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Address for Correspondence:
Apex Hospital, University Road,
Gwalior - 474011, MP, India.
Phone: 2340910, 2340924;
Mobile: 09827383008
Email: editor@imleaindia.org

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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.

Clinical Trials: Human Touch vs Cold Science

EDITORIAL

Dr Mukul Tiwari
MD, DCH, FIAP
Consultant Pediatrician, Apex Hospital, Gwalior
Zonal Chairman, IMLEA
Email: dr_mtiwari@rediffmail.com

Dr Satish Tiwari
M.D (Ped), L.L.B., FIAP, IBCLC
Professor of Pediatrics, Amravati
Founder President, IMLEA
e-mail: drsatishtiwari@gmail.com

Clinical trials means a systematic study of a new drug in human subjects to generate data for discovering or verifying the clinical claims or pharmacological and adverse effects with an aim to determine the safety and efficacy of the drug in question. The stages of clinical trials include, Phase I (Non blind open trial), Phase II (Single blind or double blind), Phase III (Large scale multi-centered) and Phase IV (Post surveillance)[1].

The clinical or drug trials are important to assess the efficacy, safety, cost-effectiveness etc before accepting any drug for the therapeutic, prophylactic or diagnostic purposes. Drug trials are an essential step for pharmaceutical companies in order to win regulatory approval to bring new drugs to market.

The magnitude

Of late, lots of Multinational drug companies are moving their clinical trials base to India. The reasons are a technically competent workforce, patient availability, low costs and a friendly drug-control system. There is another reason not mentioned officially – the companies can get away with irregularities. According to the Associated Chambers of Commerce and Industry, India was set to grab clinical trials business valued at approximately US$ 1 billion by 2010, up from US$ 200 million in 2009. Added to this, has been the mounting quantum of outsourced research facilitated by Contract Research Organizations (CROs) with the promise of cheaper and faster conduct of trials as compared to the west[2]. From 40 to 50 trials in 2003, the country saw around 1850 trials registered with the government registry in June 2011[3]. Mushrooming clinical research courses, often unregulated[4], have sprung up with an aim of servicing the need of personnel for conducting clinical research.

The controversies

As revealed in a Fairfax Media investigation, clinical drug trials are at the centre of a growing controversy in India; evidence has emerged that the patients are being put onto drug trials without their knowledge or consent, when the research subject dies, their families are left without compensation, and doctors are being paid generous commissions to enlist as many subjects as they can. So far, drug companies have been getting away with meager and arbitrary payments sometimes as less as Rs. 50,000 in case of a life lost during a trial including biological and medical devices.

If every piece of research conducted in India was available on a publicly searchable database, one would know what issues are being addressed, and if they are relevant to the population in which the research is being conducted. There are serious flaws in the current trial publication practices. There is a tendency to publish trial results only when they are positive. Information about failures should also be put in a publicly searchable database. The problem is global; almost one in three (29%) large clinical trials in the United States remain unpublished five years after they are finished and almost 78% have no results at all in the public domain. Reportedly, about 250,000 people have taken part in the above unpublished trials and were exposed to the risks involved in research without the benefits to society.

In September 2004, International Committee of Medical Journal Editors (ICMJE) published an editorial on this issue, promoting registration of all clinical trials. It was stated that, from 1 July 2005, only registered trials would be eligible for journal publication. Again, in 2007 the ICMJE stated that it would consider a trial for publication if it had been registered in any WHO Primary Registry.

Previously WHO has taken keen interest in promoting registration of clinical trials. It established WHO ICTRP (International Clinical Trials Registry Platform) which began operations on 1 August 2005. It is committed to harmonizing standards within which trial registers and databases worldwide can operate in a coordinated fashion, providing a global trial identification and search capability, and promoting compliance. This will improve research transparency and will ultimately strengthen the validity and value of the scientific evidence bas.

ICMR (Indian Council of medical research) launched the Clinical Trials Registry of India, in July 2007. It encourages registration of all clinical trials conducted in India even before the enrollment of the first participant. This move of ICMR is expected to bring transparency to clinical trials conducted in India. Clinical Trial Registry, in collaboration with Indian Journal of Clinical research, arranged a meeting of the editors of twelve Indian biomedical journals to develop policies for publication of clinical trials. The editors issued a statement urging all involved in drug trials to register their trials in the Clinical Trials Registry or any other primary clinical trial register. From January 2010 these journals were to consider publication of a trial started in or after June 2008 only if it has been previously registered.

