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Indian Medico Legal And 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.
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- 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.

Editorial:

Ethics and professionalism in Medical education

Dr. Sushma Pande

Keywords : Medical Ethics, Professionalism, Medical Education.

Since last few decades there is gradual increase in litigations and assault on doctors by patients' relatives. This can be attributed to the landmark judgment by the Supreme Court, stating that medical services to patients, for which fees are charged, will come under the purview of Consumer Protection Act 1986. This led medical practitioners to safe guard themselves using modern technical advances and sophisticated tests to keep them ahead of the consumer protection laws of the country. General public took it as dehumanization of medical services and profession leading to disruption of the doctor patient relationship. The Medical profession thus lost its credibility. It is no longer viewed as high esteemed profession in society, as it used to be in past.

There is tremendous rise in number of Private Medical colleges. Till date according to MCI, there are total 426 Medical colleges, out of which, 219 being owned by Private organizations, almost above 50% (1). Privatization in Medical Education may also be attributed to changing attitude of professionals leading to deterioration in ethics and morality. There is scarcity of role models in the medical profession.

Medicine is a continuously emerging field of science directly dealing with the pain, sufferings and death of human subjects. Conflicts arise when there is the difference in opinion or moral values or traditions in medical practice, and hence, certain code of ethics or regulations has been evolved in the past few decades in the context of medical care. The need to teach ethics, professionalism and

humanities is being recognized since long. Many national and international organizations and universities support these ethical precepts and argue for their incorporation into routine medical practice (2). Several institutes around the globe have developed curricula to include the teaching bioethics to medical graduates. The Medical Council of India (MCI), in its 'Vision 2015' document, also argues for mandatory teaching of ethics as a part of the medical curriculum (3). The Maharashtra University of Health Sciences (MUHS) has also established UNESCO's national nodal centre for bioethics on its premises. The centre would ensure that the graduate-level students get lessons on ethical practices in the field of medicine and biology.

Ethics :

A branch of philosophy dealing with values pertaining to human conduct, considering the right and wrong of actions and the good or bad of the motives and ends of such actions. The term "ethics" simply refers to a system of moral principles or standards governing conduct.

Attributes of Ethics - Four Basic Principles are

1. Autonomy - Patient has right to take decision.
2. Beneficence - A practitioner should act in the best interest of the patient.
3. Non-maleficence- Do no harm to others
4. Justice, fairness and equality to all.

Bioethics is essentially a term for moral conduct in the broad area of life sciences and medicine. It mainly relates with life-and-death issues. As described by the World Health Organization,

bioethics deals with issues related to health and health care management, animal welfare, and environmental issues. It also encompasses the following subject areas: philosophy of science, biotechnology, politics, law, medicine, and theology.

Clinical ethics tackles patient-based ethical decision making. A subset of bioethics, clinical ethics and medical ethics are often used interchangeably. This area of ethics considers different judgments as they apply to the clinical practice of medicine. Thus, clinical ethics is a system of principles governing medical conduct with respect to patients and their families.

Professionalism:

The upholding by individuals of the principles, laws, ethics and conventions of their profession. This refers to a set of core values or standards that every physician is expected to have. Medical professionalism is how we conduct ourselves as physicians while serving our patients and society in our roles as healer, medical professional and medical scientist. Medical professionalism is the basis for the trust in the doctor-patient relationship. Core values of professionalism include - Excellence, Humanism, Responsibility, Accountability, Altruism, Respect, Honesty, Integrity, Compassion, Empathy and Self dedication.

The ethics of professionalism in medicine is more concerned with the characteristics and behaviors of physicians in the context of medicine as a profession. Specifically, it examines desirable and undesirable attributes of physicians. Desirable behaviors include altruism, accountability, excellence, duty, honor, integrity, respect for others, and a commitment to lifelong learning. Undesirable conduct, on the other hand, includes abuse of power, bias, sexual harassment, breach of confidentiality, arrogance, greed, misrepresentation, impairment, lack of conscientiousness, and conflicts of interest. The ethics pertaining to professionalism not only motivate patient-physician interaction, but also outline expected behavior with other physicians, health care workers, medical students, and

preceptors. (4)

Attributes of Professionalism

1. Subordinate one's self-interest
2. Adhere to high ethical and moral standards
3. Respond to societal needs
4. Evince core humanistic values

Professionalism is shaped by several factors: heredity, parental influence, upbringing and schooling, which are beyond the control of medical education. In Medical colleges students get technical competence. Professionalism is shaped by role models through a 'hidden' rather than 'formal' curriculum. The development of professionalism requires a four pronged approach: an explicit statement of the expected behavior, role modeling by seniors combined with authentic experience, followed by continuous assessment and the creation of a culture of professionalism(5).

I feel the readers of this journal are fortunate enough to know about the legal, ethical and professional aspects of medical practice. Each one of us should realize our own responsibility towards society. Now is the time for introspection, time to inculcate ethical behavior in our day to day practice. Then, I am sure each one of us will serve as role model to coming generation.

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Review Article :

Legal aspects of Medical Records

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Dr.A.R.Marak, *Dr.Seema Konwar

Key Words: Medical record, Medical negligence, Medical Records Department, Electronic medical records

Abstract

A medical record is part and parcel of patient care, and is necessary for legal, ethical and administrative purposes. When carefully preserved, it protects the interests of patients and comes to the doctor's rescue in cases of alleged medical negligence or deficiency of service. As a component of good medical practice, every hospital should have a Medical Records Department responsible for the storage, maintenance and preservation of medical records for a minimum prescribed statutory period. In recent years, manual records are being increasingly replaced by electronic medical records, which are easily retrieved in the event of a subpoena or court order. In a nutshell, a good record is judged by its capacity to withstand the test of time and tell the whole clinical story years after it happened.

Introduction

A medical record is a document containing a chronological account of the patient's examination and treatment (1). It forms an integral part of patient care and is an important element of good medical practice. Medical evidence comprises a good proportion of civil and criminal lawsuits brought to trial in legal proceedings. Therefore, records which are properly stored can become protective armours for doctors against the fiery darts of litigation in a court of law.

As doctors and nurses go about their day to day

duties in hospital, they seldom stop to think about what they are writing in a patient's case sheet – it is such a routine activity. It is only when they face allegations of medical malpractice or deficiency of service that there is a flurry to extract and check clinical notes made months or years ago to find out what actually happened. What if that particular patient's records cannot be retrieved because they are lost or have been misplaced? What if the Medical Records Department staff had disposed the same because the patient had been discharged long back? In such a situation, the concerned doctors and hospital administration are in soup for want of documentary evidence to prove that they had done nothing wrong, or that they had acted in accordance with prevailing standards of medical care. In other words, 'Good records mean a good defence, poor records mean poor defence, and no records mean no defence.'

Functions of Medical Records

The functions of a medical record are manifold. First and foremost, it serves as a roadmap of the patient's clinical progress. In addition, it provides documentary evidence of care given to the patient. It is a form of communication between health professionals, among doctors and nurses, or treating doctors and specialists to whom they are referred. Thus, clear, complete and concise medical notes result in improved patient care and services. A case example is cited where the duty nurse gave the patient a shot of Pancuronium, a muscle relaxant, instead of Pantoprazole, an antacid, resulting in serious adverse effects, simply because she failed

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to decipher the doctor's handwriting.

The legal interests of patients are safeguarded by well-documented reports of illness or injury. For instance, if a patient sustains physical injuries as a result of criminal assault, the quantum of punishment for the accused would be decided by medical evidence of the grievous nature of the injuries in question (2). As per the Workmen's Compensation Act, a person who sustains an injury or contracts a disease during the course of employment in a factory or mine, may be entitled to financial benefits, provided the Medical Certificate issued by the treating physician is produced to support his/her claim (3). Medical records are required for the purpose of life insurance claims as the cause of death of the deceased policy holder has to be documented before the sum assured can be issued to the beneficiary. In health insurance arrangements, an authorized agent or third party administrator (TPA) would usually want to access relevant medical files and treatment notes to verify the veracity of the patient's claim for reimbursement of hospital expenses. Medicolegal injury and postmortem reports have to be produced in Motor Accident Claims Tribunal (MACT) courts to decide the amount of compensation to the aggrieved party in cases of road traffic accident (4). Finally, medical records provide data for education and research. They are a source of information for retrospective analysis of both clinical and medicolegal cases. However, such studies are performed only with the permission of the Medical Superintendent, and subject to clearance from the Institutional Ethics Committee (IEC).

