

WHITE PAPER ON LEGAL ISSUES IN HEALTH CARE - 2016

(Recommendations of '2nd National Convention on Medicine & Law – 2016')

THIS WHITE PAPER documents the recommendations of the 2nd National Convention on Medicine & Law – 2016 organized by the Institute of Medicine & Law on the 4th September 2016 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. Hon'ble Chairman and member of the Law Commission of India were also present.

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 is a platform 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 a plenary session and seven break-away sessions on transplant, HIV, dermatology, intensivists, private hospitals, public hospitals and emergency medicine. The recommendations were generally unanimous.

'Aids Society of India (ASI)' was associated in the break-away session on HIV and the 'Society for Emergency Medicine in India (SEMI)' was associated in the break-away session on emergency medicine.

Break-away session - 1

Transplant

Moderated By: *Adv. Arunava Mukherjee, Dr. Suganthi Iyer & Dr. Satish Tiwari*

Issue 1. The Uniform Determination of Death Act - Need in the Indian context

- **Death must be clearly defined to include Brain Stem Death as defined in THOA ("permanent disappearance of all evidence of life occurs, by reason of brain-stem death or in a cardio-pulmonary sense, at any time after live birth has taken place").**
- **Declaration / certification of Brain Stem Death as a form of death must be recognized specifically by a separate statute or by an official clarification.**
- **Definition and process of certification of death should be uniform**
- **Such a clarification / amendment should not be made in the THOA as it will be construed narrowly.**
- **Definition of death should be non-exclusive and amenable to further advances in medical science.**
- **Death Certificate must be standard/uniform version including Brain Stem Death.**

Is Brain Stem Death and cardio respiratory death legally the same? Can the definition of Brain Stem Death in THOA be read into the common law definition of death? Can the family of a Brain Stem Death patient be allowed to use life-support system, a scarce resource, especially in a government set-up?

The definition of death is found only in the Indian Penal Code but it is of no help. Brain Stem Death does not fulfill the criteria of 'disappearance of life' and 'irreversibility' remains the main criteria for death in THOA. Applying the definition of death in THOA to other situations creates problems, especially when the policeman tries to decipher law. A Brain Stem Death patient may take 2 hrs. to 10 days for cardio respiratory death. Furthermore, the impression about Brain Stem Death amongst relatives is that the patient is not really dead but as the doctors want organs they are declaring the patient dead. A positive assertion from the society and a new

law is therefore required to clear this ambiguity. If Brain Stem Death is brought into the definition of death, declaring Brain Stem Death as death will become a routine form of declaring death.

On the other hand, it was pointed that a new law is not at all needed. The definition of death in both Registration of Birth & Death Act and THOA is 'permanent disappearance of life'. On the contrary, a general awareness needs to be created that a certificate of Brain Stem Death is a Death Certificate. At the most, a clarification is needed from the government that Brain Stem Death can be given Death Certificate and should be treated as such. It was further pointed out that switching off the ventilator in Brain Stem Death patients is an emotive and not strictly a legal issue.

Consensus:

The definition and the process of certification of death should be uniform. Death Certificate for both Brain Stem Death and cardio respiratory death should be one and not two as is the current practice with Brain Stem Deaths. Brain Stem Death document should only be a part of Death Certificate. Even an official clarification will do as making new law takes lots of time. The definition of death should be non-exclusive and should be kept open for further advances in medical science.

Issue 2. Should identifying / certifying Brain Stem Death be made mandatory?

- **Brain Stem Death certification should not be made mandatory as Identifying and certifying of Brain Stem Death is already a "duty" of a Registered Medical Practitioner under THOA.**
- **Raising awareness through sensitization programs should suffice.**

There is resistance from doctors, especially neurologists, in identifying Brain Stem Death. Legal problems are often cited only a refuge for not declaring Brain Stem Death. Patients are not even looked at from that perspective. Failure to identify / certify Brain Stem Death is one big problem in organ donation. Brain Stem Death identification and certification should therefore be made mandatory. It was pointed that if such a course is supported by law, it will be easier to disclose and discuss Brain Stem Death with relatives. The purpose behind Brain Stem Death certification is not to have dead bodies on ventilators. Two important suggestions were made.

Certifying Brain Stem Death should be least cumbersome. Every 72 hours doctors must certify that the patient is not Brain Stem Death.

"Making a request for organ donation is now mandatory in ICU and thus the government is indirectly making identification of Brain Stem Death mandatory," said Dr. Anilkumar representing the Ministry of Health & Family Welfare. He further pointed that in some states including Tamil Nadu, Brain Stem Death certification has been made mandatory in government hospitals; there is lack of requisite expertise to identify Brain Stem Death; and parallel capacity building of experts who can identify and certify Brain Stem Death is required.

On the other hand it was pointed that the law clearly states that a registered medical practitioner is bound to identify Brain Stem Death. If there is a duty, why the mandatory clause should come? Punishing doctors if a request for donation or identification of Brain Stem Death is not made will not be possible to implement. It is essentially a medical issue. Brain Stem Death certification should not be made mandatory otherwise it will become a PCPNDT Act for intensivists. The word mandatory is inconsistent with the spirit of 'donation'. Furthermore, small nursing home not having the requisite expertise will face problems. It was pointed that Brain Stem Death certification is more of an 'end-of-life' issue and a question of trust. On the contrary hospitals must try to influence their doctors. Doctors should be encouraged to promote Brain Stem Death, but it should not be made mandatory.

One aspect was refusal of doctors to identify or certify Brain Stem Death on the pretext of lack of expertise. It was pointed that every MBBS is competent enough to examine and identify Brain Stem Death and any doctor refusing to certify Brain Stem Death on ground of lack of knowledge is negligent.

Consensus:

Identifying and certifying Brain Stem Death should not be made mandatory as it is already a "duty" of a Registered Medical Practitioner under THOA.

Issue 3. How Form 7 can be given a legal standing considering it as a persons living will for organ donation which can be then respected considering legal, ethical and social angle?

- **Family's consent should be continued to be required even when the deceased had provided written consent.**
- **If the relatives are not available to give consent statutory provisions permit the Medical Superintendent to give consent for organ donation.**

Taking family members consent for organ donation even after the patient has expressed consent in Form 7 was questioned. It was pointed that seeking re-consent from the family negates the sanctity of Form 7 filled by the patient.

