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Indian Medico Legal
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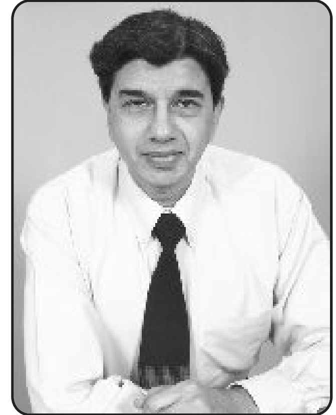
INDIAN MEDICO LEGAL & ETHICS ASSOCIATION

Aims & Objectives

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

From the Editor's Desk



Dear friends,

It brings me great joy to communicate with you through this inaugural issue of JIMLEA. With the increasing legal and ethical ramifications in medical practice it was imperative that a platform be created to address medico legal and ethical issues which today affect doctors so profoundly. IMLEA (Indian Medico Legal & Ethics Association) and its journal JIMLEA (Journal of Medico legal & Ethics Association) have been born at the most opportune time. Gone are the days when doctor patient relationship was one of complete trust. Today the scenario is so different; doctors complain that the society's expectations of their role override their altruistic capabilities while the society complains that doctors have changed .Many young doctors actually want to root out the word “noble” from their profession and want it to be like any other profession, giving them quality of life and monetary returns .There is another disturbing trend - increasing interference of Government agencies into medical institutions ;municipal authorities, labour department, Income tax, pollution department, health department, the list is long.... which disturb us doctors profoundly. In such turbulent times there is even more need to have focus on doctor patient relationship and communication skills.

Every new beginning has its own hurdles, but with patience and determination we will tide over them. There was immense support, encouragement, cooperation and guidance from various friends and colleagues throughout the country. I am especially thankful to President IMLEA Dr Satish Tiwari who envisioned this journal and gave all support to turn it into a reality ;and also to Dr Prabuddh Mittal, the executive editor who is an asset to our team. I am also thankful to Dr Charu Mittal, Dr Alka Kuthe, Dr Girish Kumthekar, Dr Nagendra Sardeshpande and the whole of editorial team.

I hope this journal will help doctors a lot ,to find information and solutions to legal and ethical issues in their practices, and share their experiences through dialogue .There are useful sections like case scenario and “Ask the Expert” to make the bulletin interactive . I sincerely hope this journal, with support from you all, will gain in relevance and popularity over time. With best wishes to all.

Dr Mukul Tiwari
MD,DCH,FIAP
Editor-in-Chief

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Dear Colleague,

Warm regards.

Please accept our heartiest season's greetings .The practice of medicine has changed drastically in the twenty first century. There have been much great advancement but, at the same time, there have also been many negative changes. The good age-old doctor-patient relationship has suffered and seems to be in dire straits. The communication skills have deteriorated. Commercialization is the obvious agenda ,especially with the emerging corporate culture in the health sector. The concept of privatization has added fuel to the fire. The patient who are willing to pay, feel that even life can be purchased with money. This has resulted in their soaring expectations. Doctors are not only affected by medico-legal cases but also many other legal problems arising out of other related issues of staff, instruments & infrastructure. The Government is coming up with newer and newer laws and restrictions on medical fraternity and hospitals. We have experienced this on many occasions which prompted us to form, along with likeminded colleagues & friends ,to form this medico-legal & ethics association.

In last few years we have encountered various medico legal problems, which as medical consultants / medico-legal experts, we have tried to solve are trying to solve, sometimes single handedly. It was then, that we realized the need of a fleet of experts to work in co-ordination. The association has thus been formed to help you in solving legal disasters in your practice. We hope that we will succeed in achieving the aims and objects of guiding the medical practitioners in their difficult times. The various membership benefits include:

1) Personal / individual professional indemnity cover of Rs.1 lac (Amount and terms decided by Executive Board) for up to five years is included (for cases after becoming member) in life membership fee.
2) Hospital insurance at concessional rate (as compared to other insurance / risk management companies).
3) Free medico-legal guidance in hours of crisis.
4) Services of crisis management committee at the city / district level.
5) Free expert opinion if there are cases in court of law.
6) Services of legal experts at concessional rates (wherever available).
7) Participation in academic activities related to medico-legal issues.

All this can't be achieved without the help of dedicated, hard working and sincere members of the association. Hence, we would like you to become the member of this association. We hope that with active & enthusiastic members like you, our association will attain greater heights as we progress further. Please send your constructive criticism, suggestions, and programs for the future.

Yours truly,

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DOCTOR PATIENT RELATIONSHIP IN CURRENT TIMES

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A good doctor patient relationship improves (1) treatment outcome, compliance with medical treatment, clinician satisfaction, patient satisfaction and reduces risk of malpractice suits .An unhappy patient is litigant patient. Doctor patient relationship, is not a new equation; it is age old, since times immemorial; only its forms have changed. It has come under much discussion in recent times since it started deteriorating ,became a big problem and doctors all over the world frantically tried to find answers to it. Doctor patient relationship has evolved over thousands of years, first as an art, then as science and now it is granted status of industry, but truly it will always remain a combination of all three.

Some medical specialties, such as psychiatry and family medicine need a good doctor-patient relationship more than others, such as pathology or radiology. The doctor-patient relationship forms one of the foundations of contemporary medical ethics. Most medical schools and universities in the developed countries teach their students from the beginning, even before their students set foot in hospitals, to maintain a professional rapport with patients, uphold patients' dignity, and respect their privacy but unfortunately; developing countries are slow in catching up in this trend.

What happened to the good old family doctor? The breed is now endangered species; vanishing fast. With the advancement in technology humanistic aspect of the medicine which used to be its hallmark is taking a back seat. There are questions unanswered; is the society asking too much from their doctors? Society expects its doctors to be noble and selfless beings but many strong trends are emerging which interfere with doctors' efforts to uphold that image.

Doctor patient relationship is deteriorating globally but doctors in India can heave a sigh of relief because the situation here is still not as bad as in Europe or USA where litigation happens at the drop of a hat. If we say that society is behaving vengefully or a huge global conspiracy is being plotted against the doctors then we would be like an ostrich who buries his head in the sand to avoid the reality .The writing is clear on the wall and we had better read it.; the relationship is changing and we have to change the way we deal with our patients. I hope most of the doctors have read the book "who moved my cheese". It teaches readers on how to cope with the changes in life. Those who have not read may procure it.

There is no need to be pessimistic on this issue .With some insight and understanding of the changing trends doctors can equip themselves to deal with the situation and evolve ways to improve the relationship. The doctor patient relationship can be not only improved, it can even become excellent .It is possible even today to practice competent and caring medicine while combining the use of science & technology.

Doctor Patient relationship is "fiduciary" (2)

The essence of doctor patient relationship can be summarized in the word "fiduciary" which is a Latin word meaning trust which is essential between doctor and patient to begin the process of healing. The patient-doctor relationship transcends ethnic, socio cultural and economic barriers. It is based on the trust and understanding that the doctor will put the needs of the patient first.

Models of doctor-patient relationship (3)

Traditionally many models have been suggested for doctor patient relationship .In 1951 Talcott Parsons, a social scientist , suggested that that amount of illness is controlled through socially prescribed roles for doctor and patients, which facilitate interaction and ensure that both parties work together to return people to a state of health and normal role performance as quickly as possible. His description of roles of doctor and patient is presented as an "ideal type" model.

Hippocratic Oath is the oldest and the first treatise written on this subject. Until the 1960s, the model of the physician-patient relationship was rooted in the Hippocratic Oath and tradition that condoned paternalism. The current emphasis on autonomy and distributive justice has changed the relationship to such extent that one might argue that the Oath has become irrelevant, specially the surgery part and abortion part.

Over the years it has been re-written and revised several times .Its major flaws are that it is doctor-centered and is silent about patient rights. Traditionally most of the medical schools around the world have subjected their students to Hippocratic oath but swearing by the Hippocratic Oath is not a rule .Many schools have other kinds of oaths as well.

American Medical Association codes was made prior to 1960 (3) .It is built mainly on the Hippocratic Oath; its flaw is that it is also silent about patient rights.

Paternalism in medical practice (4)

Both the Hippocratic Oath and the American Medical association codes prior to 1960 are paternalistic. The principles of beneficence and nonmaleficence take priority over principle of autonomy. The Doctor is a quasi-parent, he is benevolent, he always knows the best, the control he exercises over the patient is in the best interest of the patient, he is skilled and wise, and he is an authority not only in medicine but also in morality. The view about patient is that patient is a quasi-child, he is dependent, he is incapable of understanding complex medical information, he is incapable of making a wise choice concerning his health, and it is in his best interest to be left out of the decision-making process.

There have been many theories on doctor patient relationship, Talcott Parsons, in 1951 viewed the role of the doctor as complementary to the role of patient. There was Robert Veatch's model which did not gain much ground .Stewart and Roter model has found more popularity; it has four patterns-

Paternalistic - The paternalistic approach is typified by a doctor centered style. It relies on closed questions designed to elicit yes or no answers. The doctor will tend to use a disease centered model and be focused on reaching a diagnosis, rather than the patient's unique experience of illness.

Consumerist - Here the patient knows exactly what they want and forces the doctor into a patient centered approach.

Default - This is where the patient centered style fails. The doctor is trying to relinquish control but the patient is unwilling to accept it. The result is an impasse.

Mutuality - The doctor uses open questions to encourage the patient to talk about his complaint. This approach relies on taking time to listen and trying to understand the patients point of view.

Doctor and patient involvement in Stuart & Roter Model

Table-1

	PATIENT CONTROL		DOCTOR CONTROL	
	HIGH	LOW	HIGH	LOW
PATERNALISTIC		X	X	
CONSUMERISTIC	X			X
DEFAULT		X		X
MUTUALITY	X		X	

What has gone wrong?

Why Doctor Patient relationship is deteriorating?