What constitutes medical records?

All documents and paperwork related to patient care comprise medical records. These include the list below, which is not exhaustive:-

1. Clinical : Clinical and operative notes, referral letters, discharge summary, hospital bills, records of hospital expenditure, etc.
2. Investigations: Histopathology reports, histology sections, cytology slides, biochemistry reports, printouts, x-rays, CT scans, ECG, EEG.
3. Medicolegal: Medicolegal Reports,

Postmortem Reports, Death Certificate, audiovisual records, consent forms, registers.

4. Research: Clinical trial forms, clinical research data.

Forensically, a good and complete record should be able to answer the following key questions:-

WHO is the patient? It correctly identifies the patient. All the particulars pertaining to the patient, including requisitions for investigations, have to be duly filled up.

WHEN was the patient seen? The date and time when a patient was examined or an investigation/procedure done must be correctly recorded.

WHAT was the diagnosis?

WHY was a particular treatment given? The course of action taken must be justified medically, legally and ethically.

Confidentiality of Medical Records

As regards ownership, records are the property of the hospital but the information contained in them belongs to the patient. All original documents and images are usually retained in the hospital. The contents (particularly personal information) should not be disclosed to a third party without the patient's consent. Adequate precautions are taken to restrict medical information to those directly involved in patient care. According to the Medical Council of India (MCI) guidelines, any request made by a patient for his/her own records must be acknowledged and released within 72 hours (5). An unauthorized leakage of information would amount to invasion of privacy, defamation and breach of contract. In this manner, failure to maintain confidentiality could become an issue of medical negligence (6). However, there is privileged communication by the doctor to the concerned authority in the larger public interest, such as an outbreak of a communicable disease where the public health authorities have to be apprised. Similarly, there is a statutory obligation to intimate the police whenever the doctor treats a victim or perpetrator involved in a criminal act of physical or sexual assault. There may also be a court order to release certain information about a patient in the

interest of justice. In situations where the doctor or the hospital faces allegations of medical malpractice, records and case notes are produced as documentary evidence to prove that the treatment provided was as per accepted standards of medical care. Relevant patient data may be disclosed to authorized insurance agents and income tax officials for specified purposes.

Section 8(1)(j) of the RTI (Right To Information) Act exempts from disclosure information that is personal, if it has no relationship to any public activity or interest (7). A case is cited where the Central Information Commission (CIC) denied a man information regarding his fiancée's mental health and treatment, stating that medical records cannot be accessed through RTI (8).

Medical Records Department

A hospital is incomplete without a Medical Records Department responsible for proper storage, retrieval and maintenance of medical records. It is of paramount importance to safeguard their confidentiality, security and physical integrity. Hence, they are stored safely within the confines of the department and are only taken out with permission from the concerned authority on receipt of a summons to produce them in court (subpoena duces tecum). A medical record clerk is appointed to look after them and to report any theft or loss of records to the Medical Superintendent. As per guidelines from the Directorate General of Health Services (DGHS) for Central Government hospitals, outpatient records must be retained for a minimum period of five years while inpatient papers and medicolegal documents must be stored for at least ten years (9). Legally, the retention of medical records relates to the limitation period for filing a case of medical malpractice in a criminal or consumer court (10). According to Section 24A of the Consumer Protection Act, 1986 a complaint has to be made within two years of the alleged incident but this time limit can be extended at the discretion of the courts (11). The Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 states that all records, charts, forms, reports, consent letters and other documents required to be maintained under this Act shall be

preserved for a period of two years (12). In practice, every institution has its own policy as regards retention of its records. However, it would be advisable for hospital administration to identify cases with a potential for litigation and preserve them indefinitely or until they are finalized in court. In our hospital, inpatient papers are retained for ten years while medicolegal case papers are stored indefinitely. Records can be condemned when the statutory obligation to retain them draws to a close. The record clerk has to seek written permission from the Medical Superintendent before destroying the records in accordance with hospital procedure. A log book of disposed cases may be maintained to keep track of them. Destruction is preferably done under the supervision of the Medical Records Officer (MRO) by shredding, incineration or pulping, rather than by tearing and throwing in the waste paper basket.

Electronic Medical Records

In recent years, electronic/digital records have replaced their manual counterparts owing to ease of storage and retrieval (13). The preparation of electronic medical records, in the hands of an experienced operator, is definitely less time consuming than doing so with the conventional pen and paper. Digital notes typed into an electronic device are more easily deciphered than illegible handwritten ones. Problems of space constraint for storage of large and bulky files are effectively dealt with. Moreover, there is no wear and tear with time, unlike manual records. Although they do have their cons, such as privacy concerns and chances of misuse, the advantages that they offer, especially in the event of alleged medical malpractice, far outweigh any known disadvantage. It is notable that electronic records are admissible as evidence in courts of law (14,15).

Conclusion

A carefully preserved medical record has the capacity to relate a patient's clinical story years after it happened. It can speak for the dead and protect the living. Accurate case notes safeguard the legal interests of patients and shield healthcare providers from allegations of professional negligence. In an era where litigation seems

inevitable, every hospital should have an organized Medical Records Department for safekeeping of important and confidential information which can be easily retrieved when the need arises. Through the years, there has been a gradual shift from

manual to electronic medical records due to ease of storage and retrieval. The security of a computer system has to be ensured for the sake of privacy and prevention of unauthorized access to classified medical information.

Table 1: Guidelines for retention of medical records (1)

	Outpatient papers	Inpatient papers	Medicolegal cases
MCI Regulations	---	3 years	---
DGHS Guidelines	5 years	10 years	10 years
Maharashtra Govt.	3 years	5 years	30 years

Acknowledgement

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Perspective :

The call of duty- a memoir

Dr. Neloy Sinha

At the very beginning I would like to share that every medical institution in our country has many dedicated doctors, academicians, teachers, researchers and hard working post graduate trainees. It is because of their selfless work ethics people are healed and maintain good health and they have faith in the system.

Deep in the South, about 100km from Bengaluru, it was almost dark and the highway was threatened by thunder storm. The wiper was working its best to keep the windshield clear. Thus visibility was changing from clear to blur. I was on my way for an assessment assignment, scheduled tomorrow. In the next few paras I will share my experience about the teaching and training from the perspective of an assessor.

This is going to be a first hand view and reader's discretion is solicited. I may not be right always on my own ways of interpretation, but I was there at the epicentre. There is no bad medical institution, but there are excellent and good institutions and the rest can always catch up with the best. These tour reports are fragmented pieces of the broader scenario and does not include a single institution but a college.

The day starts with pleasantries and warm hand shake. That usually follows an Indian hospitality, hard to refuse. But avoiding the temptation of roasted cashew, almond, assorted biscuits and aroma of freshly crushed coffee beans one has to proceed beyond the Dean's office on the call of the duty.

The indoors are clean with sparsely used compressible mattress and bed linen. There are patients, and not surprisingly a good number of

them have something in common, an indwelling cannula. When asked, almost always I got the same reply. That is a matter of truth, trust and faith about the efficacy, unless pushed i.v, it's (medicine) not going to work. I stopped asking, because I am an observer. The bedside lab (usually in an adjacent room) is equally clean and locked securely. But the ownership is occasionally contested fiercely by the nursing staffs of the two adjacent departments. I ask for the key to the padlock and that settles the issue of ownership. For the sake of assessment something rooms or spaces from the adjacent departments are mutually cannibalised for the purpose of the day.

PG's plan for referral to the other specialities are never reflected in the bed head ticket but they vouch not to repeat the same blunder (to be caught again). Investigations are always routine. The individual patients lose their entity as well as identity profile and temporarily designed as 'case of'... The jotted vital signs, either by the PGs or by the sisters are always placid and flat lined, there are no spikes or troughs even in their own thoughts and not even any confusion about their status. There is no purpose of admission (other than impending exam or whiff of an assessment visit), plan of management or criteria for discharge, referral or recall, but destined to be discharged after 3 to 4 days. PGs with bright minds and abundance of missionary zeal are moving in the wilderness of the wards and crowded corridors of the OPDs. The Missah is yet to be there to guide and steer the young doctors bestowed upon.