On the other hand it was pointed that one must not keep only organ transplant in mind in deciding such issues. Consent may have been given at a younger age when the person may not be knowing the consequences. Advance directives given by a person who is under depression are questionable. There also exists confusion in India about the legal possessor of the dead body as different religions have different hierarchies.

It was further pointed that whenever a patient had signed the consent the family members have never said no. By filling Form 7 the person become more motivated toward organ donations. As a general practice in Tamil Nadu even if a single person of the family opposes donation, it is abandoned.

Another problem arises when the relatives are not available to give consent is a problematic area. It was pointed that there are legal provisions that if no consent of relatives is forthcoming in 48 hours the Medical Superintendent can give consent.

Consensus:

As of now there is a need for re-consent from the relatives.

Issue 4. Increasing organ donation through 'Donation after Circulatory Death' (DCD)

- **Introduction of DCD needs to be explored in our country to improve organ donation.**

Death is induced in DCD and this concept needs to be explored in India. Other countries have clear laws on futility of care, if the families assent is there, ventilator is willfully disconnected. Law does not expressly prohibit DCD in India. Today DCD is

possible only under two circumstances. First, when a Brain Stem Death is declared but the family wishes to donate only after cardiac arrest. Second, after Brain Stem Death certification while waiting for removal of organs, the donor develops cardiac arrest.

It was suggested that THOA should therefore be amended to include DCD. Uniform guidelines for DCD are required.

"Actively withdrawing ventilator will not be allowed in India for the next 50 years, even in cases where there is futility of care" said Dr Anilkumar, representing the Ministry of Health and family Welfare.

Consensus:

No consensus was reached on this issue.

Issue 5. Approaching families for organ donation - Strengthening the legal framework

- **Consent for organ donation - "opt out" needs to be considered instead of "opt in"**
- **Doctors should start building rapport with the family before assessing the patient for Brain Stem Death.**
- **Volunteering for donation should be incentivised. Non-monetary incentives should be given to the donor/family such as giving priority in receiving organs.**
- **Angiogram / CT scans could be used for Brain Stem Death certification as it becomes easier to convince the families as it is a visual image depicting "no brain activity."**

A few important suggestions were made in this regard. First, it was pointed that countries having opt-out policies rather than opt-in policies have more organ donations and this could very well be adopted in our country. Second, doctors should start building rapport with the family before assessing the patient for Brain Stem Death as this increases the chances of getting family's consent for donation.

Another suggestion was that CT angiogram should be made mandatory. Showing the photograph of brain not working convinces the family better that the patient is

dead as Indian public sees ECG as a sign of life in movies. Concerns were raised that certifying death through CT Angiograph would mean certifying whole brain death and not Brain Stem Death. Pediatric associations should give clarifications regarding pediatric Brain Stem Death.

Consensus:

CT Angiogram should not be made mandatory and should be done, merely as a substitute, when apnoea cannot be done.

Issue 6. Waiting time after cessation of circulatory activity to retrieve organs

- **The time for which doctors must wait in case of absence of circulatory activity must be fixed by law as 10 minutes. After such time, the law must permit doctors to proceed with organ retrieval.**

Currently, there are no guidelines on how much time should a doctor wait after the heart stops beating to retrieve organs. Different countries have prescribed different time.

"We will call an expert meeting to discuss this issue" said Dr Anilkumar, representing the Ministry of Health and family Welfare.

Consensus:

In a third-world country like India, 10 minutes is good enough time to wait after circulatory death to start retrieving organs, on a more cautious and safer side.

Issue 7. Time of death in Brain Stem Death

- **The time of second apnoea test must be recorded as the time of death in Brain Stem Death.**

The time of death in case of Brain Stem Death is not statutorily prescribed. It was pointed that the first apnoea test pronounces death and the second apnoea test merely confirms death and hence the time of the first apnoea test must be recorded as the time of death.

Consensus:

The time of second apnoea test must be recorded as the time of death in Brain Stem Deaths.

Non-legal but important suggestion - More awareness is required in the society about organ transplant:

- Public awareness about organ donation must be improved through advertisements.
- Hon'ble Prime Minister must promote organ donation in 'Mann Ki Baat'.
- Messages promoting organ donation must be compulsorily shown in movie theatres.
- Celebrity endorsement is required.
- School curriculum must have organ transplant.
- Medical curriculum must have chapter on Brain Stem Death and organ donation.
- Educate the public as well as the doctors that a dead body can have a beating heart. Before educating the public we should educate the doctors.

Other recommendations / unanswered questions

- Involve more professional counselors and trained transplant coordinator.
- After declaring Brain Stem Death, withdrawing life support should not be made mandatory.
- After declaring Brain Stem Death, even if the organ donation is not happening the hospital has to bear the charges of such patients.
- Only in India, neurologists have to certify Brain Stem Death twice. Why is it that we consider our clinical assessment inferior?

Break-away session - 2

HIV

in association with AIDS SOCIETY OF INDIA (ASI)

Moderated By: *Adv. Vaishnavi Subrahmanyam & Dr. Puneet Setia*

- There should be informed consent in every case where HIV testing is required. However, this should be preceded by pre test counseling and followed by post test counseling.
- Till we can ensure zero discrimination on the basis of the patient's HIV status, mandatory testing of HIV should not be done.
- HIV patients should be given insurance cover as it is done for any other disease, based on the parameters that are used for different diseases.
- HIV (along with HBV and HCV) should be removed from the exclusion list while providing professional indemnity to doctors. The matter should be actively pursued at relevant fora like courts, IRDA, media, and legislature.
- HIV positive couples should be allowed to adopt children subject to the other conditions and due diligence performed by the authorities. HIV status of prospective parents should not be a ground for summary refusal of their adoption application.
- Mandatory testing of HIV of adoptive child should be continued but solely for the child's benefit and should not be used to discriminate / disqualify them from being adopted.

Issue 1: Consent and HIV test

- There should be informed consent in every case where HIV testing is required. However, this should be preceded by pre test counseling and followed by post test counseling.
- Till we can ensure zero discrimination on the basis of the patient's HIV status, mandatory testing of HIV should not be done.