1. ***Commercialization of medical education*** (5) **:** Medical education has become quite expensive and more so in private medical colleges. The graduates who come out after spending a heavy sum are less likely to view this profession as a noble one.
2. ***The society has become consumerist*** (6) **:** Money culture is prevailing over noble values such as sacrifice and honour. A doctor is a part of the society too. Still, doctors have to remember that once they have chosen this noble profession of their own free will they should avoid temptations of material gains and try to stick to morality and dignity of their profession.
3. ***Societal trends*** **:** It's a societal trend to treat medical service as just another paid service .The awe and respect have gone out. Patient is now a consumer and more assertive and aware of his rights.
4. ***Increased specialization and lack of primary care doctors*** **:** This problem is more in metro cities. Good old family doctor has vanished. Specialists and super-specialists can't give much time and personal touch to patients .Old practice of friendly family doctor was good and should be revived. A family doctor can also facilitate better understanding between patients and specialists.
5. ***Violent society*** **:** Because of increasing conflicts and tensions in the society, people are edgy and ready to fight at the smallest pretext. Violence is everywhere in the society. This tendency extends to all service providers including doctors.
6. ***Role of media*** (7) **:** Increased reports in media about

medical errors, the power of the drug industry and the flaws in health care administration is increasing public distrust of doctors. Also increased reports about violence and lawsuits against doctors, which encourage others to follow suit.

7. ***Professional rivalry*** **:** Giving negative feedback to patients about rival colleagues is a popular pastime among some doctors. This is also responsible for a decline in the feeling of respect for doctors.

8. ***Unethical and greedy attitudes*** **:** Such attitudes of some doctors tarnish the reputation of entire community and nurtures distrust against doctors in general.

9. ***Poor communication skills*** **:** Communication skills are very important buffers against lawsuits and violence. Whenever communication fails problems begin. Most doctors have been trained in a biomedical model and have little or no training from a bio psychosocial perspective. They often don't consider that how they communicate with patients is at least as important as what they communicate.

10. ***Lack of holistic attitude*** **:** doctors should not only be well equipped with the bio-medical aspects of patient care but also understand the psychological, social and cultural dimension of health and illness. Doctors often ignore theses aspects. A study of 21 doctors at an urban, university-based clinic found that when patients dropped emotional clues or talked openly about emotions and problems, the doctor seldom acknowledged their feelings. Instead the conversation was directed back to technical talk.

11. ***Changing face of health care*** (8) **:** There is a changing face of health care in the west ; managed care is increasing,. Doctors are forced to advise less than needed admissions, investigations and delay or restrict hospitalizations.

12. ***The E Patient*** (9) **:** IT has brought about a sea change in the doctor patient equation, especially in the west; but the trend is catching up in India also. Before this phenomenon, knowledge of medicine was doctor's domain; the patient's role was only to listen and comply. The Internet has opened up the floodgates of information. There are thousands of sites ready to offer information and not just basic information but to latest developments and different treatment options. The "informed" patient thus enters doctor's office with a load of information all of which may not be fitting to his case.

The relationship can be improved (10)

The wheel can be turned, with good intentions and some will power

- **Partnership is the new mantra:** Doctors may learn to get rid of old notions of paternalism and practice partnership. In this concept doctor and patient become partners and work together through dialogue and counselling to achieve maximum benefit for the patient and peace and happiness for the doctor. Relationships based on openness, trust and good communication will enable you to work in partnership with your patients to address their individual needs. To fulfil your role in the doctor-patient partnership you must be polite, considerate and honest, treat patients with dignity, treat each patient as an individual, respect patients' privacy and right to confidentiality, support patients in caring for themselves to improve and maintain their health, encourage patients who have knowledge about their condition to use this when they are making decisions about their care.
- **Communication skills are important:** Not only doctors but the entire staff should have lessons in communication skills. Maintain, at all times, dialogue with patients/relatives. Answer and satisfy their queries in clear, understandable language with lots of eye contact. Do not look confused, shaky or hiding facts. Check posture and body language. A fascinating study of time perception found that when doctors sat down during an office visit, the patients always thought the visit was longer than when the doctors remained standing, even though the length of both visits was exactly the same. Other simple gestures, such as leaning forward, have been found to help the patients relax, as well as improve satisfaction and recall.
- **Keep them posted:** Keep them informed about patient's condition, prognosis, and expected expenditure which may change from time to time, without exaggeration or understatement.
- **Show genuine concern:** Develop true empathy for your patients; falseness always shows through the skin. Today's patients will not accept the humiliating status of a "dysfunctional biological body".

- **Humour helps:** A well meaning humour immediately earns the good will of the patients and relatives. Use more humour in your workplace.
- **Know your limits:** Never attempt efforts to treat an illness which is beyond your level of expertise. In such cases always ask for a second opinion or refer to a Centre where the level of expertise is enough to deal effectively with illness.
- **Honesty pays:** Maintain transparency; patients always appreciate these qualities in a doctor, they are good buffers against hostile behaviour from patients and lawsuits.
- **Proper documentation:** Always maintain proper documentation of cases. Never try to manipulate the records.
- **Respect patients' narrative:** Rely on patients as experts in the experience of their own illness. Traditionally, doctors have viewed the patient as "an unreliable narrator" and to chart patient observations in subjective language that implies certain skepticism, such as "the patient believes" or "the patient denies." Rotter and Hall recommend that patient's unique knowledge about his illness is just as important to treatment outcome as the doctor's scientific knowledge. They conclude, "The medical visit is truly a meeting between experts."

How to improve your communication skills?

Hereunder are some tips on improving communications skills (11)

No medical jargon please: Talk to patient in clear understandable language he understands. Using lots of medical jargon may leave patient dissatisfied at the end of interview

Avoid distractions: Distractions which are too common in practices, have lots of disadvantages ,It breaks the tempo of a medical interview, makes you lose your focus and has a way of putting off your patients, who think you are not taking them seriously.

Practice flexibility: Do not be rigid in your approaches and be quick to think of alternatives, as long as patient safety is not compromised. You feel that giving injection will be a better choice but the patient will prefer syrup, here you have to make a quick change of treatment plan; allow syrup and if the patient does not improve you can give injection later on.

Read the body language: An intelligent doctor should be quick to read the mind and body language of a patient. Suppose patient is not satisfied with the treatment and is expecting a change of medicines; if you insist on continuing with the same treatment you may leave the patient dissatisfied and may even lose him. If you still feel your stand is right and medicines should not be changed then do counselling; he will understand.

Do not go by the clock: Don't keep the consultation period too short. Increased time with patients results in better treatment outcome ,better care, saves money spent on unnecessary interventions, prevents avoidable misdiagnosis, mistreatments, patient mis-understanding.

Avoid confrontations: Do not react to emotive words and do not pounce on the patient/relative whenever they utter hostile words. At all times be conciliatory (but not flattering or artificial)

Look and be genuinely concerned: Empathy is the keyword, showing sympathy may be counter-productive.

Do not dominate the interview: It is proven that when the doctor conducts interview while seated patient likes it better and estimates value of his visit higher than when the doctor conducts interview while standing.

No prejudices: You are just a doctor and the patient is just a patient, without any considerations for race, colour, religion, personal reason etc.

Take notes while conducting medical interview: It will give you a better insight of the patient's condition and give more interview satisfaction to patient

Ask for clarification: If in doubt ask for clarifications.

Other helpful techniques to improve your communication – nodding your head, using empathy and not sympathy, keeping an open body position, making encouraging statements, repeating a sentence or part of it of the patient.

What can patients do to improve the relationship?

The entire burden of improving the DPR should not lie on doctors alone .Patients can take a step forward to do their bit. Here are a few tips

- Learn how to tell your story: Tell your problems in a coherent manner instead of weaving a spider web and confusing the doctor. Many patients tend to start with interpretation, "I think I have bronchitis"

rather than plain facts, "I've been coughing for two weeks." Use concrete examples to explain how illness affects your daily life. For example, "I'm getting worse" is less helpful than "We've buying milk in quarts because I can't lift gallons anymore." Everyday details also help the doctor understand how the medical data translates into real life.

- Study your doctor's individual style. What are his/her likes and dislikes strengths and weaknesses? Optimistic or pessimistic? Intense or mellow? Organized or absent-minded? Cautious or a risk-taker? The more you understand how your doctor thinks, the more likely you'll know which approaches will work and which won't.
- Learn about your illness so you can ask the right questions and help make decisions. Patients who take an active role in their care do better and earn more respect from the doctor. Donald A.B. Lindberg, M.D., Director, National Library of Medicine, says "An informed patient is always the best, even though that puts more pressure on us to keep up to date".
- Accept realistic treatment goals. Many chronic diseases can be managed, but not cured. "In this age of hype, patients have come to expect the impossible, doctors frequently grope in the dark, not because they are delinquent in learning, but because the science does not reach there" says Lown, a renowned DPR analyst.
- Should make wise & informed decision about choosing his doctor or the hospital .Having done this, full trust and faith should be reposed in the doctor.
- Should provide full information about the illness, allergies, past illnesses, preferences for the kind of medication (syrup/tablets/capsules), family history and all the relevant social and family background.
- Should not hesitate to ask as much information as he wants and clarify the instructions without any hesitation.
- Report immediately in case of any adverse drug reactions or other adverse happenings.
- Should understand beforehand the risk involved in a procedure or operation.
- Should ask the doctor for any alternative or choice available. This is his right.
- Should know that medical science is a biological science and lots of decisions are made on the basis of experience and personal judgments. Even though the science has advanced many things cannot be still fully explained or predicted.
- Avoid shopping around with multiple doctors and alternative systems.
- Avoid believing in hearsay, rumours and not readily believe the facts printed in non-professional publications.
- Carefully read the consent for any procedure, try to understand its implications and ask for clarifications, it required.
- Should differentiate between a complication or mishap and negligence and not blame the doctor for everything that goes wrong.

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"MY EXPERIMENTS WITH TRUTH"

GUEST ARTICLE

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Incident

Our hospital Rainbow Women's Hospital was registered under PC PNDT act on date 23/1/2008. The expiry of which was on 23/1/2013 (After 5 years as per the act). We went to apply for renewal of registration on 24th December 2013. Which comes as 32 days prior to the date of expiry. (As per rule 8(1) PC PNDT one has to apply 30 days before the date of expiry)....but the appropriate authority in the office asked for some extra documents to be attached (as such some of those documents are not required to be attached) The next day being 25th Dec 2012 was a public holiday due to Christmas; we had to complete the formalities on 26th Dec 2012 as it required a notary and signatures of gazetted officer. We submitted the application on 27th Dec 2012 which was duly accepted & acknowledged by the appropriate Authority.

On 22nd Jan 2013 (1 day prior to expiry of registration) we inquired with the special officer in PNDT as to whether to continue doing sonography as our renewed certificate of application had yet not come. The officer correctly informed that we can do sonography as our application for renewal was under consideration.