India's Clinical Trials Registry is thorough; it has all the twenty clauses included in the WHO Clinical Trials Registry Platform and also has addition clause such as: declaration of principal investigator's name and address; name of the ethics committee and approval status; regulatory clearance obtained from the Drugs Controller General of India; estimated duration of trial; site(s) of study; phase of trial; brief summary; method of generating randomization sequence; method of allocation concealment; and finally method of blinding and masking.

Though the Clinical Trials Registry is a welcome change in the Indian clinical trial registration process, there are still roadblocks ahead. There is still no legal obligation to register and since its inception in 2007, only 64 clinical trials have been registered. Efforts have been made to encourage voluntary registration, including the Clinical Trials Registry workshops in medical colleges, research institutions, state drug controllers, and non-governmental organizations are invited, but as such, such steps do not seem to be wholly adequate.

Then there is issue of ethics committees – fewer than 40 Ethics Committees in India are properly constituted and functioning. Also there is no legal requirement for investigators or members of the Ethics Committees to declare a conflict of interest. This serious issue considering that an increasing number of hospitals are now owned by drug companies. Clinical trials at such hospitals should carry a statement of disclosure about the relationship.

What should be pre-requisites for clinical trials?

The pre-requisites for the clinical trials include the following:

a) Identifying or selecting a new drug
b) Details of the mode of study to be conducted
c) Agreement from the sponsors
d) An informed consent from the human volunteers
e) Approval of the Ethical committee

What is the role of stakeholders?

The role of various stakeholders, involved from discovery of drug through its manufacturing, marketing, ethical promotion, profit making and others has always been questioned time and again. Recently, in a highlighted case, doctors were alleged to have conducted, between 2008 to 2010, secret trials on children and patients with learning disabilities. They were made to pay paltry fines of less than $100 each. Faced with mounting criticism, the Indian Council of Medical Research in 2011 sought proposals from doctors and health activists on new draft guidelines for compensation for people used in drug trials. The misrepresentation of research by drug industry for their benefit is global. According to a study on the quality of pharmaceutical advertisements in medical journals from 26 countries concluded that the quality of advertising is not what is desirable[5].

Conflict of interests

The conflict of interest includes the interest of the researcher, company or person promoting the research or the drug itself, manufacturers, distributors, prescribers and of course the end users. The interest may again be related to profit making (which includes purchase and sale), claim of the discovery of new molecule, academic interest etc. They have compiled and submitted a report on more than 200 cases in which patients were subjected to trials to check the efficacy of various new treatments without their permission. Indians are being used by companies to make money selling expensive medicines in the West. They are using illiterate and poor Indians who will never be able to afford these kinds of medicines. One of the World's largest Drugs & Vaccine manufacturing Multi National Company (GlaxoSmithKline) was ordered to pay $3 billion in

the largest health care fraud settlement in US history for its use of kickbacks, mis-branding and other misconduct to market drugs. The agreement is the largest healthcare fraud settlement which is "unprecedented in both size and scope", in history, spanning nearly every state, according to the Justice Department. It's also the largest payment ever made by a drug company. The British company illegally marketed the drug, even sponsoring dinners and spa programs in the drug's name. Glaxo also used sham advisory boards and speakers at lavish resorts to promote drug. Customers were urged to use higher-than-approved dosages and also making false claims about the safety and usefulness of such drugs. Glaxo Smith Kline was accused of withholding important safety information about the drug and illegally promoting two other drugs for unapproved uses. The goal was a culture of greed where patient safety took a back seat to profit and where drugs were promoted for disorders though there was no medical evidence that these would help[6].

The role of Judiciary

The judiciary has to be very alert, vigilant, prompt, sincere and strict in implementing the various laws and the provisions as far as the market of spurious drugs are concerned. The judiciary will also have to check, monitor the violations of various safety regulations and exaggerated claims especially for a newer drug.