Should mandatory consent for HIV testing be continued? Are we not putting the healthcare workers at risk? In case the patient refuses to give consent for HIV

testing, by taking universal precaution are we not increasing the cost of healthcare unnecessarily? The issue is not about taking consent for treatment / procedure but the legal compulsion to take consent for HIV testing.

Consent is a process that enables the patient to take the right decision. Consent is important as privacy of an individual is invaded. It is not for protecting doctor, for stopping discrimination or for prevention of infection. Informed consent forces the doctor to educate the patient on that issue which would otherwise never happen. It is also in the interest of doctors as the patients level of awareness has increased nowadays. Mandatory testing for HIV can be done for comatose or pregnant patients even without consent but the reasons for exclusion from consent are getting lesser and lesser with every passing day. It was further suggested that ideally consent should be taken for all investigations, especially for all infectious sexually transmitted diseases. Consent of the patient is not required only when public health is in danger and this is not the case with HIV.

HIV also brought the concept of counseling and counselors in healthcare. Counseling is in fact required on every issue in health. Doctors must counsel HIV patients otherwise they should not accept the patient or refer the patient to another facility. Counseling helps the patient to cope with the disease well and helps the patient in taking the right decision after knowing all the risks and benefits of treatment. On the other hand it was pointed out that it may not be possible for every doctor to have a counselor. Counselors are not easy to find or may not be competent, especially in small towns and villages. Law made 16 years back in the state of Manipur wherein to perform HIV testing, consent, pre-test counseling and post-test counseling were made mandatory was much appreciated.

Stigma regarding sex outside marriage in our society is the underlying reason for the problems faced by HIV patients and this will continue in near future. Even doctors treating HIV perceive social stigma. Furthermore, discrimination / denial / deferral of treatment to HIV patients - financially, socially medically cannot be guaranteed. Hardly 10% of doctors/hospitals do not charge extra otherwise surcharge and conditions like refusal for room sharing are imposed once HIV status is disclosed.

HIV positive patients are again tested for HIV on referrals. Even death certificates and insurance claims of HIV patients are refused / disputed.

Indian public is not health literate. Doctors have little time for patients and hence want to shy away from consent. In India, patients are least informed by doctors. Doctors are dealing with human bodies that have human minds and therefore need to be accountable. Once consent is withdrawn, counselors will be withdrawn, and the patients will remain uneducated. It was pointed that every sort of advice is offered through consent and has actually resulted in decrease of even other STI's (sexually transmitted infections).

Rural India is not ready for any change. Literacy level of patient is a cause of concern. Discrimination is decreasing but has not gone completely. Laws are for protecting the minority that is at the receiving end. As long as the society is unable to change, consent should continue and there is no scope for mandatory HIV testing. Doctors have the option of taking universal precaution.

Many other alternatives were also discussed only to be rejected. Is opt-out instead of the present practice of opt-in a viable alternative? Is video consent an alternative? Can there be only counseling and no consent for HIV testing? Is mandatory pre-test counseling feasible or not? Should the Manipur model be implemented across the country - mandatory consent for HIV testing but with pre-test and post-test counseling?

Issue 2: Discrimination in professional indemnity and patients insurance such as mediclaim

Regarding patients:

- **HIV patients should be given insurance cover as it is done for any other disease, based on the parameters that are used for different diseases.**

Regarding doctors:

- **HIV (along with HBV and HCV) should be removed from the exclusion list while providing professional indemnity to doctors.**

- **The matter should be actively pursued at relevant fora like courts, IRDA, media, and legislature.**

Patients Insurance

Insurance companies at present are not providing insurance policies like mediclaim to HIV patients. Medical claims of non-HIV treatment of HIV patients is also denied.

The justification for the aforesaid is that insurance companies are business entities working for profit and exclusions are decided on emergent and re-emergent situations. Furthermore, there is scarcity of life data of HIV patients to decide the amount of premium.

Insurance companies should not discriminate. They may charge a higher premium. Longevity of HIV patients was an issue earlier but now it is 35 years. Free treatment is available today and the epidemic is weaning.

Professional Indemnity for Doctors

Insurance companies do not provide professional indemnity to doctors treating HIV (along with HBV and HCV) patients even after strict guidelines have been issued by IRDA against this condition.

This condition is unreasonable as HIV treatment does not bring any extra risk to the doctor. This is discriminating the doctor and putting the doctor at risk which could extend upto 12 crores. It was pointed that today doctors are protected from medical negligence cases only because the HIV patient feels social stigma in disclosing HIV status but this social stigma may not last long. Furthermore, compensation in cases of medical negligence is granted on the basis of loss of patient's earning capacity and not the disease. At least the government insurance companies must provide indemnity.

It was pointed that in a democracy 4 remedies are available in such conditions - show of strength by organizing morchas, approaching courts, going to media and approaching law makers directly. It was pointed that the option of show of strength by doctors was not feasible and approaching law makers may not help as the

legislatures in India are too slow. AIDS Bill is pending in Parliament for the last 15 years. Hence filing a PIL and approaching the media should be actively pursued. The proposed PIL should seek directions from the court to IRDA to implement its own guidelines. Petitioning the Parliament should also be explored.

One suggestion was that IMA (Indian Medical Association) has its own indemnity for all doctors and doctors treating HIV patients could opt for the same.

Issue 3: Issues in adoption by HIV positive couples

- **HIV positive couples should be allowed to adopt children subject to the other conditions and due diligence performed by the authorities. HIV status of prospective parents should not be a ground for summary refusal of their adoption application.**
- **Adoption agencies and authorities need to be counseled and updated by medical professionals regarding HIV.**
- **Mandatory testing of HIV of adoptive child should be continued but solely for the child's benefit and should not be used to discriminate / disqualify them from being adopted.**

India has a rigorous process for adoption. HIV positive parents are banned from adopting. Even sero-discordant couples are considered as HIV positive parents and banned.

This blanket ban is wrong. Shorter life expectancy of parents was a relevant factor earlier but that is not the case now. Doctors must be brought into the picture before adoption and with a doctors certificate, adoption should be permitted.