On 6/2/2013, there was an advisory committee meeting of PCPNDT and our application was rejected as it was submitted delayed by a day hence the same Appropriate authority who accepted our application for renewal, along with two of his office staff came & directly sealed our sonography machine, without prior notice & the panchnama mentioned the reason as "Centre is running without valid registration as owner has failed to apply 30 days prior to the expiry of registration"

They also filed, as per their routine; a criminal case in JMFC court under PCPNDT Act though we have not yet received any summons from that court.

My Actions

I filed a writ petition in the Bombay high court challenging this impugned action.

Points in my favor

1. I myself being a medico-legal consultant knew all the provisions of PNDT Act more than appropriate authority or his lawyer.
2. I had mentioned all small important things in my initial averments in writ petition i.e. I went to municipality office on 24th December 2012 and I met medical officer or I called Dr. XYZ to ask may I continue doing sonography after 23rd Jan 2013?
3. According to Rule 8(3) PNDT Act the opportunity must be given to the person of being heard before deciding a case against him, which was not done in my case
4. In PNDT act there is no mention about the status of the centre after the expiry of the certificate, i.e if owner has applied for renewal and there is neither renewal nor rejection of his application till the expiry, what is he supposed to do? Can he continue doing sonography? Law abhors a vacuum. This important question was addressed in the order which I raised in my writ petition.
5. Appropriate Authority also did not follow the Rules as per PNDT Act i.e. they have to reject application of renewal in form C mentioning the reason for rejection and that too after hearing the applicant.
6. There was no other contravention under the PNDT Act.

Grounds as per my writ petition

The Petitioner submit that the impugned actions, notices and order of the Respondent are ex-facie illegal, arbitrary, ultra vires the provisions of PCPNDT Act, without any mandate or authority of law, unconstitutional, null and void abinitio and of no legal consequence for the following reasons:

i. Petitioner was having the registration under PC PNDT act for her centre

ii. The Respondent has failed to satisfy the basic requirement u/s 8 of PC-PNDT Rules.

iii. The petitioner was not given any opportunity of being heard or served any show cause notice at any point of time before sealing her machine.

iv. Sealing of the machine for reason "centre is running without valid registration. The owner has failed to apply 30 days prior to the expiry of registration "is unlawful as petitioner was in possession of the original registration certificate and so centre was not running without valid registration.

v. There can be no evidence of commission of offence which can be obtained from the Machine itself.

vi. Procedure for search and sealing is not in accordance of the law.

vii. The act of the respondent is without application of mind.

Final Order

21. Under Rule 8(5), it is only upon the receipt of the communication of the rejection of the application for renewal that an applicant is bound to surrender immediately to the Appropriate Authority, the certificate of registration. Thus, even assuming that the panchnama constituted a communication of the rejection as required by Rule 8(1), upto 6th February, 2013, the petitioner could not even be held / considered to have committed any offence at all. After that date, 6th February, 2013 the petitioner has admittedly not used the machine

22. Contention that during this twilight period viz. from the certificate of registration sought to be renewed is entitled to continue to operate on the basis of the existing certificate of registration. This is clear from the fact that the authorities are granted ninety days under Rule 8(6) to consider the application and it can hardly be suggested that their not deciding the same earlier disentitles the holder of a certificate of registration to operate under the certificate of registration sought to be renewed. The law abhors a vacuum. The respondents did not deny submission that in the case of an application for renewal of the registration under Rule 8, an applicant is entitled to continue to use the machine till an order of rejection under Rule 8(3) is communicated to him.

I had argued this in my writ and it was accepted by the court

24. Whether the petitioner's application for the renewal of the certificate of registration was, in fact, delayed by a day. We have come to the conclusion that the question must be answered in the negative, in favour of the petitioner

25. The petitioner had, in fact, submitted the application on 24th December, 2012. She has expressly stated the same in the petition. She has also mentioned the name of the officer to whom it was submitted. There is no denial of the same. The respondents have fairly not even denied that the said Dr. XXX was not authorized to receive the application. This is not a case of word against word. The application was, therefore, as a matter of fact, submitted in time. The petitioner cannot be penalized on account of her having been directed to re-submit the same along with certain other documents. The concerned authorities ought to have accepted the application and either granted the petitioner an opportunity of rectifying any deficiencies or rejected the same in accordance with law. They did neither. It would be a hyper-technical argument to state that the petitioner ought to have insisted upon leaving the application with the authorities and then returning the next day and rectifying the deficiencies. The petitioner's application was, therefore, filed in time.

My mentioning of the small incidence of going to municipality office in detail in my writ petition helped the court to conclude this.

26. There is no other ground for rejecting the application for renewal of the certificate of registration. In any event, no other ground has been communicated to the petitioner. The certificate of registration must, therefore, be

deemed to have been renewed in view of the provision of Rule 8.

When I filed writ petition on 13th March 2013, it was just 77th day from the day of my renewal application made on 27th December 2012. But on 27th March when it completed 90 days since application, I argued in the court for Deemed renewal under Rule 8(6), this was incorporated in the order by this way.

My mistakes

1. My machine was sealed on 6th Feb 2013 and I filed writ petition on 13th March 2013. Practically I wasted 37 days requesting various people and authorities to help me and get me out of this problem. I was under wrong impression that machine can be de-sealed in such genuine cases without an order from the court
2. I did not take anything in writing from the authorities i.e. when I went on 24th December 2013 to BMC I should have taken stamp on the application. Even I should have inquired in writing that can I do sonography after the expiry of my certificate, when my application for renewal is pending. But I put all these on affidavit and court believed in my statements as there was no denial from the government.

Conclusion:

- Never give up when you are right and your case is genuine
- Trust our courts because many of our judges are very intelligent and considerate if it's a genuine case
- This judgment will serve as precedence for others
- Our associations are willing to help but there is no system to help a member except sympathy and morale boosting, that is why many members feel that associations are not doing anything for the members in such situation. We must make some system in the association to raise the voice against the harassment of our member(s) by way of statement in media or news or strike etc...I am not sure about this suggestion about plan of action but one thing is sure from my end that there has to be some system and plan of action in place for such cases.

Model Consent Form for Vaccination

Consent for Vaccination

(These forms are to be printed/filled in local/vernacular language)

I/We have been informed about ______________ vaccine available for the immunization of my/our child. I/We have also been explained about advantages and side effects or complications occurring after the vaccination. We have been told that after vaccination the protection from the disease will be good but may not be absolute. We have also been informed about the cost of the vaccine.

I/We have been explained all these in the language known to me/us and I/we are signing this form without any pressure/coercion and after satisfying my/our queries and doubts.

Name of the Patient — Age — Sex

Name of the Relative

Relationship — Signature of the relative if subject is minor

Date & time

Place — Signature of the subject taking vaccine

LEGAL AND ETHICAL ISSUES IN MEDICAL EDUCATION

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It has now been accepted that there is “Holistic or Spiritual component” in the health of an individual. It includes integrity, ethics, the purpose in life and commitment to some higher being. The recent industrialization, commercialization and globalization have had their effect on medical education also. Though the technical and scientific developments have resulted in many positive changes: like decrease in mortality/morbidity rates, increased longevity, better quality of life etc. yet at the same time it has some negative as well as ill-effects also. There is mal-distribution of rural-urban health care providers, decrease in moral values, corporate culture in health care services and of course decreasing standards and commercialization of medical education.

Privatization of Medical Education

The mushrooming of private medical colleges and Deemed Universities has added fuel to the fire. Inconsistencies in the cases of many deemed universities is too evident to be overlooked. The myth that private institutions have better facilities has also been disproved. They often use their clout to flout norms and unfairly profit from the business of higher education. (1) These private medical schools are run by managing committees, which are under the influence of political heavyweight personalities. These politicians form the backbone of these institutions whose aim is only to mint money at any cost. Unfortunately, ethical considerations are often of least importance in such institutions. You can't only buy an undergraduate seat but also a postgraduate degree. (2) The medical education has been made a commodity for the rich. The private managements are not only fooling the students, their parents but also the government, judiciary and regulatory bodies.

The Medical Council Regulations

The Medical Council of India was constituted under the Medical Council Act 1956, in order to regulate the standard of medical education in India. But, it has been observed that the Council has failed badly in its role. During discussions it was thought that one of the reasons for this is the outdated regulations and ethics by Medical Council of India (MCI).

According to chapter, 1.4.2 Physicians shall display as suffix to their names only recognized medical degrees or such certificates/diplomas and memberships/honors which confer professional knowledge or recognizes any exemplary qualification/achievements. This regulation is very ambiguous because the word “or” for the certificates/ diplomas and honors etc doesn't apply to MCI recognized achievements only. Similarly, according to chapter 7.20 A Physician shall not claim to be specialist unless he has a special qualification in that branch. (3) Here again the regulations are ambiguous regarding whether the qualifications should be MCI recognized or any qualifications. The effect of these ambiguous regulations or guidelines is that there are many organizations, institutes or bodies who are running unrecognized courses and cheating the students, parents, peoples and the communities. The State Medical Councils which were formed to look in the matters of state wise registration of medical graduates are recognizing such (MCI unrecognized) qualifications for practicing in a particular state only. This is not only creating a confusion in the minds of medical graduates, but it also raises the very vital issue regarding the powers of the various councils as far as regulation of medical education is concerned. There is need to tackle this paradox since MCI is the highest body as far as regulation of medical education is concerned. Hence, if MCI doesn't recognize a particular course or qualification, the various state medical councils can't over rule these MCI guidelines and recognize these courses in their respective states. If a proper decision in not taken on this issue, it will create a chaos in the future because in India we have more than thirty states and each and every state can frame their own guidelines and regulations for medical education in their respective states. So, there

has to be a highest regulatory body whose decision shall prevail in case any controversy or ambiguity arises.

Role of Regulatory Bodies

As discussed earlier, the regulatory bodies like medical and dental councils have been formed with the aim of regulating the medical education and practice of medicine in different systems. Various private medical colleges mushroomed all over India defying all the prescribed MCI norms. Many institutions are conferring unrecognized degrees, diplomas, certificates etc. and thus cheating the highest regulatory body of India. Cheating of Medical Councils has become a norm rather than exception. The unethical practice is ignored and guilty doctors remain undetected and unpunished by otherwise highly qualified, resourceful and powerful medical bodies.

The Present Scenario

The medical education system has totally failed on cost-effective and input-output analysis. These industries can produce only commercially sound but morally weak graduates. They will produce doctors for the classes and not for the masses. Our health system needs “Barefoot doctors” (as experimented in China) who will serve the masses and not the classes (4).The emphasis is changing from health care for the people to health care by the people.