Then what is the role of the PGs in a teaching institute? To say in a very blunt way, in many

departments they are posted as errand managers. If you had the fortune of coming close to or watching an ant hill, the thing will be clear to you. Consider the ant hill as an ivory tower, representing the institution where one belong, the Queen is the symbolic presentation of the core management, the faculties are represented by the drones and the PGs are the labours, working day in and day out with or without understanding their exploitation.

Primarily they disburse the common and poor patients to keep the seniors' investment in the academic and research arena. They are effective in the cut paste maneuver to fix the power point slides of the boss for the next oration. Thus many departments as well as the managements are eager to recruit more PGs because they are the virtual cash cows for any institution. They are the cheap labours or bonded labours for both the Private and the Government institutions. There might be exceptions but that further proves the generic pattern of 1085 days of drudgery.

The out patients department is another story with 'Brownian movement' of the PGs in white apron. They search with a keen eye for the patient suitable for procedures. If they can learn the tricks of the trade that will ensure more than basis 'bread & butter'. Psoriasis, scabies and lousy problems can wait. Selecting a prospective candidate to feed the hungry narrow band PUVA chamber is more rewarding. The pathology department complaints of paucity of histopathological sample contributed by the dermatology dept. Reliable anonymous source confirms the strong possibility of detour.

In many institutions a closer scrutiny revealed that the apparent state of the healthy departmental library was due to generous (though temporary) contribution by the senior facilities purely out of love and saving his private PGs. The functioning LASER machines are yet to mould out of their manufacturer's polythene warranty coat. In spite of the claim of joining the consortium of e-journals, the central library personnel cannot deliver more than the summary or abstract of an article. If the experts fail, how the PGs can have access to the journals? But the departmental log book shows an impressive list of issues discussed in the journal

club. List of case presentation does not corroborate with the level of indoor patient care.

Professors in private institutions seem to be complacent with a salary of 40,000 Rs per month and magically evading the inflation by foregoing the private practice in or around the locality. Similarly RMOs are satisfied with 25,000 Rs per month and by virtue of their designation they cannot claim to be in private practice. If there are so many dedicated faculties, why the PGs are hesitant to answer about the management of their own patients? While there are institutions which demand 36 post dated cheques before admission to facilitate the disbursement of the next three years' stipend. At the end of an academic year the institutions show zero balance on the balance sheet to establish the fact that they are non profit organisations.

But I cannot write these issues in my summary report, because these are purely my assumption and biased opinion. These are not considered as intellectual short coming for the institution because there is no designated column for analytical conclusion.

Again, my report is full of important issues like consumption of total number of fractional blood units by various departments, number of operations listed in the OT list, number of PAP smears sent by the OB& Gynae Dept on the day of assessment. I am allowed to mention about the skill lab and the number of mannequins they have, about the status of the state of the art Central laboratory which is run by some highly qualified PhDs in pure or bio sciences. I have been shown the latest technology of pathology specimen transfer through the start of the art chute channels. There are designated number of lecture theatres with e learning facilities as well as good auditorium with acoustic excellence.

Lucky PGs in the institutions have their own swimming pool and other in house entertainments. I have to see also that the PGs are not in very close proximity to each other, i. e they have their single accommodation for their uninterrupted studies. I dutifully note all these physical assets and make a kind of seizure list to despatch within the next 48

hours without any comments on the quality and the guidance on education and the actual academic scenario to avoid the biased conclusion.

Usually little beyond 5 o'clock, after the data collection is over and the report is finalized and packed securely to withstand the turbulent journey through the Indian Speed Post. Again there is exchange of the visiting cards and polite formalities before parting and going back through the dark highway.

Like me there are several assessors across the country who are trying to furnish their reports but have to augment certain gut feeling because all the circumstantial evidences cannot be written in the black and white.

Epilogue :

- i) I was surely going to miss the deadline unless the editors of the Journal agreed to extend the lease by another two weeks.
- ii) The contents do not depict any particular medical institution. All the institutions are excellent in their own way. Any resemblance with any place is just coincidental. It could be 100km from Mumbai, Chennai or Delhi too.
- iii) There are several news flashes in the leading dailies that the MCI is likely to be scrapped and something new is coming up. In that scenario the above articles can be considered as a historical event.

FIRST ANNOUNCEMENT

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Review Article

Pluripotent stem cells: Pros and cons of some emerging applications

* Dr.Bharath Raj. R

**Dr.Karuna Rameshkumar

Key words :

Pluripotent stem cells, stem cell therapy, genome editing

Abstract :

Stem cells which have the unique ability of self-renewal to differentiate into more specialized cell types are essential in the maintenance of tissues. Stem cells, if they can be directed to differentiate into specific cell types, offer the possibility of a renewable source of replacement cells and tissues to treat diseases. The possibility is exciting with significant technical hurdles and intriguing ethical issues. Stem cell therapy at present in the form of transplant is done for hematopoietic conditions, inherited disorders and degenerative disorders (1-3). The stem cells can be isolated from human embryonic stem cells (ESC) or generated by reprogramming of adult somatic cells from different sources as induced pluripotent stem cells (iPSC). The CRISPR technique (clustered regularly interspaced short palindromic repeats) are DNA loci containing short repetitions of base sequences is a novel form of artificial genome editing that could allow precise and reliable genetic manipulation. The resultant reprogrammed cells can be a source for autologous transplantation(4). The differences between ESC- and iPSC-based therapies concern patient safety, efficacy and accessibility to large numbers of patients and ethical concerns about the moral status of the cells. These issues which are ethically relevant have not been answered yet completely. This article focusses on certain applications of stem cell therapy and the emerging technologies related to reprogramming of cells and production of stem cells explained through case scenarios and a discussion on

implementation of an ethical as well as safe stem cell therapy.

Introduction :

The fast paced area of stem cell research has been the focus of debate and discussion for doctors, scientists, ethicists and regulators for more than a decade. Stem cells which have the unique ability of self-renewal to differentiate into more specialized cell types are essential to the maintenance of tissues such as blood, skin, and gut that undergo continuous turnover. The stem cells facilitate in comprehension of the evolution of complex organism from a fertilized egg. Further they help in understanding directions and the methods that determine whether a stem cell chooses to carry on replicating itself or differentiate into a specialized cell type. New medications could be tested for bio safety on stem cells which are specialized from stem cell lines and which can be scaled up – reducing the need for animal testing. The need for transplantable tissues and organs far outweighs the available supply. Stem cells, if they can be made to differentiate into required cell types, offer the possibility of a renewable source of replacement cells and tissues to treat diseases. This prospect is an exciting one, but significant technical hurdles remain. This article focusses on certain applications of stem cell therapy and the emerging technologies related to reprogramming of cells and production of stem cells explained through case scenarios and a discussion on implementation of an ethical as well as safe stem cell therapy.

Patient-specific therapy is the corner stone of clinical research and is the ultimate aim of reprogramming and stem cell research. One of the main reasons for such research is the cells such

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generated may not go through immunorejection(1). But a chief concern in terms of economics and ethics is the cost. Three case scenarios are given:

Scenario 1: The parents have come for counselling to the pediatrician for their two year old child who had been diagnosed as Thalassemia major. The child is active, but requires repeated blood transfusions for survival. The pediatrician puts forth the options before them- to carry on with transfusions with iron chelation therapy, to get bone marrow transplant which is available only in few centers, but expensive and reprogram stem cell therapy which is still not come in to routine clinical practice.

Scenario 2: A 60 year old man had anemia for past one year and of late required blood transfusion for correction of anemia. He was diagnosed to have myelodysplastic syndrome. He was advised to continue medication and or to have stem cell transplant.

Scenario 3: A 60 year old female complained of repeated knee joint pains who consulted an orthopedician. She was diagnosed as a case of osteoarthritis. The consultant gave three options- repeated medication, knee replacement surgery and stem cell based treatment.

The underlying common thread in scenario 1 and 2 is the need for repeated transfusions and in all the three scenarios is the choice of stem cell transplant as an option for treatment. The first one represents inherited disorders, the second one represents an acquired condition which can lead to malignancy and the third one is a degenerative disorder. The fact that for such a spectrum, stem cell therapy has been given an option indicates the widespread application of the therapy.