On the other hand there should be no superior right of HIV parents to adopt. The child's interest is paramount. Stigma to the child having to live with HIV parents must be considered.

One suggestion was that HIV positive parents should be given preference to adopt a HIV positive child. Courts have banned HIV positive-negative marriage but permitted positive-positive marriage.

HIV status of the adoptable child is always ascertained. The question is whether HIV testing of adoptable child should be banned? It was pointed that adoptable child is the ward of the State hence tested for HIV so that treatment can be provided. The disadvantages of doing away with such testing of child far outweigh the advantages. No change in law but only advocacy is needed on this aspect.

Break-away session - 3

Dermatology

Moderated By: *Adv. Mayank Kshirsagar & Dr. Shreekant Shetty*

- **A legally acceptable mechanism needs to be evolved to endorse SOP's / guidelines recommended and approved by respectable medical associations. Alternative SOP's/guidelines should also be legally acceptable.**
- **Off label use of drugs should be regulated, especially in pediatric dermatology.**
- **Irrational combination of drugs should be regulated / discouraged, especially those containing tropical steroids. Dispensing such drugs without valid prescription of qualified doctors should be completely banned.**
- **Refills of derma medicines should be allowed only on fresh prescriptions.**
- **Production / advertisement / sale of cosmetics having active pharmacological ingredients should be strictly regulated / banned.**
- **Suboptimal doses of medicines should be completely banned.**
- **Regulate / restrict inter-disciplinary practice of dermatology by doctors of other specialties. Define clearly the qualifications required to practice various disciplines of dermatology (cosmetology, trichology, cutaneous / dermato surgery, aesthesiology, laser surgery). Clarity is required on other disciplines of medicine / surgery overlapping with dermatology.**
- **Ban quackery.**
- **Senior dermatologists should be permitted to practice newer techniques / procedures after undergoing training programs conducted by their associations.**
- **Misleading / false advertisements, especially in dermatology should be regulated / curbed.**
- **Proper guidelines for tele-consultation and e-consultation should be framed.**

- Regulations for doctors website and its content should be framed.
- Regulations banning / regulating listing of doctors on web portals and e-commerce platforms such as Just dial is required.
- While allotting CME points to doctors the relevance of the topic / issue should also be taken into account rather than only taking the man-hours spent in the CME.

Recommendation 1. A legally acceptable mechanism needs to be evolved to endorse SOP's / guidelines recommended and approved by respectable medical associations. Alternative SOP's/guidelines should also be legally acceptable.

Dermatology is one of the specialties where newer procedures / treatment protocols / drugs are discovered / practiced, far too often. Prescribing the legally acceptable medical practice is therefore necessary in view of the current medico legal environment.

A few concerns on this aspect were pointed out:

- The validity and legal acceptability of SOPs sponsored by pharmaceutical companies.
- Many SOPs for one indication / disorder each inconsistent with the others.
- SOP's in journals and articles on the internet whose authenticity and credibility is questionable.
- Acceptability of international norms/ guidelines that could be incomplete or may not have taken Indian protocol into account.

Medical associations should therefore actively formulate SOP's / guidelines / consensus reports on management of indications / disorders, especially for the newer procedures / treatment protocols / drugs. A legally accepted mechanism should be evolved so that these SOP's / guidelines / consensus reports are endorsed and / or accepted by both MCI and courts.

These SOP's / guidelines / consensus reports should be updated periodically. These should have precedence over clinical judgment of the doctor. Alternative SOP's /

guidelines / consensus reports should be recognized. Conflict of interest, if any, should be specifically disclosed. Furthermore, randomized control trials which are considered level 2 evidences, should be legally acceptable.

Recommendation 2. Off label use of drugs should be regulated, especially in pediatric dermatology.

Guidelines should be prescribed for off-label use of drugs. These guidelines should clearly specify how the drug should be used, who should prescribe it, and so on.

Recommendation 3. Irrational combination of drugs should be regulated / discouraged, especially those containing topical steroids. Dispensing such drugs without valid prescription of qualified doctors should be completely banned.

Steroids are rampantly and irrationally used in our country. Combination drugs and irrational drugs are areas of concern. It was specifically pointed that combination drugs in dermatology are aimed at non-dermatologists who thus become competent to prescribe such drugs.

Irrational combination of drugs should be discourage / banned. Certain groups of steroids should not be dispensed without a valid prescription from a qualified doctor.

Recommendation 4. Refills of derma medicines should be allowed only on fresh prescriptions.

One prescription should be used to dispense drugs only once as in the case of psychiatrist drugs.

Recommendation 5. Production / advertisement / sale of cosmetics having active pharmacological ingredients should be strictly regulated / banned.

Dermatology drugs are not given the same treatment as other drugs and are commonly treated as cosmetic products. Certain soaps and shampoos that are medicines are sold as cosmetics and therefore used as cosmetics and not as medicine by the patients. Anti-fungal creams when brought into powder form are commonly used as talcum powder rather than as a medicine. Globally certain drugs

with certain potency can be sold as OTC drugs whereas for higher potency prescription of a qualified dermatologist is required.

Production / advertisement / sale of cosmetics having active pharmacological ingredients should therefore be strictly regulated / banned. Privileging of drugs with potency (wherever necessary) should be done. Greater caution is required in labeling a particular drug as cosmetics. Cosmetics should be categorized in consultation with dermatologists (today this exercise is done by bureaucrats only). Pharmaceutical companies should observe self-restraint and not come up with certain products. Shampoos that are used as medicines should be sold as lotions so that doctors can give requisite instructions to the patient.

Cosmetics that have active pharmacological ingredients and are used as drugs should be prescribed only by dermatologists. It was pointed that this may not be possible in rural and semi-rural areas where dermatologists are not found, and hence, this suggestion that prominent instructions on the bottle and packaging of the drugs.

Recommendation 6. Suboptimal doses of medicines should be completely banned.

Suboptimal doses of derma drugs prescribed by non-dermatologists is quiet common. This results in resistance to such drugs.

Suboptimal doses of medicines, especially derma drugs, should therefore be completely banned.

Recommendation 7. Regulate / restrict inter-disciplinary practice of dermatology by doctors of other specialties. Define clearly the qualifications required to practice various disciplines of dermatology (cosmetology, trichology, cutaneous / dermato surgery, aesthesiology, laser surgery). Clarity is required on other disciplines of medicine / surgery overlapping with dermatology.