The teaching faculties in private institutions are mostly part-time, 'daily wage earners', fixed salaried, 'transient teachers' who are often sub-standard and frustrated individuals willing to 'sort things out' as per the need of the management. Most of the teachers in clinical specialties who have well-established private practices, hardly find time to teach. Serious teaching and research have been affected badly. The few who are enthusiastic are disheartened by uncongenial atmosphere. Associated with this, the commercialization of medical education has further deteriorated the already “rotten system”. Money can buy marks and merit but not the sincerity and morality. The important issue is whether the higher education shall be the right of a citizen? Should Government nationalize and act as a watch-guard in controlling the corruption and financial mismanagement in running the private institutions of “political heavy-weights”? Are we going to produce ethically and morally motivated graduates from these “Money spinning educational factories”? The long felt need is that the Government should enact a legislation to provide equal opportunities for higher/professional education to the poorest of the poor citizens.

Time for “Gurukul Medical Education”

The big hospitals exist in splendid isolation in the community, acquiring the euphemism “an ivory tower of diseases”. There is no doubt that we have to accept the development and advances in medical sciences so as to improve the health and quality of the life of an individual and the nation. Medicine will continue to evolve so long as man's quest for better health continues. But the important issue that arises is that, should we continue with commercialization of medical education? Or should we go back to simplified and basic methods of teaching medical sciences? Should there be centralization of medical education and that too in the hands of capitalists or the process should be decentralized in the benefit of common layman in the community. This is the time to review our errors and accomplishments. Can this be included in “Millennium development goals”? The government of India along with Medical Council of India is planning to start medical colleges to educate rural students and deploy them there to provide basic health care to villagers (5). Many villagers rely on indigenous systems of medicine. The doctors taught in villages or small towns (Taluka places) might prefer to work in that area following the footsteps of their “Guru”. Thus it can solve the problem of mal-distribution of doctors in remote areas. This means that technical advances in health services are not going to fulfill the dreams of Indian population as well. We are going to provide services to classes at the expense of masses. This trend can't be cost-effective in developing countries like India. What we need is health care for the people that too preferably by the people. This can be achieved only if we have more health care personnel (including qualified medical graduates) catering to the needs of community including rural community.

There are many good academicians who are engaged in private practice. Because of their busy schedule,

they are unable to keep pace with technical advances in medical sciences. Teaching liabilities may encourage them to update their knowledge by reading and attending CME, Workshops and Panel discussions etc. There is no paucity of good, morally strong medical teachers (Gurus) even in present era. In fact, the postgraduate medical education is completed under a guide (Guru) (6). Then, what is the harm if, undergraduate candidates are also taught by the Guru? Why we should not allow them to select the shishya from the community and train them for this noble profession? Can Indian method of Gurukul teaching solve this problem of commercialization? The graduates taught in Gurukul can be examined, evaluated by an authorized agency (as we are doing for undergraduate students from overseas universities) and subsequently trained for latest advances in medical sciences at specialty hospitals (Government or Corporate) with minimum expenses and as per the need. In this manner, there are more chances of producing morally strong and educationally qualified graduates. Thus we can achieve the concept of "health care for the people and health care by the people".

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BRAIN DEATH CRITERIA

Brain Death is a clinical diagnosis which can be made when there is complete and irreversible cessation of all brain function. Since it is now technically possible to sustain cardiac, circulatory respiratory and other organ function after the brain has ceased to be alive, a diagnosis of brain death can be made before the heart beat stops.

The diagnosis of brain death is based primarily on clinical criteria. A confirmatory laboratory test may be done to supplement the clinical diagnosis.

An individual with irreversible cessation of all brain function, including the brain stem, is dead.

PREREQUISITES

The presence of sedative drugs, hypothermia, shock, or other potentially reversible conditions that may depress brain function must be excluded for these clinical criteria to be valid:

1. Body temperature must be 32.2 degree (90 degree F) or higher.
2. If barbiturates are present in the blood, or were used therapeutically for control of intracranial pressure or seizures, serum levels should not exceed 1 mg % at the time of the clinical examination.
3. Screen to exclude other sedative drugs-where clinically indicated.
4. Absence of severe hypotension (shock).

CLINICAL CRITERIA

The clinical examination should be done by a neurologist, neurosurgeon, or critical care attending who is familiar with the neurological examination and with these criteria:

1. Coma with cerebral unresponsitivity
2. Apnea
3. Absent brain stem reflexes
4. Persistence of condition for 6 to 24 hours
5. Confirmatory Tests for Determination of Brain Death

Although confirmatory tests are not mandatory in most situations, additional testing may be necessary for declaring brain death in patients in whom the results of specific components of clinical testing cannot be reliably evaluated. Clinical experience with confirmatory tests other than conventional angiography, electro-encephalography, and transcranial Doppler sonography is limited. Research involving use of confirmatory tests for determination of brain death is constrained by lack of blinded evaluation, absence of interobserver reliability data, and sparse use of control groups.

SURROGACY: LEGAL AND ETHICAL ISSUES

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Traditionally, being blessed with a child is regarded by many as the ultimate happiness in life. Sharing love and raising a family make their life complete. Unfortunately, for many it remains a dream. The inability to have children can be traumatic and extremely painful for them and their future plans. Around ten to fifteen percent of married couples are unable to have children and because of ever-rising prevalence of infertility world over, this has led to advancement of assisted reproductive techniques (ART). No doubt assisted reproduction is a great scientific achievement. But the ethical and legal repercussions of these techniques are always debatable issues. Various cultural, religious and economic diversities in the society make the problem more complex. The ethical dilemma is faced by doctor, couple, donor, child, society and the whole country. Among the many applications of the new reproductive technologies; surrogate motherhood has such far reaching consequences. It has been hotly debated in courts and legislatures. In the name of surrogacy, many irregularities are being committed, a money making racket is perpetuated. What distinguishes surrogacy from other reproductive technologies is not the technology itself but the circumstances of its application—an arrangement whereby one woman bears a child for another, with the intent of relinquishing the infant at birth. When infertile woman or couple is not able to reproduce, surrogacy comes as an alternative remedy. It refers to a contract in which a woman carries a pregnancy “for” another couple. By signing the contract, the infertile couples and individuals can have the children they desire, with genetic pool from one or both parents.

Surrogacy dates back to biblical times. An interesting biblical scenario is the story of Sarah, the wife of Abraham. Sarah could not have children in the beginning. She gave her handmaid, Hagar, to her husband, Abraham to produce them a child. The method used was copulation. The outcome of this arrangement did not prove to be a productive one and ended in a disaster. In this scenario the spouse became jealous, the surrogate became proud and refused to give the identity of the child and consequently the spouse had both her and her child ousted.(1)

The surrogate arrangement is most often made between a couple (where the wife is infertile) and a “surrogate”; in the contract signed by both parties. The surrogate agrees to be artificially inseminated with the infertile woman's husband's sperm, to bear a child, and at birth to give up all parental rights and transfer physical custody of the child to the “commissioning couple.” Although superficially, this arrangement appears to be beneficial for all parties concerned, there are, a number of moral and ethical issues regarding surrogacy, which has become more of a commercial racket, and there is an urgent need for framing and implementation of laws for the parents and the surrogate mother.(2) Monetary compensation may or may not be involved in surrogacy arrangements.(3)

Distinction between Commercial and Altruistic surrogacy:

Commercial Surrogacy **–** Surrogacy arrangements which involve financial reward. If the surrogate receives compensation beyond the reimbursement of medical and other reasonable expenses, the arrangement is called commercial surrogacy;

Altruistic Surrogacy **–** Surrogacy arrangements entered into between family members or friends for altruistic reasons without monetary transaction.

The commercial surrogacy in some jurisdictions is a crime and couples entering into commercial arrangements will be liable for criminal sanctions, while in others they will not.

Commercial Surrogacy in India:

Number of infertile couples from all over the World approach India where commercial surrogacy is legal since 2002.(4) It is also legal in Ukraine, and

California while it is illegal in England, many states of United States, and in Australia, which recognize only altruistic surrogacy. In contrast, countries like Germany, Sweden, Norway, and Italy do not recognize any surrogacy agreements. India has become a favorite destination of fertility tourism.(5) Each year, couples from abroad are attracted to India by so-called surrogacy agencies because cost of the whole procedure in India is much less as compared to what it is in United States and United Kingdom. The Home Ministry in January 2013 enacted discriminatory rules banning gays and singles of either sex from surrogacy in India.

Commercial Surrogacy and Indian Culture

Although Commercial surrogacy has been legalized in India it is a burning question that how far such legalization has been accepted by Indian culture? In India, surrogate mothers face high levels of social stigma. Many times the surrogate mothers who are generally poor women are treated as disposable bio-medias. In addition, many Indians link surrogacy with commercial sex-work and this comparison further stigmatizes the surrogate women. Many surrogates in lieu of secrecy spend the entire duration of pregnancy in surrogate hostels, segregated from their families and society. Culturally reproduction is acceptable only within marriage. Therefore child bearing for financial gain may be seen as 'dirty work', 'baby-selling' or 'womb-renting/selling'.(6) There are number of legal, ethical, emotional, social and medical issues that are associated with the concept of surrogacy with one key issue being the legality of the surrogacy process, which varies a great deal from one country to another.

Legal issues

Artificial Insemination Donor (AID) and In- Vitro Fertilization (IVF) have made it possible to have a child in another mother's womb when the intended couples/individuals are unable to conceive and/or carry a child on their own in the natural manner. Even a lady without a uterus but with functioning ovaries may have her child with the help of a surrogate mother. But this technique raises series of controversies depending on legitimacy of motherhood in the eyes of law. According to the Fertilization Act 1990, UK, the carrying mother is the mother in law (7). Genetic mother can get legal parenthood only by legal procedures. Apart from this, the legal aspects of surrogacy in any particular jurisdiction tend to accord following controversial issues (3).

- Are surrogacy agreements enforceable, void, or prohibited?
- Does it make a difference whether the surrogate mother is paid (commercial) or simply reimbursed for expenses (altruistic)?
- What, if any, difference does it make whether the surrogacy is traditional or gestational?
- Is there an alternative to post-birth adoption for the recognition of the intended parents as the legal parents, either before or after the birth?
- Who would be the parents if the resultant pregnancy happens to be malformed child?
- Whether the jurisdiction of the country would allow termination of pregnancy if it causes physical, mental trauma to surrogate mother?
- If the arrangements fall foul, will it amount to adultery?

