. This is viewed as an “enabling”, as opposed to mandatory,
- Recommends “expeditious” decisions by a division bench of the High Court. Declarations binding on civil and criminal courts in subsequent proceedings
- Recognizes patients' right to receive palliative care
- Directs Medical Council of India (MCI) to formulate guidelines on EOLC – needs further discussions between ISCCM, IAPC and MCI

**Discussion with Medical Council of India (MCI)  
needs to happen:**

- Deleting the word Euthanasia from the MCI Act and replacement of the text regarding withdrawal of treatment and withholding of life support is necessary
- Educational modules or chapters in undergraduate and post graduate medical curricula regarding End of Life care needs to be developed

**Institute of Medicine & Law:**

Institute of Medicine & Law (IML) provides education, information, and services related to medical laws. IML's actionable content and analyses are delivered to doctors, hospitals, and lawyers on multiple platforms in real time.

IML is India's foremost authority on medical laws possessing the best resources in terms of legal professionals and experts. Its detailed knowledge bank is continuously updated with the latest developments and is optimally utilized to provide medico legal solutions to the benefit of healthcare providers.

IML has been conducting an annual exercise of drafting and adopting a 'SOP on Patients Consent' ([www.patientsconsent.com](http://www.patientsconsent.com)) together with major national medical associations like IMA, ASI, FOGSI, API, IOA, IRIA, AIOS, ISA, ISCCM, and CSI among others. This SOP is today accepted as a standard, comprehensive, and legally compliant document on patients consent in India. The science of medicine as well as law are dynamic in nature, these will keep bringing in newer challenges in newer areas. This annual event will address these developments and raise, discuss, and deliberate these issues, and suggest practical solutions to doctors and hospitals. It will also update the policy makers with the lacunae in the legal and regulatory framework on an ongoing basis and ensure that the outcome of this exercise is taken to its logical conclusion.