In the triad of physician, researcher and the patient, who has the final say in the treatment options? While the patient has every right to exercise his autonomy for treatment options, she/he should have adequate information to exercise it. The physician and the researcher in their enthusiasm to implement a new technology should be well aware of the adverse effects and be willing to discuss them. The information hungry patient always finds ways to get information – in the past through

general libraries and in the present through surfing the internet. Physicians should be strong enough to cope with the informed patients and the patient needs to realise that with the empowerment and knowledge comes the responsibility to take part in the treatment options including the ones in the trial period such as induced pluripotent stem cell therapy.

Stem cell therapy in cartilage repair in orthopedics

Pluripotent cells will be able to differentiate into any three germ layers as the name implies. These cells can be isolated from embryonic stem cells (ESC) or generated by reprogramming of adult somatic cells from different sources as induced pluripotent stem cells (iPSC). The basic technology of iPS cell generation has evolved from 2007 when Takahashi and Yamannaka generated such cells from murine fibroblasts(5). Efforts are being made to increase the safety of the production and delivery of these cells.

Both in developing countries like India and developed countries like USA and Europe, hip and knee replacement surgeries are the most commonly performed surgeries with an estimated 15 to 20,000 joints being done in a year in a country like India(3). A projection for the total number of replacements by 2030 in India is around 40,000, with the geriatric population health conscious about being fit in their old age (6). In early onset arthritis, if the cartilage damage can be sorted out with the help of stem cells, the chances of the patient needing a primary total knee replacement comes much later stage in life. With the advances in stem cell, meniscal tears which are often excised as most commonly is seen in the white zone leading to early onset of arthritis, can also be sorted out by giving the meniscus a chance to heal and allowing the body to have normal biomechanics during the gait pattern (7,8). Osteoarthritis is a chronic degenerative disorder of the joints, characterized by an activation of inflammatory process which results in gradual deterioration of articular cartilage. Hence the repair capacity is markedly compromised. The application of mesenchymal stem cells to improve the reparative process is a strategy which has found

many takers (9, 10). The various reasons include – the mesenchymal stem cells have the potential for differentiation into cells of mesodermal lineage such as chondrocytes, adipocytes and osteoblasts, and possess immuno modulatory effects of the surrounding cells to facilitate the repair.

The different sources of mesenchymal stem cells (MSC) include bone marrow, adipose tissue, and synovium(9). Among these mesenchymal stem cells extracted from the synovial membrane by harvesting the synovial membrane through arthroscopy in a low invasive way with minimal complications is more successful compared to the other two. MSCs have also been isolated from periosteum, trabecular bone, Wharton's jelly and skeletal muscle. The last one is sex dependent. Stem cells derived from skeletal muscle cells of male donors have a higher potential for chondrogenic differentiation and cartilage regeneration(10) Stem cell based treatment include both injective treatment as intra articular injection and surgical transplantation(11). Innovation of new technology is important; however, a high level of evidence is needed when implementing new technologies into clinical practice. The role of randomized clinical trials to provide evidence based practice in orthopedics is limited. This may be due to ethical issues – randomizing patients to different procedures, variability in surgical techniques which may require intraoperative modifications and challenges in blinding to name a few. Treatment of articular cartilage lesions by stem cells has shown reasonably good results (8). But fully functional cartilage surface with mechanical functions has not been reported yet. In spite of promising results, more controlled studies are required to achieve both efficacy and safety in patients, as the clinical conditions related cartilage are not life threatening but involves quality of life.

Induced pluripotent cells (iPSC) vs embryonic stem cells (ESC)

The differences between ESC and iPSC-based therapies concern patient safety, efficacy of treatment, accessibility to large numbers of patients and controversy about the moral status of the cells. These ethically relevant issues are yet to get an

answer. Research on both ESCs and iPSCs is in rapid phase and as the new applications emerge, both scientific and ethical differences between these cells must be reevaluated.

In ESC research, each government has its own set of laws or placed restrictions on what may be done with embryos and ESCs. Other ethical issues surrounding such research include informed consent, improper inducement, and safety risks for women donating eggs necessary for the creation of embryos through in-vitro fertilization(12). iPSCs have been promoted as ethically uncomplicated alternatives to ESCs. So the ethical issues surrounding iPSCs have been evaluated in comparison to those involving ESCs. The use of iPSCs as an alternative to ESCs may eliminate both the health risks to the donor and the issues of appropriate compensation, as individuals would donate cells through a non-invasive procedure for research leading to the donor's own therapeutic use as mentioned earlier.

If researchers do uncover full embryonic potential in iPSCs, the cloning controversy will also enter the scene, as the resulting cells would be exact genetic matches of their human donors. If iPSCs do not possess the ability to be completely reverted to embryonic potential, or if regulations against such reprogramming are effective, still being genetically identical to the donor would be a favorable factor. iPSCs are more easily obtained than ESCs owing to fewer research restrictions and greater ease of production, iPSCs may in course of time provide practical and affordable options for production in large scale and regular clinical use of patient-specific therapies. If this becomes the case, iPSCs can eliminate some of the ethical concerns over the unequal distribution of medical therapies based on wealth.

Although iPSCs may seem to directly lend themselves to the idea of patient-specific gene therapies, their usefulness in this field may not be so straightforward. The implications of using genetically altered cells in human therapies may predispose to increased health risk posed by the potential oncogenic, or cancer-causing, nature of the added genes in iPSCs. There is also general

hesitancy to alter the human genome in a way that may have larger or more permanent modifications than desired. Others argue that failing to maintain the purity of the human genome can be the beginning of events leading to human cloning, human-animal genetic admixtures that may harm the human identity.

Reprogramming and genome editing of cells

The CRISPR technique, a new research tool (clustered regularly interspaced short palindromic repeats) are DNA loci containing short repetitions of base sequences is a novel form of artificial genome editing. This technique allows more precise and reliable genetic manipulation and represents the future of genomic editing and engineering (13). Initially it was observed in bacteria. CRISPR technology came to the forefront few years back, when scientists realized that the sequences matched those in the genetic material of viruses that attack bacteria. The concept of genome editing started with the two prominent enzymes called nucleases (Zinc-finger nucleases (ZFNs) or transcription activator-like effector nucleases (TALENs)), which bind to and cleave DNA at specific sites (14,15). The limiting factor in the application of these two enzymes is the production of different nucleases for the target DNA sequence. This was expensive in terms of expertise, time and money. The nucleases were not precise, leading to undesirable “off-target” DNA cuts.

With CRISPR, the researchers found that CRISPR’s use of RNA to target the DNA sequence and deliver the cleaving enzyme has significant advantages over the ZFN and TALEN tools. CRISPR’s action is more precise, with less off-target cleaving action. Feng Zhang and team at the Broad Institute encoded multiple guide sequences into a single CRISPR system. This allowed them to edit several different sites within the genome simultaneously (14). Rudolf Jaenisch’s lab at the Whitehead Institute made targeted cuts in mouse genomes (16). They developed mice with sophisticated genome edits—including the insertion of up to 3,000 base pairs of DNA—in one step. They confirmed that non-specific DNA cleavages using the system are quite rare. For

biomedical researchers, this means that mice useful for research into specific diseases can be engineered in weeks, not years, a huge potential boon to pre-clinical progress. The application is phenomenal. But, even without the problems of off-target DNA damage, finding safe ways to deliver gene edits in living human patients remains a formidable hurdle to overcome.

Questions have been raised what this could mean—not only for research and clinical genetic applications but potentially for broader genetic engineering of human IVF embryos, if manipulation of the human germ cells becomes a feasible possibility. If the genome editing can be shown to be useful and possible and safe, then it will eliminate technical difficulties and can revolutionize treatment for inherited diseases. The legal opinion on this is varied in different countries. As per the current regulatory landscape human gene modification in germ cells is not totally prohibited worldwide and there is room for further investigation.

It is now possible to correct a specific point or single mutation at its endogenous locus in patient-specific iPSCs. The gene expression of the corrected form is restored on cell differentiation (13-15). The ideal approach to curing a genetic disease such as β -thalassemia is to correct the mutations that cause the disease. Generation of induced pluripotent stem cells (iPSCs) from the patients’ own somatic cells could provide a rich source of cells for correction of the β -thalassemia mutation. The mutation-corrected iPSCs could be differentiated into hematopoietic stem cell for autologous transplantation as for child in Scenario 1. Such an approach would avoid the problems of immune responses to allogeneic transplantation and the possibility of insertional mutations associated with viral vectors. Even for a 60 year old man as in Scenario 2, where he has to complete responsibilities, it will be a gift of life.