Although laws differ widely from one jurisdiction to another, some generalizations are possible (3).

1) The historical legal assumption has been that the woman giving birth to a child is that child's legal mother, and the only way for another woman to be recognized as the mother is through adoption. Even in jurisdictions that do not recognize surrogacy arrangements, if the genetic parents and the surrogate mother proceed without any intervention from the government and have no changes in decisions by both parties, they will likely be able to achieve the effects of surrogacy by having the surrogate mother give birth and then give the child up for private adoption to the intended parents.
2) Even jurisdictions that do not prohibit surrogacy may rule that surrogacy contracts (commercial, altruistic, or both) are void. If the contract is either prohibited or void, then there is no recourse if party to the agreement has a change of heart. If a

surrogate changes her mind and decides to keep the child, the intended mother has no claim to the child even if it is her genetic offspring, and they cannot get back any money they may have paid or reimbursed to the surrogate; If the intended parents change their mind and do not want the child after all, the surrogate cannot get any reimbursement for expenses, or any promised payment, and she will be left with legal custody of the child.

3) Jurisdictions that permit surrogacy sometimes offer a way for the intended mother, especially if she is also the genetic mother, to be recognized as the legal mother without going through the process of abandonment and adoption. Most jurisdictions only provide for a post-birth order, often out of an unwillingness to force the surrogate mother to give up parental rights if she changes her mind after the birth.

4) A few jurisdictions do provide for pre-birth orders, generally only in cases when the surrogate mother is not genetically related to the expected child. Some jurisdictions impose other requirements in order to issue birth orders, for example, that the intended parents should be heterosexual and married to one another.

International Surrogacy involves bilateral issues, where the laws of both the nations have to be at par/uniformity else the concerns and interests of parties involved will remain unresolved and thus, giving due regard to the concerns and in order to prevent the commercialization of the Human Reproductive system, exploitation of women and the commodification of children, the law commission has submitted its report with the relevant suggestions.

Indian Council for Medical Research (ICMR) Guidelines:

The ICMR has given Guidelines in the year 2005 regulating Assisted Reproductive Technology procedures. The Law Commission of India has submitted the 228th Report on "need for legislation to regulate assisted reproductive technology clinics as well as rights and obligations of parties to a surrogacy." The following observations had been made by the Law Commission.(4)

a. Surrogacy arrangement will continue to be governed by contract amongst parties, which will contain all the terms requiring consent of surrogate mother to bear child, agreement of her husband and other family members for the same, medical procedures of artificial insemination, reimbursement of all reasonable expenses for carrying child to full term, willingness to hand over the child born to the commissioning parent(s) etc. But such an arrangement should not be for commercial purposes.

b. A surrogacy arrangement should provide for financial support for surrogate child in the event of death of the commissioning couple or individual before delivery of the child, or divorce between the intended parents and subsequent willingness of none to take delivery of the child.

c. One of the intended parents should be a donor as well, because the bond of love and affection with a child primarily emanates from biological relationship. Also, the chances of various kinds of child-abuse, which have been noticed in cases of adoptions, will be reduced. In case the intended parent is single, he or she should be a donor to be able to have a surrogate child. Otherwise, adoption is the way to have a child which is resorted to if biological (natural) parents and adoptive parents are different.

d. Legislation itself should recognize a surrogate child to be the legitimate child of the commissioning parent(s) without there being any need for adoption or even declaration of guardian.

e. The birth certificate of the surrogate child should contain the name(s) of the commissioning parent(s) only.

f. Right to privacy of donor as well as surrogate mother should be protected.

g. Sex-selective surrogacy should be prohibited. (8)

The Law Commission has strongly recommended against Commercial Surrogacy. However, this was a great step forward with an expectation of legislation to come by early 2011 with the passing of the ART Bill aiming to regulate the surrogacy business as discussed below.

Giving due respect to Apex Court directions, the Assisted Reproductive Technology (Regulation) Bill 2008 enacted by the Parliament in the 58th year of Republic Of India (9) in its Chapter VI mentions about regulation of research on embryo and includes permission of ICMR for research. Chapter VII, Section 34 mentions Rights & Duties in relation to surrogacy as follows:

1. Both the couple or individual seeking surrogacy through the use of ART, and the surrogate mother shall enter in to surrogacy agreement which shall be legally enforceable.

2. All expenses, including those related to insurance, of the surrogate related to pregnancy achieved in furtherance of ART shall, during the period of pregnancy and after delivery as per medical advice, and till the child is ready to be delivered, to the biological parent or parents, shall be borne by the couple or individual seeking surrogacy.

3. Notwithstanding anything contained in sub-section (2) of this section and subject to the surrogacy agreement, the surrogate mother may also receive compensation from the couple or individual, as the case may be, for agreeing to act as such surrogate.

4. A surrogate mother shall relinquish all parental rights over the child.

5. No woman < 21 years of age and > 45 years of age shall be eligible to act as a surrogate mother under this Act, provided that no woman shall act as a surrogate for more than 3 successful live births in her life.

6. Any woman seeking or agreeing to act as a surrogate mother shall be medically tested for such diseases, sexually transmitted or otherwise, as may be prescribed, and all communicable diseases which may endanger the health of the child, and must declare in writing that she has not undergone intravenous medical treatment or received a blood transfusion.

7. A surrogate mother shall, in respect of all medical treatments or procedures in relation to concerned child registered at a hospital or such medical facility in her own name, clearly declare herself to a surrogate mother, and provide a name or names and addresses of the person or persons as the case may be, for whom she is acting as a surrogate, along with the copy of the certificate mentioned in clause 17 below.

8. No surrogate mother shall undergo embryo transfer more than three times for the same couple.

9. The birth certificate shall bear the name(s) of the genetic parents/parent of the baby.

10. The person or persons who have availed of the services of surrogate mother shall be legally bound to accept the custody of the child/children irrespective of any abnormality that the child/children may have, and the refusal to do so shall constitute an offence under this Act.

11. Subject to the provisions of this Act, all information about the surrogate shall be kept confidential and shall not be disclosed to anyone other than the Central Data Base of the Indian Council of Medical Research, except by an order of a Court of competent jurisdiction.

12. A foreigner or foreign couple not resident in India, or a non- resident Indian individual or couple/ seeking surrogacy in India shall appoint a local guardian who will be legally responsible for taking care of the surrogate during and after the pregnancy as per clause 34.2, till the child/children are delivered to the foreigner or foreign couple or the local guardian. Further, the party seeking the surrogacy must ensure and establish to the ART Clinic through proper documentation that the party would be able to take the child/ children born through surrogacy, including where the embryo was a consequence of donation of an oocyte or sperm, outside of India to the country of the party's origin or residence as the case may be.

13. A couple shall not have simultaneous transfer of embryos in the woman and in a surrogate.

Chapter VIII mentions about offences and penalties. His/ her name will be removed from the register or the Council for a period of two years for the first offence and permanently for any subsequent offence. The bill is still pending with Government and has not been

presented in the Parliament. The proposed law has taken consideration of various aspects including interests of intended parents and surrogate mothers. The proposed draft needs to be properly discussed, and its ethical and moral aspect should be widely debated by social, legal, medical personnel, and the society before any law is framed.

Case Laws

In Jan Balaz v Union of India, the Gujarat High Court conferred Indian citizenship on twin babies fathered through compensated surrogacy by a German national in Anand district. The court considered the surrogacy laws of countries like Ukraine, Japan, and the United States. Because India does not offer dual citizenship, the children will have to convert to Overseas Citizenship of India if they also hold non-Indian citizenship. The case is still pending on appeal before the Supreme Court of India.

In Israeli gay couple's case JT 2008 (11) SC 150, the gay couple Yonathan and Omer could not in Israel adopt or have a surrogate mother. They came to Mumbai. Yonathan donated his sperm. They selected a surrogate. Baby Evyatar was born. The gay couple took son Evyatar to Israel. Israeli government had required them to do a DNA test to prove their paternity before the baby's passport and other documents were prepared.

In Baby Manji Yamada vs Union of India & Anr. 29 September, 2008 SC, the case is concerned with production/custody of a child. The Supreme Court of India in this Japanese Baby's case in 2008 has held that commercial surrogacy is permitted in India with a direction to the Legislature to pass an appropriate Law governing surrogacy in India.(4) At present the Surrogacy Contract between the parties and the Assisted Reproductive Technique (ART) Clinics guidelines are the guiding forces. The law commission of India has specifically reviewed the Surrogacy Law keeping in mind that India is an International Surrogacy destination.

Ethical Issues

Although in 2005, ICMR issued guidelines for accreditation, supervision, and regulation of ART clinics in India, these guidelines are repeatedly violated.(10) Frustration of cross border childless couples is easily understandable who not only have to cope up with language barrier, but sometimes have to fight a long legal battle to get their child. Even if everything goes well, they have to stay in India for 2-3 months for completion of formalities after the birth of baby. The cross border surrogacy leads to problems in citizenship, nationality, motherhood, parentage, and rights of a child. There are occasions where children are denied nationality of the country of intended parents and this results in either a long legal battle like in case of the German couple with twin surrogate children or the Israeli gay couple who had to undergo DNA testing to establish parentage or have a bleak future in orphanage for the child. There are also a number of ethical issues that are or should be considered by the biological parent or parents and the surrogate mother prior to initiating the process in addition to ensure legal procedure.(3)

- To what extent should we be concerned about exploitation, commodification, and/or coercion when women are paid to be pregnant and deliver babies?
- To what extent is it right for society to permit women to make contracts about the use of their bodies? To what extent is it a woman's human right to make contracts regarding the use of her body? Is contracting for surrogacy more like contracting for employment/ labor, or more like contracting for prostitution, or more like contracting for slavery? Which, if any, of these kinds of contracts should be enforceable? Should the state be able to force a woman to carry out "specific performance" of her contract if that requires her to give birth to an embryo she would like to abort, or to abort an embryo she would like to carry to term?
- What does motherhood mean? What is the relationship between genetic motherhood, gestational motherhood, and social motherhood? Is it possible to socially or legally conceive of multiple modes of motherhood and/or the recognition of multiple mothers?
- Should a child born via surrogacy have the right to know the identity of any/all of the people involved in that child's conception and delivery?