Dermatology / cosmetology practice is today lucrative and hence doctors from other disciplines are also proclaiming and practicing as such. Some doctors claim to be

cosmetologists merely by attending a conference of cosmetologists. Ophthalmologists, gynecologist, ENT surgeons, dental surgeons - all claim to be cosmetologists. Lack of well-defined privileging by the regulator is the root cause of this problem.

Plastic surgeons do cosmetic surgeries whereas hair transplant is done by dermatologists also. There are a few areas where expertise is clearly overlapping.

Inter-disciplinary practice should therefore be regulated. Procedures that can be done only by particular specialties must be well defined and demarcated and the others must be clearly excluded from performing the same. Clear definition and privileging of cosmetologist, trichologist, cutaneous/dermato surgeon, aesthesiologist, and laser surgeon is required.

One suggestion was that MCI should permit plastic surgeons trained in cosmetology to practice cosmetology and similarly dermatologists trained in plastic surgery could be permitted to perform hair transplant.

More clarity is also required in case of overlapping specialties.

Recommendation 8. Ban quackery.

Quackery is widely prevalent in India. Courts have held that non-allopaths practicing allopathy are quacks. Beauticians and parlours are openly using lasers and Botox.

Aayush doctors must be expressly banned from claiming to be dermatologists / cosmetologists. Regulations / clarifications are required for clinics of non-dermatologists employing qualified dermatologists in their panel and then claiming to be dermatologists / cosmetologists.

Recommendation 9. Senior dermatologists should be permitted to practice newer techniques / procedures after undergoing training programs conducted by their associations.

Today the basic curriculum prescribed by MCI for dermatologists includes all cosmetologist procedures. But this was not part of the curriculum a few years back.

Senior dermatologists therefore face legal issues in practicing newer techniques / procedures that were not part of their MCI prescribed curriculum when they qualified as dermatologists.

It was pointed that a few years back there was a global debate on who should be called as HIV specialist. It was decided that any doctor practicing HIV for two years as HIV specialist should be called as HIV specialist as more HIV specialists were needed at that point in time.

Guidelines should be framed for fellowships in newer techniques / procedures by respectable association. Training workshop organized by respectable associations for such doctors in newer techniques / procedures should be considered as acceptable.

Recommendation 10. Misleading / false advertisements, especially in dermatology should be regulated / curbed.

Wrong and inflated claims made by clinics / doctors is another area of concern. It is rather surprising that some homeopaths are openly advertising as cosmetologists and making tall claims. Are practitioners of homeopathy permitted to advertise in this country?

Advertisements on healthcare needs to be strictly regulated and strict action must be taken against those who are found violating the same.

One suggestion was that celebrities endorsing such clinics / treatment should be sued in court as there are recent judgments of higher courts holding celebrities personally liable for appearing in false / misleading advertisements.

Recommendation 11. Proper guidelines for tele-consultation and e-consultation should be framed.

Concerns were raised about the legality of the patients consulting doctors and / or sending photographs on mobiles and / or emails. It was pointed that tele / e-consultation is a grey area. Furthermore, concerns were raised whether only first consultation or even follow-up on mobiles / emails would fall under the grey area.

Laws should be made on tele-consultations / e-consultations at the earliest as its save time of both doctors and patients and in the need of the hour.

Recommendation 12. Regulations for doctors website and its content should be framed.

MCI should expressly permit doctors to have their own website having relevant information. A doctors website should not be considered as an advertisement. Testimonials from patients should not be permitted.

Recommendation 13. Regulations banning / regulating listing of doctors on web portals and e-commerce platforms such as Just dial is required.

Companies like Just Dial who advertise doctors and medical services pose a unique problem to the medical fraternity. On one hand they put the name of the doctor freely in their database without express permission of the doctor and on the other hand they promote homeopaths and doctors who pay them as the topmost dermatologist / cosmetologist. Furthermore, the database is shared / stolen / publicized by other such companies.

There is therefore an urgent need to regulate such companies / services.

One suggestion was that such companies should be sued in a court so that a clear message against this malpractice.

Recommendation 14. While allotting CME points to doctors the relevance of the topic / issue should also be taken into account rather than only taking the man-hours spent in the CME.

Break-away session - 4

Intensivists

Moderated By: *Adv. Yogendra Singh, Adv. R. J. Singh, Adv. Madhur Rai*

- **Living Wills / Advance Directives / DNR Instructions must be legally recognized.**
- **Statutory rules/regulations must be framed for informing the patient's family about end-of-life situations.**
- **Statutory guidelines are much needed for with-holding / withdrawing life-support.**
- **Law required to enable doctors to refuse treatment / admission in case of 'futility of care'. Valuable resources could thus be made available for more needy / treatable patients.**
- **Statutory prescribed "Treatment Refusal Form" from family members of an incompetent patient is required. Clarity needed in cases where there is a conflict of opinion amongst patient's family members about further treatment.**
- **Mandatory end-of-life committee / assessor in each hospital.**
- **More focus should be on palliative care.**
- **Privileging of intensivists must be defined and broadened preferably by their associations.**
- **Accreditation of ICUs by NABH/NABL.**
- **Cost of treatment of an abandoned terminally-ill patient should be taken care of by the government.**
- **Inclusions / exclusions in insurance care must be well defined.**
- **Clear demarcation / definition of right of physicians vis-à-vis right of hospitals.**
- **Uniform national law on assault on doctors/hospitals.**
- **Have one national law on healthcare issues rather than States framing their own laws. If this can be achieved for GST why not healthcare which is so very important?**

- **Courts need to be sensitized more on healthcare issues.**

Living Wills / Advance Directives / DNR Instructions must be legally recognized

Living Wills / Advance Directives / DNR Instructions of the patient are not legally valid in India. Furthermore, there are instances where the family of the patient direct that life-support must be withheld or withdrawn. Even the recent Terminally-ill patients Bill clearly prohibits any such directives coming from the patients.