The implications of genome editing are profound and disturbing. If we can engineer a gene with a disease-causing mutation so that it expresses a non-mutated protein thereby curing the disease what more is required? If we can comprehend how

the genome itself is engineered ,will other ,non - disease traits like appearance and athletic ability can also be manipulated? Will couples be able to choose in -vitro fertilization so that they can plan to get a child with optimum qualities even before it's born?

Issues yet to be addressed

First ,the far fetched but a definite possibility of human cloning from one person's skin cells into germ cells . Scientists already have reported progress that could lead to either which gives an individual an option of choosing parenthood at any time from any tissue .

If these cells are used to study or treat degenerative diseases such as Parkinson's or Alzheimer's ,it will be important to know the donor's health history . The donor's personal information and health history must always be linked to the cells .It may be impossible to maintain donor privacy . The foundation of ethical norms of consent and withdrawal may no longer be feasible .

Finally ,the most important aspect - the economics . New concerns may arise about equitable treatment of the donor . In the current era of rapid technology ,in which the individual skin cells may turn into expensive treatments , pharmaceutical testing tools ,or models to study disease ,should the individual get to share in the profit? The famous Moore's case v. Regents of California where he lost the case in spite of his cells being used by the physicians with vested interest and pharmaceuticals , amply illustrates the complex issues involved (17) The case was the background for the novel by Michael Crichton (18) Should the individual donor have a say in the commercial products that his cells ultimately produce?

Summary :

Induced pluripotent stem cell research and applications has high potential in the treatment of many diseases for which there is no cure or treatment at present . After the development of iPSC technology ,the opportunity to perform stem cell research is easier and less controversial compared to embryonic stem cells technology . The ethical issues are many and keep evolving as the technology evolves ,but to name a few-donor's

privacy vs .patient's treatment ,donor's equitable treatment and commercialization vs .distributive justice in the patient care ,cloning vs choice of parenthood with its own pros and cons and sustainability vs overstepping the nature's boundaries . Therapies based on iPSCs require efficient and discerning regulatory bodies and stringent analysis before they can be implemented in full scale to clinical therapies .

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Contribution in JIMLEA

All the readers of this issue and the members of IMLEA are invited for contributing articles, original research work / paper, recent court judgement or case laws in the forth coming issues of JIMLEA. This is a peer-reviewed journal with ISSN registration. Please send your articles to Dr Sushma Pande, e-mail: drsushmapande@gmail.com.

Registerable Medical Qualifications

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Keywords : Medical Degrees, MCI, Medical Councils, Recognized Qualification.

Introduction

There is plethora of Medical undergraduate qualifications granted by medical institutions inside or outside India may not be registerable with MCI. These are not related to Naturopathy, Alternative medicine, Homeo, Unani, Sidha degrees but related to proper modern medicine courses available in medical institutions inside or outside India. One may be prosecuted under IPC s. 467 read with 471 for fake qualification.

What is the legal status of such courses?

The Health Ministry has also informed the state of Haryana that "As far as recognition of any system of medicine was concerned, only three councils under the Government of India — namely MCI, CCIM and CCH — are authorized to do so. No other council has any authority to recognize any degree related to medical sciences or register the medical practitioners and no other council can issue any registration certificate to practice any type of medicine anywhere in India".

As per the Indian Medical Council Act, 1956, no medical college can start a course without the Centers prior permission. Three apex bodies regulate post-graduate education in India: the Medical Council of India (MCI), the National Board of Examinations (NBE) and state medical councils (SMCs). By exact definition, "recognized" post-graduate qualifications are those that are recognized by MCI and are included in the first schedule of the Medical Council of India Act. Though MCI recognizes most of the post-graduate courses conducted by NBE, the qualifications

offered by NBE in the subjects of Family Medicine, Maternal and Child Health, and Hospital and Health Administration are not recognized by MCI. However, that does not make these courses invalid, simply because NBE was established by an act of parliament for the very purpose of awarding post-graduate medical qualifications.

According to the respective state government resolutions, the diploma courses offered by College of Physicians and Surgeons (CPS), Mumbai are recognized by the Maharashtra and Gujarat medical councils. At present, these CPS diplomas are not recognized by MCI.

The qualifications recognized by MCI automatically stand recognized by SMCs, but the reverse is not true. Therefore, for a qualification to be eligible to be registered as an "additional qualification" in the SMC register, it has to be recognized either by MCI or at least by that particular SMC. Diplomate of National Board (DNB) qualifications in subjects which are not recognized by MCI (which have been mentioned earlier above) are not eligible for registration as "additional qualifications" in the SMC register. But as stated previously, all qualifications bestowed by NBE are supported by the Central Government and are very much valid. Hence, it is better to use the term "valid" rather than "recognized" for post-graduate medical courses. In this letter, the term "recognized" means "valid".

Position of paid foreign under graduate degree

The Medical Council of India has made it clear that it will not recognize any foreign medical degree anymore. The council, which regulates all medical colleges in the country, has not permitted foreign

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universities either to start India campus or start a medical course leading to degree equivalent to MBBS in India. As per regulation 9 of the screening test regulations under the Act, Indian Medical Council Act, 1956 the eligibility certificate is valid for candidates only to join a medical institution outside India and obtain a primary medical qualification. They have to undergo screening test on return before they can be registered with any Medical Council. The certificate cannot be used by any student to join an institution in India saying the degrees are awarded by foreign universities.

So many non – MCI unrecognized allopathic degrees available as post graduate courses in form of diploma, degree for payment of fees or payment. eg MD from university of Seychelles and Indian citizens who had obtained medical qualification from Tanzania, Philippines decided to consider the case of the Indian citizens who had obtained medical qualifications from Seychelles on similar basis in view of the law laid down by the Hon'ble Supreme Court of India in *Medical Council of India v. J. Saai Prasanna* {Judgment dated 09/05/11}. The Medical Council of India in similar cases, namely, *Priya Nair and Others* before High Court of Delhi and *Shri Shivaji Dnyandeo Patil* and other filed before the Hon'ble High Court of Bombay has acceded to prayers and accordingly granted registration if the person has qualified the Screening Test. The Board also noted that in accordance with the provisions of "Eligibility Requirement for taking admission in an undergraduate medical course in a Foreign Medical Institution Regulations, 2002 the candidates who have been admitted after 16/04/2010 amendment in any foreign medical institution the candidates must have studied for the entire duration of the course in the same foreign medical institution.

Medical diploma factories in India

Reputed medical journals dedicate to advertisements endorsing unrecognized post-graduate diplomas, fellowship and certificate courses conducted by private institutions and hospitals for MBBS doctors. Judgments make it amply clear that any post-graduate medical course

conducted under any title (diploma, postgraduate diploma, certificate, fellowship etc.) becomes illegal unless it is recognized by MCI and / or the central government.

Since three parallel bodies (MCI, NBE and SMCs) already conduct post-graduate courses independent of each other, the obvious question arises – can we have more? Let us try to understand the ethical and legal issues involved. According to the MCI ethics code regulation 7.20, a physician should not claim to be a specialist unless he / she has a special qualification in that branch. Practicing a specialty, without having a qualification in that branch, amounts to flouting regulation 7.20 of the ethics code. In 2008, the Madras High Court quashed a State government order (GO) which had allowed a certificate course in Diabetology without the prior permission of MCI.

The judges reasoned that the executive power of every State should be exercised ensuring compliance with the laws made by Parliament and any existing law applied in that State. Therefore, the GO was ruled unconstitutional and preventable in view of Entry 66 of List I of the constitution. The judges clearly stated that no course in medical education by any name could be started without the permission of MCI and the central government. In 2011, the Madras High Court declared 11 post-graduate diploma courses conducted by Tamil Nadu Dr MGR University as illegal since they were being conducted without the prior approval of MCI or the central government. Justice N Paul Vasantkumar said "The university is not empowered to grant permission to any institution or medical college to conduct any PG diploma course in medical sciences without prior approval of the central government as required under section 10A(1) of the Medical Council of India Act, 1956." The judge also pointed out that according to the MCI ethics code regulations, 2002, a physician is supposed to suffix only recognized qualifications. The honorable judge said that "Without such recognition, if any person is allowed to suffix PG diploma in medical sciences along with MBBS degree, the general public will definitely get an impression that the physician is a

specialist. Special status can be claimed by any physician only after getting an approved PG diploma and not half-baked diploma courses offered by the university."