- Commercial surrogacy agency is ethically condemned.
- Effect on the offspring who is deliberately put in such a situation needs further evaluation.

Some highly controversial and key ethical issues need to be discussed:

- Attachment & involvement with the Gestational Mother – In a surrogate situation, the gestational mother needs to physically and emotionally detach herself from the child once it is born. This can be a very taxing process both physically and emotionally. She will not likely be the child's primary caretaker. Then a legal question that arises in terms of what – if any – involvement she will have with the child once born.
- Identity of the Child – There are also ethical considerations in terms of informing the child of his or her surrogate mother, as doing so may have an effect on the child's self-identity.
- In addition to the above issues, there is also the factor of surrogate mother compensation. It is typically expected that the intended parents of the child will reimburse the surrogate mother for her medical and other related expenses. This can be too expensive for an economically poor infertile couple. It means that the surrogate technology is a remedy for rich people and not for common man.
- Surrogacy could be thought of as being a luxury whereby the intended parents will pay a fee to the surrogate mother for carrying their baby and in some cases it could even be thought of as pregnancy-for-hire.(11)

The Indian movie in Marathi language, which was released few years back, titled as “Mala Aai Vhayachay” (“I Want to Be a Mother”), brings to the surface several cultural, social, ethical, economic, and professional social work issues.(12)

In the future, commercial surrogacy in India can take one of four paths. It can continue to exist in a loosely regulated environment. The Indian government can pass laws to regulate the industry, requiring a central registry of surrogate women and intended parents, creating minimum payments for surrogates, and creating agencies to inspect and help maintain a quality standard of care. Furthermore, this regulation should also provide protection and non-binding clauses for the surrogate mothers in case they suffer during the surrogacy process, either physically or mentally. India can follow in the footsteps of countries such as England by making gestational surrogacy legal, but only in altruistic cases. Finally India can implement a ban especially on commercial surrogacy to preserve the rights and dignity of the Indian women, and to end the potential exploitation that is occurring.(6)

Conclusion

The right to reproduce is a fundamental human right of everyone. But as discussed previously, surrogacy is not within the reach of a common Indian couple. May be, at times it is the fantasy of rich modern society and readily available and cheaper media for foreigners, which should be discouraged to prevent misuse of technology. In India, there are a large number of orphan children seeking for mercy and still it remains a paradox that people are engaging in the practice of surrogacy. The reason may be that, the adoption of a child in India is a complicated and a lengthy procedure. As a result, they resort to the options of IVF or surrogacy. The Hindu Adoption and Maintenance Act, 1956 does not permit non-Hindus to adopt a Hindu child, and requirements of immigration after adoption face further hurdles. (13) There is a need of comprehensive adoption law, simple and applicable to all its citizens, irrespective of the religion or the country they belong to as Non-Resident Indians, Persons of Indian Origin or Overseas Citizens of India. This will bring down the rates of surrogacy. Any research in the field of medicine is aimed at betterment of human life. The role of ethics is to play a safeguard against the possible abuse of advanced technologies. The ultimate objective should be to restore happiness in the family as well in the society. Altruistic and not commercial surrogacy should be promoted. (14) Our Mother India should not be considered as a land of fertility tourism. Laws should be framed and strictly implemented to cover the grey areas and to protect the rights of women and children.

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MEDICO LEGAL WORKSHOP

PEDICON 2014, INDORE

8th January, 2014 | Time 8.30 a.m. - 5.00 pm

Topics

• Consent, • Documentation, • How to fight a medico legal case, • Medical errors and negligence, • Criminal liability, • Ethical issues, • Medico legal issues in critical care, • Sudden /unexpected death in Hospital, • Violence & Media – how to tackle, • Medico legal issues in different specialties, • What kind of indemnity policy should I take?, • Doctor patient relationship, • Communication skills, • Various laws and much more ...

Contact

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Informed Consent: An Ethical Obligation or Legal Compulsion?

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Informed consent is a vital document while performing all surgical and aesthetic procedures, particularly in the current day practice. Proper documentation and counseling of patients is important in any informed consent.

INTRODUCTION

Medical practice today is not simple because of various factors impinging on the doctor-patient relationship. Mutual trust forms the foundation for good relationship between doctor and patient. Today, patients tend to be well- or ill-informed about the disease and health. With the hype created in the print and visual media regarding 'beauty', 'shape, size and appearance of body parts', 'quality and quantity of hair', etc., patients tend to come to dermatologists with unreasonable demands and unrealistic expectations. Therefore, providing adequate information and educating the patient about realities and obtaining informed consent before subjecting a patient to any test/procedure/surgery is very essential.

ETHICAL ANGLE

The concept of consent arises from the ethical principle of patient autonomy. Patient's has all the freedom to decide what should or should not happen to his/her body and to gather information before undergoing a test/ procedure/ surgery. No one else has the right to coerce the patient to act in a particular way. Even a doctor can only act as a facilitator in patient's decision making.

LEGAL ANGLE

There is also a legal angle to this concept. No one has the right to even touch, let alone treat another person. Any such act, done without permission, is classified as “battery”[3] - physical assault and is punishable. Hence, obtaining consent is a must for anything other than a routine physical examination.In simple terms, it can be defined as an instrument of mutual communication between doctor and patient with an expression of authorization/permission/choice by the latter for the doctor to act in a particular way.

IMPLIED VS. EXPRESSED CONSENT

The very act of a patient entering a doctor's chamber and expressing his problem is taken as an implied (or implicit) consent for general physical examination and routine investigations. But, intimate examination, especially in a female, invasive tests and risky procedures require specific expressed consent. Expressed (explicit) consent[5] can be oral or written. Written consents are preferable in situations involving long-term follow-up, high-risk interventions and cosmetic procedures and surgeries. It is also needed for skin biopsy, psoralen with ultraviolet A (PUVA) therapy, intralesional injection, immunosuppressive therapy, electrocautery etc.[6]

Consent is necessary for photographing a patient for scientific/educational/research purpose or for follow up. Specific consent must be taken if the identity of the patient is likely to be revealed while publishing.[l7]Consent is a must for participation in clinical trials and research projects.[l8]

INFORMED CONSENT

Informed consent must be preceded by disclosure of sufficient information. Consent can be challenged on the ground that adequate information has not been revealed to enable the patient to take a proper and knowledgeable decision. Therefore, accurate, adequate and relevant information must be provided truthfully in a form (using non-scientific terms) and language that the patient can understand. It cannot be a patient's signature on a dotted line obtained routinely by a staff member.

DISCLOSURE OF INFORMATION

The information disclosed [9] should include:

- The condition/disorder/disease that the patient is having/suffering from
- Necessity for further testing
- Natural course of the condition and possible complications
- Consequences of non-treatment
- Treatment options available
- Potential risks and benefits of treatment options
- Duration and approximate cost of treatment
- Expected outcome
- Follow-up required

Patient should be given opportunity to ask questions and clarify all doubts. There must not be any kind of coercion. Consent must be voluntary and patient should have the freedom to revoke the consent. Consent given under fear of injury/intimidation, misconception or misrepresentation of facts can be held invalid.

PRE-REQUISITES- Patient should be competent[10] to give consent; must be an adult and of sound mind. In case of children, consent must be obtained from a parent. In case of incapacitated persons, close family members or legal guardians can give consent. Adequate information should be provided to a prudent patient during informed consent.

Prudent patient means a reasonable or average patient. To decide whether adequate information has been given, courts rely on this "Prudent Patient Test". It is not easy to answer the question, How much information is "adequate"? A netizen may expect and demand detailed information. On the other hand, an illiterate may say that "I do not understand anything, doctor, you decide what is best for me!" If a patient knowingly prefers not to get full information that attitude also needs to be respected as a part of patient's right to autonomy.[11]

Patients' perception of risk of a medical intervention is also highly individualistic, variable and unpredictable. The information provided to a patient should include all material risks. But, the list of risks and side effects cannot be exhaustive to the level of absurdity and impracticality. For example, hardly any patient can go through the product information leaflet included in any drug pack and if some body does, it is unlikely that the drug is consumed. So, what is expected is that the doctor should provide information that a prudent[3] or reasonable patient would expect to make a knowledgeable decision about the course of action to be taken in the presence of alternatives.

EXCEPTIONS TO DISCLOSURE

Therapeutic privilege[4]

If a doctor is of the opinion that certain information can seriously harm a patient's health - physical, mental or emotional - he has the privilege to withhold such information. But, it should be shared with close relatives. This situation usually does not occur in cutaneous aesthetic surgical procedures.

Placebo

Use of placebos in certain self-limiting conditions or in patients with high psychological overlay or in those who insist for some form of medication[10] is justified as there are high chances of benefit to the patient with negligible risk. Revealing the truth to the patient takes away the very purpose of administration of placebo.

BLANKET CONSENT

An all-encompassing consent to the effect "I authorize so and so to carry out any test/procedure/surgery in the course of my treatment" is not valid. It should be specific for a particular event. If, consent is taken for microdermabrasion, it cannot be valid for any other procedure like acid peel. Additional consent will have to be obtained before proceeding with the latter.

If a consent form says that patient has consented to undergo laser resurfacing by Dr. X, the procedure cannot be done by Dr. Y, even if Dr. Y is Dr. X's assistant, unless it is specifically mentioned in the consent that the procedure may be carried out by Dr. X or Dr. Y (or his authorized assistants).

DOCUMENTATION

It is important to document the process of consent taking. It should be prepared in duplicate and a copy handed over to the patient. It should be dated and signed by the patient or guardian, the doctor and an

independent witness. Assisting nurse preferably should not be a witness. Like all other medical records, it should be preserved for at least 3 years.

INFORMED REFUSAL

Patient has got the right of self-determination. If, a doctor diagnoses varicella in a child, the parent may choose to avail no treatment because of religious belief. Doctor's duty is to explain the possible consequences of non-treatment and benefits of treatment and leave the decision to the parent. Such informed refusals must be documented clearly.[10] But, a patient's freedom cannot impinge on the rights of others or cause harm to a third party or community. Therefore, the said parent's freedom of choice cannot extend to sending the child to school, as the infection can spread to other children.

Discharge against medical advice also falls into this category and needs to be properly recorded in the case sheet with signature of the patient/guardian.