Supreme Court said that unregulated clinical trials of new drugs were causing "havoc" in the country as it ordered the health ministry to monitor any new applications for tests. The comments were made during a hearing on a petition detailing deaths and health problems caused by clinical trials carried out on Indians, often without their knowledge or consent. According to the court, the Indians are being used like "guinea pigs", and ordered the health secretary to monitor all new applications for trials from pharmaceutical companies. The bench said, "There has to be some sense of responsibility (on the part of the government).You have to protect the health of the citizens of our country. It is your obligation. Death must be arrested and illegal trials must be stayed"[7].

The role of Government

The role of policy makers and government is very important if we want to control the menace of drug trials, ethical use of the essential/ proper drugs and prevention of the misuse of spurious drugs. The role starts from drafting of a proper legislation to the proper implementation of the existing laws. According to data provided by DGCI, Serious Adverse Events of deaths in clinical trials reported during 2008-11 were 2031. During last four years, 2008-12 the total number of clinical trials registered was 2376, according to Health Ministry data. Most of these trials were spread across number of centers and involved number of patients. After over 2,242 deaths during clinical drug trials in last five years, government plans to regulate the $500 million sector by bringing changes in drug laws to make lapses by pharma Multi National Corporations (MNCs) a punishable offence and enhance compensation among other steps. Recently, the health ministry issued a gazette notification making amendments to the Drugs and Cosmetics Rules, 1945. The prescribed changes make it compulsory for all such panels to be registered before giving approvals to clinical trials.

The role of academic organizations

The academic organizations or academicians can provide the evidence based, scientific, unbiased recommendation for the use of any drugs/ medicine. There should not be any conflict of interest between the researchers or academicians as far as the ethical and scientific studies are concerned. The results shouldn't be manipulated for personal interests, profits or gains. It was observed that a group of doctors and a voluntary organization – claim several patients seeking medical help in the central state of Madhya Pradesh were used in drug trials. Doctors are being told what to say - word for word - by the drug manufacturers in their assessment of the drugs they are supposed to be trialing, a parliamentary committee has found. There must be a 'code of conduct' on which the academia- industry relationship must subsist[8].

The Role of Medical councils

As per Medical Council of India regulations 7.22, Clinical drug trials or other research involving patients or volunteers as per the guidelines of ICMR can be undertaken, provided ethical considerations are borne in mind. Violation of existing ICMR guidelines in this regard shall constitute misconduct.

Consent taken from the patient for trial of drug or therapy which is not as per the guidelines shall also be construed as misconduct. According to, "Indian Medical Council (Professional Conduct, Etiquette and Ethics) (Amendment) Regulations, 2009; in dealing with pharmaceutical and allied healthcare industry a medical practitioner shall always ensure that there shall never be any compromise either with his / her own professional autonomy and / or with the autonomy and freedom of the medical institution.

Ethical Issues

There are many ethical issues which needs discussion when we think of any drug or clinical trials. There are so many legal and ethical issues involved with clinical trials and the government has to take initiative in this context. Low costs, weak laws and inadequate enforcement and penalties have made India an attractive destination for the tests, activists say. It has been alleged that illegal and unethical clinical trials were being done on poor persons including juveniles, tribals and dalits who were used as guinea pigs for testing of drugs and vaccines produced by multinational corporations. Ethics committees are set up by various healthcare institutions to ensure the protection of the rights, safety and well-being of human subjects involved in clinical trials. Ethics committees are required to have at least seven members — pharmacologists, legal expert, clinicians, scientists, etc. The idea is to ensure that there are proper ethics committees in place to monitor ongoing trials. Till now, there were no guidelines or rules for such ethics committees operating in the country. "There are ethical violations at every level". "There is a lack of accountability, a lack of monitoring and regulation."

Medical errors and medicines

It is a well accepted fact that any drug which has action will also have some adverse reaction. It is the balance between the adverse reactions and safety margins which increases the pharmacological value of a drug. Today healthcare delivery has become a very complex and tightly inter-locked system. A lapse at any one step is bound to have repercussions on the next steps. Adverse Drug Event is injury resulting due to the administration of drug. It also includes any unintended and undesirable effect of a drug. Medication errors that lead to iatrogenic injuries are a well-known worldwide phenomenon and are common, costly, and clinically important. Incidence rates of adverse drug events amongst adults admitted to the hospital have ranged from 2 to 7 per 100 admissions. What should be done is generally known as the five rights - the right drug, right dose, right route, right time and right patient. Safety is more than just the absence of errors. Safety has multiple dimensions[9].