Living Wills / Advance Directives / DNR Instructions must be legally permitted. The patient must have a right to state what procedures (CPR, ventilator, etc.) would be permitted or not permitted. The patient must have the right to appoint a surrogate decision-maker who will take appropriate decisions when the patient is unable to take such decisions. In the absence of the aforesaid, how must the doctor react to such demands made by the attendants / relatives must also be clearly defined.

Statutory rules/regulations must be framed for informing the patient's family about end-of-life situations

As a society, we don't want to talk about death. End-of-life decisions are usually taken over a period of time and not in one sitting. Furthermore, there is always a conflict between clinicians and administrators. Hospital administrators create problems when doctors discuss end-of-life issues with the patients relatives / attendants. Administrators state that DNR is not included in the hospital's policy and they do not want the doctor to speak about the same. Hence, statutory rules/regulations are required making it mandatory for the healthcare providers to inform the patient's family about end-of-life situations.

This will ensure that the clinicians don't face any opposition from the administrators, the relatives / attendants get the requisite information on time and can take appropriate decisions accordingly.

Another key recommendation was directed towards doctors. It was pointed that one common concern of relatives / attendants of such patients is - why were they not informed about this situation a few days back or on the day of admission and were

made to spend money unnecessarily. It was suggested that the doctors must counsel the attendants of such patients early rather than have a policy of wait-and-watch. Counseling the family helps. The family and attendants must be counseled to "let the patient die with dignity".

Statutory guidelines are much needed for with-holding / withdrawing life-support

Today, law is clear that withholding / withdrawing of life-support is illegal in India. But the ground realities are different. Doctors are practicing it. Even agencies like NABH are not clear on end-of-life issues and have failed to give requisite clarifications when the same is sought by healthcare providers. The Supreme Court's judgment in Aruna Shanbaug's case has created more confusion in the minds of the healthcare provider and further compounded the problem. Hence the need for statutory guidelines or a new law for withholding / withdrawing life-support.

The following factors must be taken into account by the policy makers:

- Facilitation of death (active / passive euthanasia) should not be mixed with postponement of death (end-of-life decisions).
- Cost has a big role to play in taking end-of-life decisions.
- A blanket permission to withhold / withdraw life-support has the potential of being misused by both doctors and relatives.
- Law needs to protect doctors as and when they take or facilitate such decisions.

One important recommendation was that the term "allowing natural death (AND)" must be used instead of terms like suicide, doctor-assisted suicide, euthanasia, etc.

Law required to enable doctors to refuse treatment / admission in case of 'futility of care'. Valuable resources could thus be made available for more needy / treatable patients

Patients who could be categorized under 'futility of care' pose a big problem to intensivists, especially two categories. First, ICU's in government hospitals that are usually flooded with such patients who are shifted from private hospital ICU's. Second, patients whose healthcare bill is paid by the government and their

attendants do not want to take such patients home as they may have to care and the treatment is free. This is resulting in other patients who genuinely need care being unable to get appropriate treatment.

It was pointed that laws in some other countries are so strict that treatment of such patients is not permitted even if the family insists. There are instances, where such patients are then brought to India.

Legal clarity is therefore needed in cases where the concern is about 'futility of care'. Healthcare providers must have the authority to refuse treatment or further treatment to such patients. There was consensus that it is difficult, rather impossible, to define objective parameters of 'futility of care'

Statutory prescribed "Treatment Refusal Form" from family members of an incompetent patient is required. Clarity needed in cases where there is a conflict of opinion amongst patient's family members about further treatment.

Doctors face problems when different relatives of an incompetent patient (unconscious, not oriented) come at different times and express different opinion, often conflicting, about the future course of treatment. For an intensivist, this situation turns into a nightmare, when a few relatives do not want to continue treatment with that doctor/hospital or at all while the others want to continue.

MCI or the government should therefore prescribe a "Treatment Refusal Form" from the family members of an incompetent patient. The other aspects of how and when should such a form be taken, by whom, and hierarchy of relatives competent to sign the form must also be specifically specified.

Mandatory end-of-life committee / assessor in each hospital.

Every hospital could have end-of-life assessors / committee very similar to transplant co-coordinators

More focus should be on palliative care.

Healthcare providers in India are not giving enough attention to palliative care. Hence, more focus is required on palliative care.

It was further recommended that every oncology department must have a palliative department/ward

Privileging of intensivists must be defined and broadened preferably by their associations.

Intensivists are often called upon and perform certain medical acts like performing ultrasound that are not strictly within their area of expertise but keeping in view the exigencies in intensive care they are invariably performed. Cost is also a factor that rather forces the intensivist to perform such acts.

MCI should clearly define and broaden the privileges of intensivists. Medical societies should also supplement the aforesaid by bringing out consensus guidelines at shorter intervals.

One important recommendation to intensivists was that whenever they are performing such acts a second opinion must be taken from the relevant specialty, as is the practice in US and other countries.

Accreditation of ICUs by NABH/NABL.

ICU's must be separately and specifically accredited by NABH / NABL.

Cost of treatment of an abandoned terminally-ill patient should be taken care of by the government.

Patients, especially terminally-ill are often abandoned. In all such cases, a mechanism should be evolved whereby the cost of treatment is taken care of by the government or government funded insurance.

Inclusions / exclusions in insurance care must be well defined.

We must define the boundaries of insurance care. Insurance does not pay for palliative care hence the relatives want the patient in ICU.

Clear demarcation / definition of right of physicians vis-à-vis right of hospitals.

A doctor is abused both from the government as well as the hospital administrator. Doctors practicing in corporate hospitals have intense pressure in cases where the patient can survive but are unable to pay. Where does the doctor stand in such a situation?

MCI or other policy makers need to clarify on this aspect.

Uniform national law on assault on doctors/hospitals.

Doctors often get assaulted when discussing with attendants of terminally-ill patient. Such incidents are more common in ICU's. Hence the need of a national law on violence against doctor

Break-away session - 5

Public Hospitals

Moderated By: *Adv. Pratiksha Mishra & Dr. Promod Kohli*

- In all cases involving government hospitals, the government alone should be held vicariously liable and if compensation is awarded, it should be paid by the government.
- All government hospitals must mandatorily have a Grievance Redressal Cell, with well-defined guidelines and it must be a mandatory pre-requisite for any patient seeking Redressal under CPA, to first file the complaint with this cell.
- Public hospitals must have a printed uniform information leaflet, specific for a disease / operation and consent form limited to one page, in a simple format.
- In cases of progressive or regressive disability, in case a certificate is demanded, this stage of the disability must be mentioned with the rider that the final disability certificate can be given later on re-assessment.