Advertisement for fake degrees

Want a medical degree? How about MBBS, BAMS, DAMS or even MD and that too without clearing any entrance exam or PMT test. The college even makes a rather profound claim that a "Doctor who has passed out from here is entitled to practice in any state without any restriction..."

As an afterthought, it adds a rather cryptic proviso: "But the degrees are not for a government job." But a closer look reveals that the degrees offered by the 'college' do not measure up to the acronyms. The stream of medicine that is taught here is neither allopathic nor ayurvedic. Nor, for that matter, is it any known standard recognized in this country.

In fact, MBBS here stands for 'Bachelor of Medicine in Biochenic System', BAMS stands for 'Bachelor of Allopathy patent Medical Specialties and for 'Bachelor of Allopathy patent Medicine and Surgery'. The all-time favorite MD (a one-year course) stands for 'Doctor of Medicine in patent/Biochenic system of Alternative Medicine. The 'medical college' offering these degrees is located in the NIT area and is affiliated to the 'Council of Patent Medicine, Patna, and the Medical Board of Biochenic System, also based at Patna. The college authorities claim that the system of medicine taught in the premises is an 'alternative system' of medicine; it is further contended that there are 153 alternative systems, which are duly recognized in various parts of the world. Union Health Department and various recognized bodies like the Medical Council of India (MCI), the Central Council of Indian Medicine (CCIM) and the Central Council of Homeopathy (CCH) reveal that the courses or degrees offered by the 'college' are not only unauthorized but also illegal and unrecognized.

Supreme Court in Yash Ahuja and others versus Medical Council of India and others, 2009:

Even foreign MBBS degree holders from other countries in India without undergoing screening test are not about to practice allopathic medicine.

When the Medical Council Act prohibits registration of MBBS degree holders from other countries in India without undergoing screening test, it is not open to the medical practitioners of other system of medicine to claim their right to practice in modern medicine without qualification in the said system. In fact, the conduct of screening test for foreign MBBS Degree holders to register in India was upheld by the Medical Council Act, 1956 was amended by the Indian Medical Council (Amendment) Act, 2001. As per Section 13(4A), a person who is a citizen of India and obtains medical qualification granted by any medical institution in any country outside India recognized for enrollment as medical practitioner in that country after such date as may be specified by the Central Government under sub-Section(3) shall not be entitled to be enrolled on any medical register maintained by a State Medical Council or to have his name entered in the Indian Medical Register, unless he qualifies the screening test in India prescribed for such purpose and such foreign medical qualification after such person qualifies the said screening test shall be deemed to be the recognized medical qualification for the purpose of this Act for that person. The amendment made to the Indian Medical Council Act in introducing a screening test for those who qualified outside India also shows the concern of the Government in the matter of public health.

Position of paid foreign post graduate degree degrees :

Recognized medical post graduate qualifications granted by medical institutions outside India not included in the second schedule: Notification Dated 7th March, 2008 issued by Government of India Ministry of Health & Family Welfare (Department of Health & Family Welfare) New Delhi, In exercise of the powers conferred by sub section 4 of the Section 13 of the Indian Medical Council Act, 1956 (102 of 1956), the Central Government, after consultation with the Medical Council of India, hereby makes following further amendments in Part II of the Third Schedule to the said Act, namely: - In the said Schedule under the heading "Part II recognized medical qualifications

granted by medical institutions outside India not included in the second schedule”, after the entries relating to the qualification Doctor of Philosophy (Ph. D.) in Medical Sciences (Dagastan Medical Institute), U.S.S.R.* and below the explanation of the asterisk (*), the following shall be added, namely:

- a) “All post graduate medical qualifications awarded in Australia and recognized for enrolment as medical practitioners in the concerned specialties in that country;
- b) All post graduate medical qualifications awarded in Canada and recognized for enrolment as medical practitioners in the concerned specialties in that country;
- c) All post graduate medical qualifications awarded in New Zealand and recognized for enrolment as medical practitioners in the concerned specialties in that country;
- d) All post graduate medical qualifications awarded in United Kingdom and recognized for enrolment as medical practitioners in the concerned specialties in that country;
- e) All post graduate medical qualifications awarded in United States of America and recognized for enrolment as medical practitioners in the concerned specialties in that country;

MCI unrecognized allopathic degrees – may land you in unnecessary prosecution :

There are so many non – MCI unrecognized allopathic degrees available as post graduate courses in form of diploma, degree and fellowship offered by Indian central and state universities, deemed universities and corporate hospital in collaboration of some foreign organization hospitals, IGNOU and some NGO’s but same are not registerable with MCI hence one may be prosecuted under IPC s. 467 read with 471 for fake qualification

Position of honorary degree

Position of honorary fellowship offered as member, fellow or honorary doctorate by IMA, IAP RCPH, RCOG, similar other royal colleges based abroad but same are not registerable with MCI hence one

may be prosecuted under IPC s. 467 read with 471 for fake qualification like FRSH, MRSH, CGO, CCH etc.

Position of college of physicians and surgeon, Bombay degree and diploma

CPS Fellowships & Diploma Courses are notified by Government of Maharashtra vide notification no. MMC/1096/111/96/Act and vide GR Extraordinary 4-B through notification no. PGM.1010/CR-18 (Part 2)/10/EDU-2 and in the Maharashtra Medical Council Act 1965.

Government of Gujarat has recognized all the Fellowships and Diplomas of CPS to strengthen the infrastructure of the medical fraternity in the state of Gujarat vide Gujarat Government Gazette no. GP-17-MCG-102011-2213-J dated 14th October 2011 notified by Health & Family Welfare Department, Government of Gujarat under the Gujarat Acts. CPS courses are recognized in State of Rajasthan, Union Territory of Dadra and Nagar Haveli.

CPS is registerable since its existence in:

- i. West Bengal Med Council vide Bengal Medical Act 1914.
- ii. Tamil Nadu Med. Council vide TN Medical Act 1914
- iii. Punjab Med. Council vide Punjab Med. Reg. Act 1916
- iv. Orissa Med. Council vide Orissa Medical Registration Act 1961

CPS is Recognized by Govt. of Malaysia at par with other university.

Do not use misleading qualifications like CCH, CGO, ARSH, MRSH, FRSH and FICA, MD(AM) on your letter heads.

Many of us write along with MBBS, CCH, CGO, ARSH, MRSH, FRSH and FICA, MD(AM) etc. and worst you do not any of such degrees and write the same on letter head like Dr. Anirban Choudhury who got his MBBS degree from West Bengal. Later, he was registered as a medical practitioner with the West Bengal Medical Council (WBMC). A few years ago, he shifted to Mumbai and was registered with the MMC.

A complaint was lodged with the MMC, saying

Choudhury was an MBBS, but on his letterhead, he claimed to be a cardiologist. Moreover, he also claimed to have cleared a super-specialty examination. In the letterhead, he also stated that he was a Member of the Royal College of Physicians (MRCP).

The MMC had sent a show cause notice to him and during the course of the hearing; Dr. Choudhury admitted to his mistake and gave the assurance that he would rectify it at the earliest.

A month later, when the complainant brought to the notice of the MMC that Choudhury had still not changed his qualification on his letterhead, he was again summoned before the MMC. After being given a fresh hearing, the MMC passed an order, saying, his registration had been suspended for two months.

Writing CCH, CGO, ARSH, MRSH, FRS and FICA, MD(AM) etc. degrees on letter head not only invite deregistration from medical council as in case of Dr. Anirban Choudhury but also invite provisions of Indian Penal code(IPC), 415, 420, S.

67 and 471, which simply means such people can be booked by police for cheating and fabricating documents or using fake degree documents as genuine, and courts may hear cases and convict them of such offences and may send to jails.

Do's and don'ts

1. Make proper enquiry before undertaking Medical under graduate and post graduate qualifications granted by medical institutions inside or outside India are registerable with MCI or not.
2. Make proper enquiry before undertaking Medical post graduate qualifications granted by medical institutions inside India are registerable with state medical council and MCI or not.
3. So many alternative medicines courses are fake.
4. So many institutional PG courses are fake.
5. Practicing with UG or PG fake degree is punishable offence under Indian penal code.