In an emergency situation, for example intestinal perforation, a doctor may have to operate even in the absence of consent, to save the life of the patient. It is possible that even with such an intervention, the patient may not survive. Assuming that the doctor is competent and has exercised due care and diligence, doctor cannot be held responsible for patient's death, as he has acted in good faith and in the best interest of the patient. This protection is given under Section 88 of Indian Penal Code.[10]

CONCLUSION

Obtaining consent is not only an ethical obligation, but also a legal compulsion. The level of disclosure has to be case-specific. There cannot be anything called a standard consent form. No doctor can sit in comfort with the belief that the “consent” can certainly avoid legal liability. This is highlighted by the note of The California Supreme Court:[12]

“One cannot know with certainty whether a consent is valid until a lawsuit has been filed and resolved.”

One can only take adequate precaution and act with care and diligence. Maintaining good relationship with patient often works better than the best informed consent!

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Professional Assistance / Welfare Scheme

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

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

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

Contd...28

Readers Ask, Experts Answer

Expert
Dr. M C Gupta
(Former Professor and Dean)
MD (Medicine), LLM
Advocate (Delhi Bar Council No. 857/2001)
e-mail: mcgupta44@gmail.com

Q. *Please answer the following questions in relation to the MTP Act:*

i) Does the term MTP include the following: Missed abortion/ incomplete abortions D&C?

ii) If not what is to be written in column no 18 , in case of such abortion requiring D&C?

iii) If yes why do we need to send records of abortion cases separately to civil surgeon?

iv) When MTP is performed non-surgically (by giving pills), is it necessary to enter the details in the admission register?

A. 1. The term MTP is not defined in the Act or the rules or the regulations made under it. However, meaning apparently imparted to it by the legislature is clear from section 3(2), which reads—"(2) Subject to the provisions of sub-section (4), a pregnancy may be terminated by a registered medical practitioner....".

Missed abortion and incomplete abortion occur on their own without any act or even knowledge on the part of the medical practitioner. Hence these events cannot be called as MTP. If the medical practitioner has to perform D&C following a missed abortion/ incomplete abortion, it cannot be called as MTP.

2. It is not clear what you mean by column no 18. There is no such column in any form or register prescribed by the MTP Act/ Rules etc.

3. It is not clear what you mean by "why do we need to send records of abortion cases separately to civil surgeon". As per Regulation no. 4(5) of the MTP Regulations, 2003, only the report of "MTP" has to be sent. There is no question of jointly or separately. Regulation no. 4(5) reads:

"(5) Every head of the hospital or owner of the approved place shall send to the Chief Medical Officer of the Sate, in form II a monthly statement of cases where medical termination of pregnancy has been done."

4. As regards the admissions register, regulation 5(1) is reproduced below—

"5. Maintenance of Admission Register, -

(1) Every head of the hospital or owner of the approved place shall maintain a register in form III for recording there in the details of the admissions of women for the termination of their pregnancies and keep such register for a period of five years from the end of the calendar year it relates to."

It is clear that:

- When a woman in whom MTP has been performed and who has been admitted in the hospital for this purpose, necessary details have to be entered in the Admission Register.
- When a woman in whom MTP has been performed on OPD basis and who has not been admitted in the hospital for this purpose, there is no question of entering her particulars in the Admission Register.

Q. *It is proposed to set up an IVF centre having an ultrasound machine. Which of the following people (Gynecologist / Sonologist / Gynaec / Embryologist / other staff) will have to be registered under the PCPNDT Act?*

A. 1. For a centre to be registered under the PCPNDT Act, Form A (given in the PCPNDT Rules, 1996) has to be filled, which is titled—"Form of application for registration or renewal of registration of a genetic counselling centre/genetic laboratory/genetic clinic/ultrasound clinic/imaging centre"

2. Subsections (d) and (e) of section 2 of the Act,

reproduced below:

(d) "Genetic Clinic" means a clinic, institute, hospital, nursing home or any place, by whatever name called, which is used for conducting pre-natal diagnostic procedures.

Explanation- For the purposes of this clause, 'Genetic Clinic' includes a vehicle, where ultrasound machine or imaging machine or scanner or other equipment capable of determining sex of the foetus or a portable equipment which has the potential for detection of sex during pregnancy or selection of sex before conception, is used.

(e) "Genetic Laboratory" means a laboratory and includes a place where facilities are provided for conducting analysis or tests of samples received from Genetic Clinic for pre-natal diagnostic test.

Explanation- For the purposes of this clause, 'Genetic Laboratory' includes a place where ultrasound machine or imaging machine or scanner or other equipment capable of determining sex of the foetus or a portable equipment which has the potential for detection of sex during pregnancy or selection of sex before conception, is used."

3. It appears that the proposed IVF centre will fall under the category of "Genetic Clinic".

4. Item 10 of Form A reads—

   "10. Names, qualifications, experience and registration number of employees (may be furnished as an enclosure)"

5. It appears from item 10 that only those employees need to be listed who have a registration no. This would include all persons registered with a professional council such as the medical council or the nursing council. Thus the Gynecologist / Sonologist / Gynaec will have to be listed under item 10. The embryologist will have to be listed if he is registered with the medical council. Other staff need not be listed.

Professional Assistance / Welfare Scheme (Contd...)

experts shall be done as per the pre-decided remuneration. Payment issues discussed, agreed and processes shall be laid down by the members of these scheme.

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

Research Briefs

Understanding attitudes toward adolescent vaccination and the decision-making dynamic among adolescents, parents and providers
(BMC Public Health 2012, 12:509)

This study sought to identify potentially modifiable barriers in the vaccine decision process among adolescents, parents and healthcare providers that could be addressed through interventions implemented within the adolescent's atmosphere. Participants conducted a qualitative study of adolescents, their parents and healthcare providers, recruited from four primary care practices in Michigan. For each practice, three separate focus group discussions (adolescents, parents and healthcare providers, for a total of 12 focus groups) were conducted to explore vaccination attitudes, possible interventions to improve vaccine uptake and access to and use of technology for vaccination interventions. Themes that emerged from the focus group discussions were categorized using an inductive, iterative process, and analysis focused on highlighting similarities and differences among the three perspectives. Participants included 32 adolescents, 33 parents and 28 providers. The majority of parents and adolescents were female. Lack of knowledge about recommended adolescent vaccinations was universally recognized among the three groups and was perceived to be the underlying driver of low immunization rates. Notably, each group did not appear to fully appreciate the challenges faced by the other stakeholders with respect to adolescent vaccination. Adolescents were seen as having a greater role in the vaccine decision-making dynamic than previously suggested. Provider-based interventions such as educational tools and reminder-recall notices were identified as important components of any immunization program. Overall, there was high receptivity among all stakeholders toward integrating technology such as email and Internet into new vaccination interventions. This study identified potentially modifiable attitudinal barriers to adolescent vaccination among the three key stakeholders. However, there were notable differences in attitudes and preferences across the three perspectives, indicating that for an intervention to be successful it will require a dynamic partnership with the target audiences.

Informed consent- how much and what do patients understand?
(Am J Surg. 2009 Sep; 198(3):420-35)

A study was conducted at Alfa Institute of Biomedical Sciences (AIBS), Athens, Greece, to evaluate the degree of patients' understanding of several aspects of the informed consent process for surgery and clinical research. The participants conducted a systematic search of Pub Med (1961-2006) to identify relevant articles. They retrieved 23 and 30 eligible for inclusion articles regarding informed consent for surgery and clinical research, respectively. Regarding surgery, adequate overall understanding of the information provided and of the risks associated with surgery was shown in 6 of 21 (29%) and 5 of 14 (36%) studies providing relevant data, respectively. Regarding clinical research, adequate understanding of the aim of the study, the process of randomization, voluntarism, withdrawal, and the risks and the benefits of treatment was shown in 14 of 26 (54%), 4 of 8 (50%), 7 of 15 (47%), 7 of 16 (44%), 8 of 16 (50%), and 4 of 7 (57%) of studies providing relevant data, respectively. Satisfaction by the amount of the given information was shown in 7 of 12 (58%) studies involving surgery and 12 of 15 (80%) studies involving clinical research. The study concluded that further attention should be drawn on enhancing patients' understanding regarding several components of the informed consent process for surgery and clinical research.

Medical ethics and ethical dilemmas
(Niger J Med. 2009 Jan-Mar; 18(1):8-16)

Ethical problems routinely arise in the hospital and

outpatient practice settings and times of dilemma do occur such that practitioners and patients are at cross-roads where choice and decision making become difficult in terms of ethics. In a study conducted at department of Pharmacology & Therapeutics, College of Medicine, Ambrose Alli University, Ekpoma, Nigeria, participants attempted to make a synopsis of the basic principles of medical ethics, identify ethical dilemmas that doctors often encounter and discuss strategies to address them as well as emphasize the need for enhanced ethics education both for physicians and patients, particularly in Nigeria. Literature and computer programmes (Medline and PsychoInfo databases) were searched for relevant information. The results showed that that although the fundamental principles of ethics (respect for autonomy, beneficence, non-maleficence and justice) do not give answers on how to handle a particular situation, they serve as a guide to doctors on what principles ought to apply to actual circumstances. The principles sometimes conflict with each other leading to ethical dilemmas when applied to issues such as abortion, contraception, euthanasia, professional misconduct, confidentiality truth telling, and professional relationship with relatives, religion, traditional medicine and business concerns. Resolution of dilemmas demand the best of the doctor's knowledge of relevant laws and ethics, his training and experience, his religious conviction and moral principles as well as his readiness to benefit from ethics consultation and the advice of his colleagues. The conclusion was that ethics education should begin from the impressionable age in homes, continued in the medical schools and after graduation to ensure that doctors develop good ethical practices and acquire the ability to effectively handle ethical dilemmas. Also, education of patients and sanction of unethical behaviour will reduce ethical dilemmas.

Missed diagnoses and drug errors make up for the majority of malpractice claims against doctors in primary care.