What needs to be done?

There is a tremendous scope for improvement in the drug trial procedures .From Primum non nocere (non malificience) to complete transparency, there are many areas where there is need for the overhaul of the system. A few suggestions are hereunder

1) There is need to form a Committee of Experts, consisting of members of civil society especially, the All India Drug Action Network, to examine the present legal provisions concerning clinical trials both in India and abroad and to make recommendations for framing guidelines.

2) Strengthen the approval procedures and monitoring mechanism for clinical trials and to ensure safety, rights and well-being of trial subjects, which includes the amendments notified in the Drugs and Cosmetics Rules, 1945.

3) The government should further amend the Drugs and Cosmetics Act to make lapses by pharma MNCs a punishable offence under law,

4) Ensure accountability of this hitherto unregulated sector.

5) Categories for grant of compensation shall be fixed depending on death, severe injury and minor injury and minimum compensation amount should be notified.

6) Transparency is one of the core guiding principles in the ICMR Ethics Guidelines. Institutions and investigators need to put more information into the public domain and ensure timely public dissemination of trial data. The result must be disclosed in the public domain irrespective of whether the drug has succeeded or failed.

7) The number of Ethics Committees (ECs) in the country is rising, but there is no clear estimation

of the total numbers. The quality of conduct of ECs is often quite variable, and also there is no standardized training or orientation for members. Unless there is mandatory registration of ethics committees and an accreditation process, it would be difficult to ensure that ECs are optimally focusing on their core duty of protection of research participants. In a positive development, some ECs in India have voluntarily undergone accreditation through the Forum for Ethical Review Committees in the Asian and Western Pacific Region (FERCAP), and the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRP).There is a need for formal training of EC members in ethics, and networking of ECs. The Forum for Ethics Review Committees in India (FERCI), which recently conducted its first national conference, could serve as a platform to respond to these needs.

8) The role of good mentorship/Guidance is crucial in training research investigators. If the mentors demonstrate and require that trainees conduct research of a high standard, it can help a great deal in producing researchers for the future, who do not cut corners and believe strongly in scientific integrity.

9) Transparency is one of the core guiding principles in the ICMR Ethics Guidelines. Institutions and investigators need to put more information into the public domain: About the kind of research they are carrying out, the rationale for choosing a certain set of participants and the interventions, the standard of care in the research, ancillary care and post-trial obligations etc. While it might not be possible to always disclose proprietary information related to the intervention or some elements about the research, the relevant ethics committee should at least insist on full information being provided. Publication of trial results in public domain should be made compulsory, whether the drug has been successful or failed. There is a tendency to publish trial results only when they are positive.

10) Ethics committee should demand to see the budget of the study, the details of any MoUs signed with the sponsors, as well as details of other sites (in a multi-site study).

11) There is a global need to enhance the public understanding for research, and to develop a civic dialogue around what kind of research is necessary. This will help in creating widespread support for scientific endeavors.

12) Mechanisms of communication being present between research participants and the communities they belong to, and between the researchers and ECs will help avoid misunderstandings developing due to a trust deficit. Scientists should also use the media at local and national levels to explain the rationale for the research which is being conducted, and how it relates to the health priorities in that context.

13) A very good step would be if the Drugs Controller General of India makes it obligatory for all trials to be registered on the Clinical Trials Registry site before permission is granted to conduct them. The failure to do so should carry a penalty. In addition, while registering trials, the composition of hospital ethics committees, which approved the trial, should be disclosed

New regulations in medical research mean that is now more costly and difficult than ever before to conduct trials into new medicines. New regulatory approval and research strategies are urgently needed to speed the development of new, effective, and safer treatments for children if we are to continue to improve the cure rate, reduce toxicity compared to existing treatments, and minimize side effects in later life. Finding subjects for clinical trials can pose challenges for drug makers. The Food and Drug Administration is looking into ways to approve what it calls “breakthrough” therapies. The law defines a “breakthrough” therapy as one that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition. There's always the human factor that sometimes need to understand that even if a particular treatment may not benefit them, it may help others in the future. It's all about finding the right site with the direct access to the patient being sought it becomes an art at some point. Ethics committees, set up to monitor clinical trials in the country, will now have to be mandatorily registered with the central drug regulator. India, as an emerging economy needs to continue to promote a

strong culture of research and development, including in the health sector. However, attention needs to be paid to ensuring that stringent quality checks are built in, and that investigators conduct research in an impeccable manner. Failure to do so will dent the credibility of the research enterprise, affecting not just investigators or institutions conducting research, but also those planning to do so[10]. Finally, we have to decide whether the drug trials shall have human touch or it should be evidence based cold science alone.