Indian Medico- Legal Ethics Association

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 and medical 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 and extent of practice, number of beds in case of indoor facilities and depending upon the other liabilities.
- 5) The financial contribution towards the scheme shall be as follows:
- 6) The hospital can become the member of this scheme only if all the members associated with the hospital have their personal professional indemnity under the scheme.
- 7) A trust / committee / company/ society shall look after the management of the collected fund. The scheme shall initially be run in collaboration with the New India Assurance or National Insurance Company.
- 8) The Financial assistance will be like Medical Indemnity welfare scheme, where indemnity part

		Annual Fee for Individual
1	Physician / doctors with OPD Practice (Non Consultants/ Experts)	Rs/- 65 per lakh
2	Physician / doctors with Indoor Practice / Consultants	Rs/- 125 per lakh
3	Physician / doctors with Indoor Practice of Surgery	Rs/- 250 per lakh
4	Physician / doctors with super-specialty, Anesthetist etc	Rs/- 360 per lakh
5	<ul style="list-style-type: none"> ● 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. 	

	No. of Beds	Five Lakhs	Ten Lakhs
1	< 5	Rs/- 7500	Rs/- 12000
2	6 – 10 beds	Rs/- 10000	Rs/- 18000
3	11- 25 beds	Rs/- 15000	Rs/- 26000
4	26- 50 beds	Rs/- 25000	Rs/- 45000
5	51 – 100 beds	Rs/- 35000	Rs/- 65000
6	101- 200 beds	Rs/- 70000	Rs/- 120000
7	> 200 beds	Rs/- 2 Lakhs	Rs/- 3.5 Lakhs

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

Medical colleges/ Corporate hospitals after discussing with hospital administration.

This scheme is for single case; amount shall be calculated on individual to individual basis for extra assistance.

5% concession on payment for three years and 10% concession for payment for five years on individual to individual basis.

- shall be covered by government / IRDA approved companies or any other private company.
- 9) The amount shall be deposited in the Central Indemnity Reserve Fund (CIRF) of the association. 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.
 - 10) Experts will be involved so that we have better vision and outcome of the scheme.
 - 11) The payment to the experts, Legal and med-legal experts shall be done as per the pre-decided remuneration. Payment issues discussed, agreed and processes shall be laid down by the members of these scheme.
 - 12) If legal notice / case is received by member he should forward the necessary documents to the concerned person.
 - 13) Reply to the notice/case should be made only after discussing with the expert committee.
 - 14) A discontinued member if he wants to join the scheme again will be treated as a new member.
 - 15) 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.
 - 16) 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.
 - 17) The scheme can cover untrained hospital staff by paying extra amount as per the decision of expert committee.
 - 18) A district/ State/ Regional level committee can be established for the scheme.
 - 19) There will be involvement of electronic group of IMLEA for electronic data protection.
 - 20) 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].
 - 21) Telephone Help Line: setting up and manning will be done.
 - 22) Planning will be done to start the Certificate / Diploma / Fellowship Course on med-leg issues to create a pool of experts.
 - 23) 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 undertaken for beneficiary of scheme by suitable medium.

The members of Professional Assistance Scheme

Name	Place	Speciality
1 Dr. Dinesh B Thakare	Amravati	Pathologist
2 Dr. Satish K Tiwari	Amravati	Pediatrician
3 Dr. Rajendra W. Baitule	Amravati	Orthopedic
4 Dr. Usha S Tiwari	Amravati	Hospi/ N Home
5 Dr. Yogesh R Zanwar	Amravati	Dermatologist
6 Dr. Ramawatar R. Soni	Amravati	Pathologist
7 Dr. Rajendra R. Borkar	Wardha	Pediatrician
8 Dr. Alka V. Kuthe	Amravati	Ob.&Gyn.
9 Dr. Vijay M Kuthe	Amravati	Orthopedic
10 Dr. Neelima M Ardak	Amravati	Ob.&Gyn.
11 Dr. Vinita B Yadav	Gurgaon	Ob.&Gyn.
12 Dr. Balraj Yadav	Gurgaon	Pediatrician
13 Dr. Dinakara P	Bengaluru	Pediatrician
14 Dr. Shriniket Tidke	Amravati	Pediatrician
15 Dr. Shraddha Tidke	Amravati	Gen Practitioner
16 Dr Gajanan Patil	Morshi	Pediatrician
17 Dr Madhuri Patil	Morshi	Obs & Gyn
18 Dr Kiran Borkar	Wardha	Ob & Gyn
19 Dr Prabhat Goel	Gurgaon	Physician
20 Dr Sunil Mahajan	Wardha	Pathologist
21 Dr Ashish Jain	Gurgaon	Pediatrician
22 Dr Neetu Jain	Gurgaon	Pulmonologist
23 Dr V P Goswami	Indore	Pediatrician
24 Dr Bhupesh Bhond	Amravati	Pediatrician
25 Dr R K Maheshwari	Barmer	Pediatrician
26 Dr Jayant Shah	Nandurbar	Pediatrician
27 Dr Kesavulu	Hindupur AP	Pediatrician
28 Dr Ashim Kr Ghosh	Burdwan WB	Pediatrician
29 Dr Narasimha Vathsalya	Banglore	Pediatrician
30 Dr Lalchand Charan	Udaipur	Pediatrician
31 Dr Ashish Satav	Dharni	Physician
32 Dr Kavita Satav	Dharni	Ophthalmologist
33 Dr D P Gosavi	Amravati	Pediatrician
34 Dr Narendra Gandhi	Rajnandgaon	Pediatrician
35 Dr Apurva Kale	Amravati	Pediatrician
36 Dr Prashant Gahukar	Amravati	Pathologist
37 Dr Asit Guin	Jabalpur	Physician
38 Dr Sanjeev Borade	Amravati	Ob & Gyn
39 Dr Usha Gajbiye	Amravati	Pediatric Surgeon
40 Dr Satish Agrawal	Amravati	Pediatrician
41 Dr Ashwin Deshmukh	Amravati	Ob & Gyn
42 Dr Anupama Deshmukh	Amravati	Ob & Gyn
43 Dr Jyoti Agrawal	Amravati	Pediatrician
44 Dr Sonal Kale	Amravati	Ob & Gyn
45 Dr Gopal Belokar	Amravati	ENT
46 Dr Amit Kavimandan	Amravati	Gastroenterologist
47 Dr Vinamra Malik	Chhindwara	Pediatrician
48 Dr Rishikesh Nagalkar	Amravati	Pediatrician
49 Dr Rashmi Nagalkar	Amravati	Ob & Gyn
50 Dr Ramesh Tannirwar	Wardha	Ob & Gyn
51 Dr Sameer Agrawal	Jabalpur	Pediatrician
52 Dr Sheojee Prasad	Gwalior	Pediatrician
53 Dr V K Gandhi	Satna	Pediatrician
54 Dr Shyam Sidana	Ranchi	Pediatrician
55 Umesh Khanapurkar	Bhusawal	Pediatrician
56 Dr Sushma Khanapurkar	Bhusawal	Gen Practitioner
57 Dr Samir Bhide	Nashik	Pediatrician
58 Dr Rajendra Vitalkar	Warud	Gen Practitioner
59 Dr Kalpana Vitalkar	Warud	Ob & Gyn
60 Dr Kausthubh Deshmukh	Amravati	Pediatrician
61 Dr Pratibha Kale	Amravati	Pediatrician
62 Dr Milind Jagtap	Amravati	Pathologist
63 Dr Varsha Jagtap	Amravati	Pathologist
64 Dr Rajendra Dhole	Amravati	Physician
65 Dr Veena Dhole	Amravati	Dentistry
66 Dr Nilesh Toshniwal	Washim	Orthopedic
67 Dr Swati Toshniwal	Washim	Dentistry
68 Dr Subhendu Dey	Purulia	Pediatrician
69 Dr Laxmi Bhond	Amravati	Pediatrician
70 Dr Sangeeta Bhamburkar	Akola	Dermatologist
71 Dr Aniruddh Bhamburkar	Akola	Physician
72 Dr Nilesh Dayama	Akola	Pediatrician
73 Dr Paridhi Dayama	Akola	Pediatrician

Medico Legal News

Dr. Anil Lohar

Delhi hospital, doctors ordered to pay Rs 64 lakh for negligence in screening eyes of a premature baby

The National Consumer Disputes Redressal Commission (NCDRC) has ordered Maharaja Agrasen Hospital, New Delhi and three of its doctors Dr G S Kochhar (paediatrician), Dr Naveen Jain (paediatrician) and Dr S N Jha (ophthalmologist) to pay Rs. 64 lakh as compensation to the mother of a premature child for the doctors' negligence in screening the infant's eyes resulting in the infant becoming blind for life.