Issue 1. Removing Government Hospitals & Medical Colleges from the ambit of Consumer Protection Act

Issue 2. Redefining the vicarious liability of doctors / teachers in Government Hospitals & Medical Colleges

The judgment pronounced by the Supreme Court in the case of V. P. Shantha v/s Indian Medical Association brought even certain government hospitals within the purview of the Consumer Protection Act.

In view of the difficult working conditions in government hospitals, they should be brought out of the purview of the CPA. The difficulties relate to the shortcomings in the infrastructure, funds, manpower, work culture etc. which are often responsible for the deficiencies of service that happen in these hospitals. In the difficult work conditions, the performance & outcomes are likely to be sub-optimum.

On the other hand it was pointed that the aforesaid cannot be a justification for negligence / deficiency of service to the care seekers. The care seeker has a right to quality of care even from government hospitals as the tax payers (including the care seekers) are funding these organizations.

In the alternative and by consensus the following was suggested:

- a. Since government is the employer, and majority of deficiencies are related to hard & soft infrastructure and systems, in all cases involving government hospitals, the government alone should be held vicariously liable and if compensation is awarded, it should be paid by the government. The only exception could be if the patient is able to prove specific negligence on the part of the doctor, unrelated to the infrastructure factors.
- b. The government however would be free to take administrative departmental action after internal enquiry, to recover costs or take any other administrative action against the erring doctor, if desired.
- c. All government hospitals must mandatorily have a Grievance Redressal Cell, with well-defined guidelines and it must be a mandatory pre-requisite for any patient seeking Redressal under CPA, to first file the complaint with this cell. Many trivial issues are likely to get resolved in this cell itself. In case the matter is not resolved, the patient will be free to approach the consumer court
- d. For all medical negligence cases, screening should be done by an expert committee or there should be a credible expert opinion, from a doctor of the concerned specialty, before the complaint is admitted under CPA. This screening should be done at the admission stage itself.

Issue 3. Implementing the Supreme Court diktat in Samira Kohli case – simple consent forms needed

Public hospitals have unprecedented number of patients. Furthermore the level of literacy is low as they are usually from socially and economically backward sections. The Supreme Court has already laid down in the case of Samira Kohli v/s Dr. Prabha Manchanda that in India there is no need to take informed consent but only 'real' consent. It was suggested that the consent document could be split in 2 parts.

The first part should be an information leaflet, specific for a disease / operation. It must be given to a patient and asked to read, discuss & understand its contents. These leaflets can be prepared uniformly across the nation for all government hospitals. They may be prepared in different languages and may be coded for ease of use.

The second part should be consent form that should be limited to one page, in a simple format. Besides the patient data, it should indicate that the patient has read, discussed & understood the contents of the leaflet bearing a particular code number provided to the patient; had also discussed the details with his treating doctor and his team and is well aware about the nature of the disease / procedure; alternate options available with their pros & cons; expected benefits and potential risks; possibility of extension; modification or abandonment of the procedure; estimate of expenses; estimate of period of hospitalization; and period off work. It should be signed by the patient (if competent) and next of kin (if patient himself is incompetent) and by the treating doctor.

It was suggested that such leaflets & consent forms should be drafted & printed in a uniform manner, by NHM and supplied to different hospitals.

Issue 4. Need to frame statutory guidelines for giving Disability Certificates

At present, different protocols are being followed by different hospitals like ESIC, Railways, State / Central Government and so on. They should be made uniform. The PWD Act under the Ministry of Social Justice & Empowerment already has detailed guidelines, protocols and proformas and these are available on its official website. It was suggested that information about these guidelines should be disseminated effectively among the stakeholders and doctors. It was also discussed that the disability certificate is generally given for a permanent disability, marking the type & extent of the disability. In cases of progressive or regressive disability, in case a certificate is demanded, this stage of the disability must be mentioned with the rider that the final disability certificate can be given later on re-assessment.

Break-away session - 6

Emergency Medicine

in association with SOCIETY FOR EMERGENCY MEDICINE IN INDIA (SEMI)

Moderated By: *Adv. Shikha Dhandharia, Dr. Mukesh Yadav & Dr. Vivekanshu Verma*

- Need for a broad and comprehensive law for all kinds of child abuse wherein sexual abuse is only a part of the same.
- Awareness / sensitization / education of all stakeholders is needed at every level. Even law enforcers need to be sensitized. MCI should ensure that this law is taught comprehensively in MBBS.
- Mandatory screening of patients must be strictly enforced. There is need to have good evidence based screening tools. NABH should also come out with mandatory screening guidelines.
- A notification / circular by Child Welfare Committee (CWC) to all hospitals for mandatory reporting is required.
- Minor errors should be dealt leniently. Doctors should not land in jail for technical fault like delayed reporting. Doctors should be penalized only after internal enquiry.
- Categories of offence, their severity and respective punishment must be laid down.
- Format of reporting to police should be prescribed.
- Compulsion to involve female doctors should be removed till the time we have enough female doctors in emergency medicine.
- Provisions regarding penetration should be relooked.
- Need to have funding provisions to implement this law, especially in government hospitals.

Provisions in Indian Penal Code to deal with sexual abuse are present and were used earlier. POSCO came into existence as India signed international conventions and also because of our constitutional mandate and other national policies. Most

countries have comprehensive laws on child abuse. Has any change come by making this new law? One big problem with this statute is that it is not clear what it seeks to achieve - to improve detection, to improve the process of handling/treatment after detection, to improve rehabilitation of the sufferer or all.

POSCO deals with only sexual abuse of the child and not other forms of child abuse such as battered or exploited child. From the perspective of a doctor, especially the ones in emergency medicine, all instances of child abuse have to be dealt with and not only sexual abuse. Other forms of abuse can also become fatal. There is a need for a broad and comprehensive law for all kinds of child abuse and sexual abuse should only be a part of the same.