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MODEL FORMAT

Consent For Surgical/ Invasive Diagnostic procedures

(Can be printed/filled in local/vernacular language)

Name of procedure _____ Name of the Doctor /Surgeon _____

I/we have been explained and I/we understand the nature of patient's condition and disease process, and the benefits/risks associated with the same. We have also been explained about the failure rate of this procedure/operation.

I/We understand and acknowledge the major risks, complications and side effects (immediate and long term) associated with the surgery, procedures and the anesthetic drugs used for these procedures.

I/We have been informed that there is always possibility of some unexpected complications or finding after starting the procedure. I hereby consent for the additional surgery/procedure as per the need (if arises).

I/we further state that we have been informed regarding anesthetists (including their procedure/complications), assistants, qualified residents and nursing staff.

We have also been informed that the date and time of surgery or procedure may vary due to circumstances beyond control.

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

Name and signature of the patient _____ age/sex _____

S/o / D/o _____

Name, address, signature and relation of the relatives _____

Name and signature of witnesses _____

Date & time _____

Misdiagnosis: Where Do We Stand?

Dr. Charu Mittal
MD, DNB (Obs & Gyn) Consultant Gynecologist, Gwalior
Ex-Asst Prof., Medical College, Baroda, Gujarat
Managing Editor, JIMLEA
Member, Ethics & Medico-legal Committee, FOGSI

Introduction

Preventing mistakes is most of the battle. If one gets mistake-free diagnosis & mistake-free treatment, then almost certainly one gets the best possible health care and the patient only succumbs if the disease is beyond the current range of medical science.

Causes of Medical mistakes are many & varied. Medical mistakes are sadly common. Unfortunately, everyone is human & mistakes are part of humanity.

Medical mistakes can arise at various levels such as Health practitioner, nursing staff, specialist, pathology, Hospital administration, pharmacists, pharmaceutical companies & many other places. The patient can also make various mistakes.

Types of medical mistakes[1]

- Misdiagnosis
- Medication errors
- Surgery errors
- Noso-comial infections
- Laboratory test errors
- Administrative errors or technical errors

About 70% of all errors are believed to be preventable.

The remainder are presumably non-preventable errors such as a patient reacting to a drug who had no previous history of an allergy to the drug.

How common is Misdiagnosis?

Although there is a general feeling that misdiagnosis is quite common, with many people giving anecdotal accounts of their own experiences, it's difficult to get exact data as there is a relative lack of such studies.

Studies of medical errors

To Err is Human: Building a Safer Health System is a report issued in November 1999 by the U.S. Institute of Medicine[2].

Institute of Medicine report, "Crossing the Quality Chasm", 2001

Headline in "Telegraph" Sep 2009: One in six NHS patients 'misdiagnosed' Doctors were making mistakes in up to 15% of cases because they were too quick to judge patients' symptoms, they said, while others were reluctant to ask more senior colleagues for help[3].

National Patient Safety Foundation Survey: A phone survey in 1997 to review patient opinions about medical mistakes showed that 42% of people believed they had personally experienced a medical mistake: that affected them personally (33%), a relative (48%) or a friend (19%). Of these people, the type of mistake they had experienced was "Misdiagnosis or treatment error" in 40% but did not separate misdiagnosis from treatment errors. Unfortunately, the wording in the study for misdiagnosis was "misdiagnosis or wrong treatment", so it is unclear exactly how many were true misdiagnoses or wrong condition treated versus the wrong treatment for the correctly diagnosed condition. In other questions, people reported that they believed their doctor failed to make an adequate diagnosis in 9% of cases, and in another question 8% cited misdiagnosis as a causal factor in the medical mistake[4].