(Source : The epidemiology of malpractice claims in primary care: a systematic review .BMJ open -2013-002929)

Missed diagnoses, specially of cancer, heart attack, and meningitis—and drug errors make up for the majority of malpractice claims against doctors in primary care, finds an analysis of published data in the online journal BMJ Open. Researchers carried out an extensive search of published research in English about the number and causes of malpractice claims in primary care in April 2012 and again in January 2013.Out of a total of 7152 studies, 34 were eligible for inclusion in the analysis. Fifteen studies were based in the US, nine in the UK, seven in Australia, two in France, and one in Canada.In the US, studies indicate that malpractice claims brought against primary care doctors accounted for between 7.6% and 16% of the total. In the UK, GPs made up the greatest proportion of an overall 20% increase in claims between 2009 and 2010, with claims against them more than doubling between 1994 and 1999.In Australia, GPs accounted for the highest proportion of claims and the highest number of new claims on the national Medical Indemnity National Collection database for both 2009 and 2010.Missed diagnoses were the most common source of malpractice claims, accounting for between a quarter (26%) and almost two thirds (63%) of the total. And the most common consequence of this in the claims filed was death, ranging from 15% to 48% of claims made for missed diagnoses. Among adults, cancer and heart attack were the most commonly missed diagnoses in the claims made. Others that cropped up frequently included appendicitis, ectopic pregnancy, and fractures. Among children, the most frequent claims related to meningitis and cancers. The second most common sources of malpractice claims were drug errors, the proportion of which ranged from 5.6% to 20% across all the studies.

A substantial proportion of claims were rejected , only one third of US claims and half of UK ended up in compensation .Another trend was highlighted ;the number of claims brought against US doctors has remained fairly stable over the past two decades, but claims against Australian and UK GPs have been rising. Researchers pointed out that the threat of litigation can result in “defensive medicine” and over diagnosis and treatment, and that doctors who are sued find the legal process very distressing.

Medico Legal News

Mumbai IVF clinics create parents, but also problems

It's heartening that India, because of cost effective packages, has emerged as a top global destination for surrogacy .But there is a dark side to it; there's been growing international concern about the way surrogacy is practised in India. Each year thousands of foreigners head to India to avail of surrogacy facilities at In Vitro Fertilisation (IVF) clinics. In many cases their joy of becoming parents is short lived because back home their country of origin may or may not recognise surrogacy. There are many examples; Baby Manjhi's case, for instance, is an eye opener. Her parents, a Japanese couple, were divorced after she was conceived by a surrogate Indian mother. Since the Indian law does not grant single men custody of a girl child, her father had to wait for three months to take her home.

A French national may have to lose his twin sons because surrogacy is not legally accepted in France. Such cases prompted the consul generals of eight European countries to send a letter to IVF clinics in Mumbai stating that the clinics must direct foreigners to get clearances from their embassies before initiating the surrogacy process. This is already stated in Indian Council of Medical Research (ICMR) guidelines but is flouted by many IVF clinics.

According to a medico legal lawyer there are lots of cases where ICMR guidelines have been flouted. Like in the case of French national. The IVF clinic was aware of French law on surrogacy, yet it went ahead and did it.

(Source- www.ndtv.com/15.7.2010)

Doctor Murdered Brutally by Patient's Relative

Indian doctor Rajan Daniel's was brutally murdered inside hospital in Abu Dhabi by a man who blamed him for his relative's death. The man, a Pakistani national, had a big knife in his hand when he stormed into the hospital and slit the doctor's throat in view of hospital staff and patients.

Dr Rajan belonged to Kerala from India and had been working in the hospital since 2007. He was a soft spoken man and was quite popular with the staff and patients. The manner of murder was extremely brutal; the man marched straight into the urology clinic and forced the doctor on his knees before slitting his throat like a sheep .The man then waited at the hospital until the police came and arrested him. The man was armed with a big knife and killed the doctor after the death of his relative. An eye witness said "The man appeared furious...He blamed the Indian doctor for his relative's death and attacked him without giving him a chance to defend himself...It was a heinous crime."

(Source-www.emirates247.com/crime/local/2012-11-05)

Invisible Drug trials

Publish your data, or we will do it. This is a warning to drug companies issued by scientists at Johns Hopkins University in Baltimore, Maryland. Disappointed that only about half of all clinical trials are published. They want to change that, by convincing researchers and journals to print data that have been publicly released through other means, such as litigation and Freedom of Information Act requests, but, practically speaking, are sitting dormant in the filing cabinets or computers of individual scientists.

The name of this proposal is RIAT (Restoring Invisible and Abandoned Trials). It was published today in BMJ and also endorsed by PLOS Medicine. This was brainchild of an Indian scientist Peter Doshi, who studies comparative effectiveness research, and his colleague, Swaroop Vedula, who was analyzing reporting biases involving the drug gabapentin. Gabapentin's maker Pfizer had been sued for the way in which they marketed the drug for unapproved indications.

(Source - news.sciencemag.org/scienceinsider/13.6.2013)

Patient's death: MMC bars doctor from practice for 3 months

Thane: The Maharashtra Medical Council has suspended the registration of a doctor for a period of three months, after finding him guilty of "gross medical negligence" over death of a patient he treated about three-and-half years ago. Dr X, a registered medical practitioner having a multispecialty hospital was punished after the council members unanimously agreed on the decision, the council said in an announcement.

The Council acted on a complaint of a Mr BN, who alleged that it was due to the gross negligence and casual attitude of the doctor who had operated upon his wife ABN, 48, at the hospital, for obesity that resulted in her death.

The complainant told the council that the surgery was conducted on her in 2009, who was in the hospital for 5 days. After being discharged she had complained of uneasiness and severe pain in abdomen and was again admitted to the hospital after 6days.

Again she was discharged the next day only to be readmitted to the hospital after 3days and she died the following day, he said.

The patient was taken to two other hospitals as her conditioned worsened and complications increased during this period. She died at the second hospital while under care of Dr X, the council was further informed.

A committee of medical experts from Pune was appointed to go into the causes of the death of the patient which also submitted its report to the council.

"As far as the surgery is concerned, there is no negligence on part of the doctor. However the postoperative care which ought to have been taken does not seem to have been proper," the Council noted. The pathological reports of Blood Urea Nitrogen (BUN) 25mg/dl and Serum Creatinine 1.5 mg/dl from first day had tremendously increased up to 186 mg/dl and 8.4 mg/dl at second hospital respectively and the doctor failed to take notice of it and further failed to judge the appearances of suspected leak from the operative site and development of septicaemia.

The said fact was thoroughly pointed out in the committee report of BJ Medical College and Sassoon General Hospital, Pune. The council members were unanimous in accepting the report of the committee.

Further, the council said, Dr X failed to refer for postmortem to know exact cause of death. The doctor who appeared before the council made a written submission to it where he denied the allegation calling it concocted, imaginary, unreal and fictitious story for accumulating sympathy and pity out of the untimely death of the complainant's wife.

In their order president of the MMC and Judicial Assessor have further ordered that the doctor should not carry out any medical practice during the suspension period anywhere and the violation of the order will invite legal action.

The complainant also included the name of another doctor Y of the same hospital but the council did not find any points to take action against him and action was taken only against Dr X.

(Source: http://zeenews.india.com/news/maharashtra/patient-s-death-mmc-bars-doctor-from-practice-for-3-months_867868.html)

Training on Medical Ethics and Communication Skills

Tranvancore Cochin Medical Council

wants all fresh MBBS graduates to undergo

Training on Medical Ethics and Communication Skills

as it found these two qualities lacking among the doctors who are joining service in the various hospitals across the state.

The council meeting decided to write to all college heads for conducting this from the present academic year

(Source: http://timesofindia.indiatimes.com/topic/Medical-Council-of-India)

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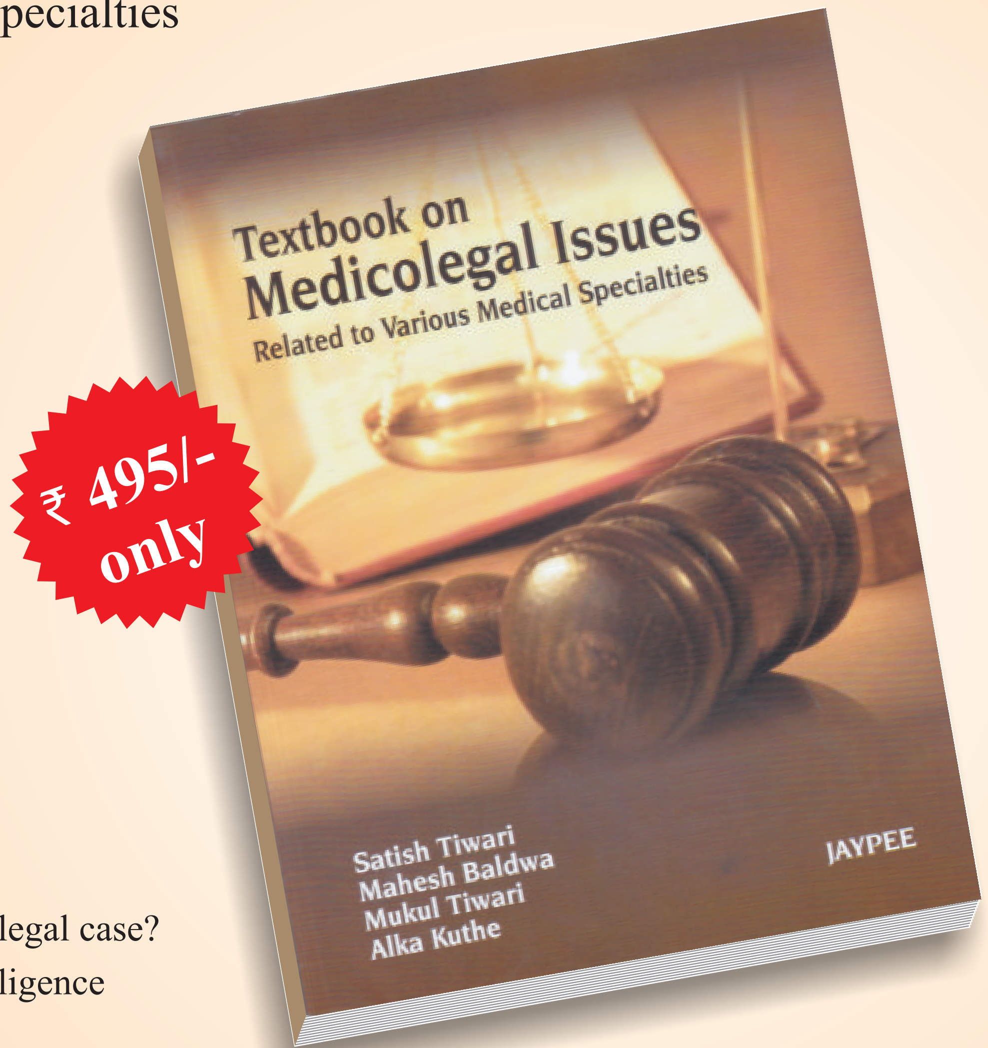

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