Awareness / sensitization / education of all stakeholders is needed at every level. It cannot be a one-time activity but continuous. For doctors, POSCO is not a priority as it is in the non-core area and therefore special efforts to make them aware is required. Sensitizing only doctors will be less beneficial, rather efforts should be to involve below doctor-level manpower. Even law enforcers need to be sensitized. This law is not part of the medical curriculum. MCI should ensure that it is taught comprehensively in MBBS.

There is need to have good evidence based screening tools, that can even be used by a non-skilled person to screen large number of patients at the entry level. Once mandatory screening of patients is enforced reporting will inevitably start. Some fine / action can be taken against hospital who do not screen. Furthermore, like JCI, NABH also should also come out with mandatory screening guidelines. Enforcing screening guidelines in non-accredited hospitals (90%) will even then remain a cause of concern.

Non-reporting happens to be an area of concern. It was pointed that doctors are not reporting because they are not aware of the law; do not have enough resources; are not convinced about the next step after detection; have doubts whether the police/family will co-operate; apprehend problems if the report is negative especially political interference; and preservation of evidence is a big problem. Apprehension of doctors of being called to the court too often was also cited as one of the reason for

poor reporting. A notification / circular by Child Welfare Committee (CWC) to all hospitals for mandatory reporting is required.

It was suggested that minor errors should be dealt leniently. The doctor has to prepare a 8-page report and for any technical fault the doctor should not land in jail like in the case of PCPNDT Act. It was pointed that apprehensions about getting arrested under the act was unfounded and the offence is non-cognizable. Better co-ordination is needed between doctors and law-enforcing agencies. Categories of offence, their severity and respective punishment must be laid down. Format of reporting to police is not prescribed. It was pointed that anyone, even a nurse can inform the police and the doctor's duty is to merely ensure that the information has reached police station.

Funding provisions to implement this law is absent, especially in government hospitals. There are 5 additional manpower required to implement this law but public hospitals are not able to depute even one. Hence, the need to create funding mechanism to make this law work.

Female doctors in emergency medicine are rare. It was therefore suggested that as of now the compulsion to involve female doctors should be removed till the time we have enough female doctors in emergency medicine.

There are other problems in POSCO. Majority of patients present themselves to GP's and not to hospitals. Doctors cannot disconnect the human side of medicine with law and hence humanitarian and social aspects have to be taken into consideration. Hospitals are refusing to accept such patients. Media visibility on POSCO is missing. Provisions regarding penetration are questionable and should be relooked. Social audit after reporting is necessary but again missing.

The culture of reporting adverse incidents is not present in India. Increase in reporting of such incidents must be perceived as a positive sign of POSCO working and not vice-versa. Public and government both have to become mature.

Plenary Session 1.

National Law for Ambulances – Need of the Hour

Key Note Speaker: *Dr. Mahesh Joshi*

- **We need a law on ambulances but as a part of a comprehensive Emergency Medical Services Act.**
- **The system should be regionalized; outcome and research driven, and accountability of the system must be ensured.**
- **Proper funding must be ensured as it is the key to sustenance**

Today, emergency medical services (EMS) in India are provided in isolation. Many agencies are involved in EMS such as ambulances, hospitals, community, law enforcing agencies, court, police, and accreditation agencies. Motor Vehicles Act, Clinical Establishment Act, NABH standards, MCI guidelines, Supreme Court guidelines, Good Samaritan Law, State Emergency Medical Services Acts, NGOs also have a role to play. It is important for all agencies, laws and guidelines to converge into emergency medical system and work towards a common goal. But this is not happening.

EMS is created to reduce mortality and morbidity in emergencies and should be judged by the number of morbidities that have been reduced. But only number of calls and response time are taken into account. No documentation of what care was given, who had given care, was the standard protocol followed, what was the outcome, is ever done.

Access to care, transportation, care during transportation, where does the patient reach at the end of transportation, how is the patient triaged / treated /disposed as transfer / transported to another facility / discharge are important aspects of EMS. Ambulance forms a very small chain. Ambulances should not be treated in isolation,

but linked and integrated with hospital-based care system, to get optimum results. Furthermore, EMS should not become only an ambulance transportation service.

A national law only on ambulance will therefore never suffice.

There must be sufficient funding otherwise EMS laws will fail. It was pointed that even EMTALA (US emergency law) which was meant to stop dumping of non-insurance patients to government hospitals failed and resulted in closing of more than 30% of emergency departments as there was no mechanism to reimburse the cost of treatment.

The other recommendations were that emergency care system must be regionalized for sustenance. EMS services should be driven by research. It was pointed that in the state of Andhra Pradesh ambulances services were started for road accident but are today used more often for deliveries and mortality in road accidents have not reduced.

Lastly, the government needs to be serious about EMS. It was pointed that most of the state ambulance services do not have an official position of Medical Director and are largely run by people who run logistics / operations.

Plenary Session 2.

MCI's guidelines for a doctor's website

Key Note Speaker: *Dr. Mahesh Joshi*

- **MCI should come out with clarification / regulation expressly permitting the doctors to have their own website.**

Doctors in India are hesitant to have their own websites fearing that this is contrary to MCI regulations. At times, this pushes patients towards quacks, as information about qualified doctors is not available on the web, the most commonly referred medium by one and all. Doctors need their own websites so that patients get relevant information when they need it.

A website should not be looked as a way of advertisement but as a medium of passing relevant information. MCI should therefore come out with clarification / regulation expressly permitting the doctors to have their own website.

Doctors could be permitted to post information on their websites regarding their qualification / expertise; time of meeting patients; patient appointments; geographical directions on how to reach; information on specialized services; instructions regarding common procedures performed by the doctor; pre/post procedure instructions; commonly asked questions from the patients; and so on.

It was pointed that recently the Bar Council of India has come out with guidelines permitting advocates to have their websites.

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 organized the first ever 'National Convention on Medicine & Law - 2015' (www.medicineandlawconvention.com), a platform to identify the legal issues relating to medicine, discuss them threadbare, and suggest remedial measures. Doctors, medical associations, hospitals, lawyers, judges, regulators, and policy makers were part of this initiative.

IML has been conducting an annual exercise of drafting and adopting a 'SOP on Patients Consent' (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.