Most common misdiagnoses

A 2009 meta-analysis identified the 5 most commonly misdiagnosed diseases as: infection, neoplasm, myocardial infarction, pulmonary emboli, and cardiovascular disease. Physician familiarity with this information is variable[5].

Outpatient vs. inpatient

Misdiagnosis is the leading cause of medical error in out patient facilities. Ever since the National Institute of Medicine's ground-breaking 1999 report, "To Err is Human," found that up to 98,000 hospital patients die from preventable medical errors in the U.S. each year; government and private sector efforts have focused on inpatient safety.

Diagnosis mistakes: there are various mistakes that

can cause a misdiagnosis of a condition. Misdiagnosis can be one of the most costly of medical errors, leading to delayed, omitted, or inappropriate medical treatments. Any missed diagnosis can be a serious medico-legal problem too.

Self-diagnosis mistakes: when patients diagnose themselves, mistakes are very common. Patients should always seek professional medical advice and should not rely on internet health information.

Not diagnosed: some conditions are not obvious and may be missed, especially if they have no major symptoms.

Wrongly diagnosed: diagnosed as having the wrong condition.

Wrong sub-type of disease diagnosed: the diagnosis might have the correct overall disease, but wrong subtype.

Complications not diagnosed: the diagnosed disease may have various complications that also need to be diagnosed and treated.

Underlying disease not diagnosed: there may actually be an underlying hidden disease causing the already diagnosed disease.

Associated diseases not diagnosed: some types of conditions cluster together, even though they do not cause each other.

Failure to diagnose other people: infectious diseases need to be checked in family members and other exposed people; genetically associated diseases indicate family members may be at higher risk and may need screening.

Why Does Misdiagnosis Occur?

There are many ways that a diagnosis can go wrong. There can be contributing factors from any of the players such as:

- Patient
- General practitioner, Specialist
- Tests (laboratory or pathology tests)

Patient

Patients can contribute to a wrong diagnosis in the following ways:

- Self diagnosis
- Not reporting symptoms
- Failure to complete ordered tests

Doctor - GP/ Specialist

Since the doctor has to make a diagnosis, it is certainly possible to make the wrong diagnosis. The many ways that this can occur are:

- Doctors know only common diseases
- Over-publicized diseases may be over-diagnosed
- Different doctor skill levels
- Doctor bias: If we see a certain disease frequently, we will diagnose it frequently, and might make an error if it is not that disease, but something with similar symptoms.
- To save patient money
- Choice not to analyze deeply
- Lack of time

Lab & pathology tests

The various medical tests that are used to confirm or rule out diagnoses can also sometimes fail. They are useful diagnostic tools, but are not perfect.

- Human errors
- Error margins: denoted by false positives, false negatives. The following case illustrates this limitation of lab tests.

Consumer Disputes Redressal Commission

Sailesh Munjal and Anr. vs AIIMS on 20 May, 2004

The couple had approached the institute in 1989 for prenatal diagnosis as one of their sons suffered from Thal Major & they wanted to know the risk of similar condition in current pregnancy. CVS was performed, tissue sent to UK for genetic diagnosis, where fetus was reported as Thal Minor. Mother was also reported as Thal minor. Pregnancy continued & baby delivered however found to be Thal Major after birth requiring treatment.

Allegation: Misdiagnosis due to maternal contamination of fetal tissue leading to birth of child with Thal major and mental and financial stress of caring for this child.

Defence: no scientific technology can be claimed to be 100% perfect; in all prenatal tests based on DNA technology a small percentage (1 to 2%) of error in the result is possible.

Adequate care was taken in processing the sample however possibly wrong diagnosis was made because of a possible technical error in DNA diagnosis and not due to maternal contamination. On the basis of the report received, defendant had advised the Complainant and his wife that the risk of the disease in the foetus was low (about 1%) which is inherent error rate in DNA-based prenatal diagnostic tests. The parents decided to continue with the pregnancy.

Judgment: inspite of error or imperfection in testing this does not amount to negligence. However it must be ensured that affected child should receive necessary treatment and blood transfusion facilities at institute as needed. No order as to costs.