According to the complaint and the child's mother, Pooja Sharma, the baby was in the hospital for nearly five weeks, but during this period the doctors did not carry out the eye screening and as a result no one noticed that the infant's retina was displaced. It was much later when she noticed the baby's abnormal visual response that an eye-check up was done which showed total retinal detachment.

The hospital and its doctors had denied the allegation of negligence and had claimed that the screening was carried out and it had not revealed any problems.

However, a bench of Justice J M Malik (Presiding Member) and Dr S M Kantikar (Member), in its order dated May 10, 2016, said, "We are not convinced whether the ROP (Retinopathy of Prematurity) screening was done by the ophthalmologist on 26.4.2006. The progress sheet is devoid of details about ROP examination viz who performed it, the method, instruments used and drugs (midrates/tropicamide)/anaesthesia used during ROP testing... Thus 'No record means, it was Not done'."

The order further said, "Because ROP is sequential and timely treatment has been proven to reduce the risk of vision loss, it is imperative that at-risk infants receive carefully timed retinal examinations and that all physicians who care for at-risk, preterm infants should be aware of the importance of timing. It should be borne in mind that, screening

for ROP needs to be initiated timely after birth to prevent blindness. It is the responsibility of the caring paediatrician to initiate screening by referring to an ophthalmologist and it is the responsibility of the ophthalmologist to do correct screening and treatment. This has immense medico-legal implications because if a child goes blind due to missed or late screening, then the paediatrician and the ophthalmologist are at a very high risk of litigation."

Source: <http://www.indiamedicaltimes.com/2016/05/17/> By IMT News Bureau

J&J ordered to pay \$55 million to a woman who claimed the use of its talc caused ovarian cancer

New Delhi: Johnson & Johnson was on Monday ordered by a US jury to pay \$55 million to a woman who claimed the use of its talcum powder for feminine hygiene caused ovarian cancer.

In February, the company had been directed to pay \$72 million as compensation to the family of a woman who had died of ovarian cancer, reports The Hindu.

J&J, which is reportedly facing over 1,200 cases accusing it of not adequately warning consumers about its talc-based products' cancer risks, said it plans to appeal against the verdicts.

Source: <http://www.indiamedicaltimes.com/2016/05/04/> By IMT News Bureau

Hyderabad hospital directed to pay Rs 47 lakh as compensation for death due to medical negligence

The National Consumer Disputes Redressal Commission (NCDRC) has directed Yashoda Hospital, Hyderabad to pay Rs 47 lakh to the wife of a patient who died due to medical negligence.

According to the complainant D Uma Devi, her husband D Sadasiva Reddy was suffering from jaundice. He got admitted in Yashoda Hospital, Hyderabad on May 13, 2008. He was advised

Asstt. Professor, Grant Medical College, Mumbai. E-mail : drloharanil@gmail.com

ERCP (Endoscopic Retrograde Cholangio-Pancreatography) with CBD endoscopy.

On May 14, 2008, during ERCP procedure, the doctors administered anaesthesia (Propofol), which resulted into fatal complications in the patient, therefore ERCP procedure was abandoned. The patient was brought out of the operation theatre in an unconscious (comatose) state. He never recovered from coma. After long struggle of two and half years, the patient died on October 12, 2010.

The hospital attributed this sorry state of affairs to the sudden cardiac arrest while conducting ERCP procedure.

Alleging medical negligence, the complainant approached the Andhra Pradesh State Consumer Disputes Redressal Commission, Hyderabad against Yashoda Hospital. The State Commission directed the hospital to pay Rs 10 lakh as compensation. Aggrieved by the impugned order, both the parties filed cross appeals before the National Commission.

In its order passed on April 11, 2016, a bench of Justice J M Malik (Presiding Member) and Dr S M Kantikar (Member), while enhancing the compensation amount from Rs 10 lakh to Rs 47 lakh, said, "The ERCP procedure was not followed by the doctors as per standard guidelines, the Propofol was administered without monitoring and caution. The cardiac arrest was not managed properly, therefore patient suffered coma. Thus, it is the case of medical negligence."

Source : [http://www.indiamedicaltimes.com/2016/04/20/By IMT News Bureau](http://www.indiamedicaltimes.com/2016/04/20/By%20IMT%20News%20Bureau)

Gynaecologist held guilty of negligence in woman's death, gets 3-month RI

In a 16-year-old case, the Bandra magistrate's court has pronounced a senior Mahim gynaecologist guilty of medical negligence in a woman patient's death and sentenced him to three months' rigorous imprisonment. It also granted the family a compensation of Rs 25,000.

Sarasheej Shete, a railway technician, had accused Dr Sharad Gogate of negligence after his wife Sunita (34) died at his nursing home during childbirth in October 2000. The family alleged that the senior doctor, despite living only a floor above his nursing home, was not around in the most crucial hour when she suffered complications.

The order passed by additional chief metropolitan magistrate S M Chandgade comes 16 years after the family lodged a complaint with the Mahim police. The judge held that the doctor failed to exercise proper care and caution in managing the high-risk delivery. The magistrate also fined the doctor Rs 50,000, a part of which is to be given to the family as compensation.

Speaking to TOI, Dr Gogate (67) said he would appeal against the judgement in a higher court. "I cannot divulge any details of the case as the matter is sub-judice. We have appealed to the sessions court. I know that my conscience is clear," said the doctor, who has been practising for nearly 30 years and has delivered over 5,500 babies.

Source : <http://timesofindia.indiatimes.com/> May 26, 2016

AIIMS directed to pay Rs 1 lakh by consumer forum for negligent eye treatment

The All India Institute of Medical Sciences (AIIMS) has been directed to pay Rs 1 lakh by a consumer forum in Delhi to the parents of a girl child for alleged negligence in carrying out transplantation of cornea in her eye.

South Delhi District Consumer Disputes Redressal Forum bench presided by Justice N K Goel asked the hospital to pay the money to the parents of Haryana resident Baby Priyanka, noting that three corneal graftings in her left eye failed consecutively as they were done "without proper care and caution".

According to the complaint, three corneal graftings were performed in the girl's left eye on different dates between 1998 and 2001 by the junior/trainee/new doctors without there being any senior doctor and the junior/trainee/new doctors did the treatment for their practical/learning purposes.

The complaint added that post treatment the girl lost sight in her left eye and was advised for fourth corneal grafting in June 2005 at AIIMS.

AIIMS had denied the allegations levelled against it, reports Indian Express.

Source : [http://www.indiamedicaltimes.com/2016/06/20/By IMT News Bureau](http://www.indiamedicaltimes.com/2016/06/20/By%20IMT%20News%20Bureau)



INDIAN MEDICO-LEGAL & ETHICS ASSOCIATION

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(Surname)

(First name)

(Middle name)

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E-mail : _____

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- A) Experience in legal field (if any) : _____
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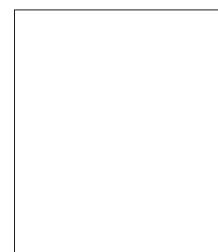
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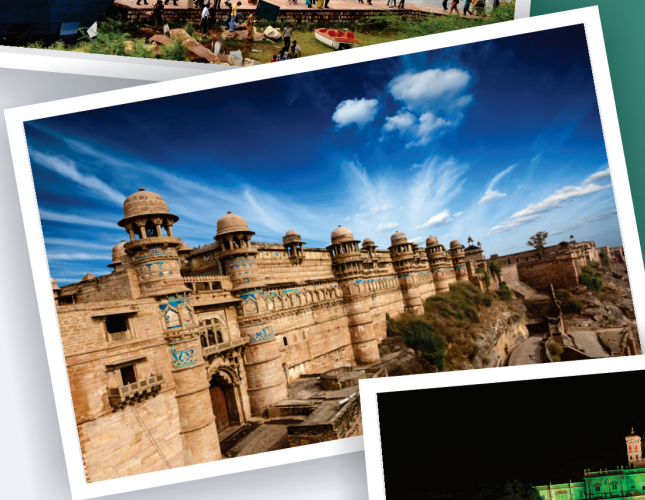


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