Error of Judgment vs Negligence

Bona-fide mistake is an Error of Judgment. Mistaken diagnosis [Error of judgment] is not negligence as no human being is infallible - Lord Fraser

Madhya Pradesh High Court

J.N. Shrivastava vs Rambiharilal & Ors. on 27 June, 1980

Diagnosis: acute appendicitis, operated found normal appendix however hugely enlarged GB reaching upto right iliac fossa, GB fundus. Cholecystecomy done.

Allegations: wrong diagnosis, removal of GB without consent.

Comments by judge: "A mistaken diagnosis is not necessarily a negligent diagnosis nor would it imply an absence of reasonable skill and care on the part of the doctor".

"Where a great emergency which could not be anticipated arises, and to rule that it is the surgeon's duty to act in order to save the life or preserve the health of the patient; and that in the honest execution of that duty he should not be exposed to legal liability."

Delayed Diagnosis

A delayed diagnosis is the failure to correctly diagnose a condition. It can occur where no condition is diagnosed at all, or when the wrong diagnosis is given. Delayed diagnosis of any kind is problematic for diseases where an early diagnosis leads to higher cure rates. Delayed diagnosis occurs either due to failure to assess symptoms correctly, or the mismanagement of diagnostic tests.

Consumer Disputes Redressal Commission

Rani Devi vs Dr. Agarwal & Ors. on 14 May, 2002

Deceased husband of the complainant approached the Respondent with swelling on neck, fever & certain other complaints. Consulting Physician advised him for gland biopsy & FNAC. Patient got done FNAC s/o "Cytologically consistent with features of tuberculosis, lymphadenitis associated with secondary pyogenic infection". Seeing this report, doctor started treatment for TB. In the meantime, the deceased contacted Respondent No. 2 who also advised & suggested treatment for TB. Same was repeated after 2 months. Upon not getting any relief, the deceased went to Bhopal and got a biopsy done at Tandon Pathology Lab that diagnosed the hence deceased as having cancer. Confirmation of this came from the Cancer Hospital, Gwalior. The husband of complainant died 3months after biopsy.

Allegation: Wrong diagnosis on the part of all the Respondents. Had they diagnosed the deceased having cancer in time, he would have been treated and saved.

Argument: If there is anyone at fault it is the deceased. He was advised gland-biopsy and F.N.A.C. He only got one test done. Had he got his biopsy done initially, that would have determined the status of the patient. Doctors can only treat based on diagnostic report. There has been no negligence on their part.

Judgment: There is no evidence to prove the basic tenet of medical negligence. Even the main allegation of wrong diagnosis is not proved. No evidence is led in this regard. No cross-examination of the doctor, no expert evidence that the diagnostic test or the line of treatment adopted/advised was not as per medical norms. In the absence of this, the petition fails and is dismissed. No order as costs.

Over-Diagnosed Diseases

There are certain diseases that get over-diagnosed more often than others. This means that the doctor gives this disease as the diagnosis, when in fact there is some other cause or disease.

Under-Diagnosed Diseases

Some diseases get missed more often than others and cause a Failure to Diagnose & lead to majority of malpractice lawsuits.

This is common for conditions that have either no symptoms or only vague or mild symptoms.

Under-diagnosed due to lack of awareness

Rarer conditions under-diagnosed

Dr. Kunal Saha vs Dr. Sukumar Mukherjee & Ors. on 1 June, 2006

Complainant's wife initially diagnosed as a c/o Allergic vasculitis and kept on high dose steroids. No improvement on treatment and was diagnosed as suffering from Toxic Epidermal Necrolysis (TEN) a rare and often fatal disorder whose treatment is largely supportive.

Patient was shifted from Calcutta to Mumbai where patient was kept in strict isolation and monitored closely however she deteriorated and ultimately succumbed. Case filed against all doctors involved in treatment with demand for compensation around 78crores. Complainant (himself a doctor) alleged wrong diagnosis and wrong treatment and high dosage.

Judgement: Diagnosis of such a rare disease is difficult and not simple and depends upon expertise of the medical practitioner, particularly, a Dermatologist. In such a case, can a patient or his relative expect from the medical practitioner that the patient in all cases should be cured. Court noted the interference by complainant in treatment and refusing certain investigations such as skin biopsy. Appeal was dismissed. However when case reached Supreme Court in Oct 2013 compensation of 6 crore was awarded with interest for negligence in treatment and use of incorrect high dose of steroids by attending doctors and hospital.

Types of Wrong Diagnosis

- Totally / Completely wrong diagnosis
- Not sick
- Wrong disease
- Disease missed
- Delayed Diagnosis
- Complications missed
- Wrong subtype of disease
- Medication as underlying cause missed
- Underlying disease missed
- Related disease missed
- Unrelated diseases missed by coincidence

Misreported diagnosis: Wrong labeling of reports has often resulted in consequent damage to the patient followed by claims for compensation. E.g: wrong print of report, wrong print of name, exchanged report of same name patient. This type of case can be described as 'right diagnosis, wrong patient'. However, it can also be a case of 'wrong diagnosis, right patient". For instance, a sonologist missed congenital anomalies in antenatal USG and a malpractice claim followed. "It is a human error but still the onus happens to be with the consultant radiologist". If adequate care is not taken while performing the procedure or reporting, it can be a case of deficiency in service/ negligence.

Inverted lesion group: giving a diagnosis which never existed e.g presence of an IUCD when pt has never used, IUFD when fetus is alive, normal pregnancy as molar pregnancy, normal fetal head as anencephaly.

Complications Misdiagnosed: An important aspect of the diagnosis of a disease is to also diagnose any other complications the main disease may have caused.

This means detecting complications at the original diagnosis, and also ongoing vigilance in watching for any complications that may appear later. This may mean the need for extra diagnostic tests, ongoing screening, and perhaps specialist visits.

Wrong Sub-type Misdiagnosis: Diagnosis of the wrong subtype of a disease is a partial misdiagnosis. Doctors sometimes get the basic disease right but misdiagnose the subtype. Not all subtypes need to be

determined. For example, there are dozens of different subtypes of the common cold, caused by a variety of different viruses such as adenoviruses and enteroviruses. It is rarely important to determine the exact subtype and most doctors do not try to do so and would need specialized tests if they had to separate them. This is all unnecessary as the treatment of a common cold is largely unchanged regardless of exactly which subtype is present

Misdiagnosis of Underlying Condition: An underlying condition is a second condition that a patient has in addition to the first diagnosed condition, and this underlying condition is believed to cause the first condition. In this case, the underlying condition is the true primary condition, since it occurred first, and the originally diagnosed condition is actually called the "secondary" condition. E.g: Metabolic syndrome or PCOS underlying obesity: As an example, women who have the condition of obesity or being over-weight might simply have poor lifestyle habits. On the other hand, they might have an underlying condition such as metabolic syndrome or polycystic ovary syndrome.

Failure to diagnose an underlying condition is a reasonably common occurrence and represents a partial misdiagnosis. In some cases, the misdiagnosis is critically important (such as: hemochromatosis-caused diabetes is curable), and in other cases it is less so; a full diagnosis of underlying metabolic syndrome does not necessarily help treat obesity, though it makes it more important to watch out for other conditions and risk factors for heart disease.

The underlying condition has the first disease as one of its symptoms or complications

Misdiagnosis of associated/ related conditions

Failure to diagnose a related condition is a partial misdiagnosis. There may be related conditions or symptoms present during diagnosis and there may also be an increased risk of contracting related conditions in the future. Vigilance with regard to related conditions is important. Patient and doctor must be aware of related conditions and their symptoms.

What are associated conditions?

Associated conditions are conditions that appear to be related in statistics, but do not have a clear medical relationship. Having a disease may make it more likely that you will have a related disease. Reasons for an association with another disease can vary greatly. There may be an association or relationship between conditions because: Having one condition increases the risk of getting another (i.e. the first disease is a risk factor for the second). Having a particular condition indicates that you are in the risk group for other similar conditions (e.g. having one STD may indicate sexual behavior, puts patient at risk for other STDs). Two conditions may be caused by the same underlying condition (i.e. a third underlying condition): for example, diabetes and hypertension may be related due to underlying metabolic syndrome.

A second condition causes the original condition (i.e. it is an underlying condition).

A second condition is caused by the first disease (i.e. it is a direct symptom or complication).

Underlying conditions cause the disease and complications are caused by the disease. Clearly, both are related to the disease. Associated or related conditions can also be present however these conditions do not cause and are not caused by the original condition.

Misdiagnosis in the emergency dept

The rates of misdiagnosis in the emergency dept or ICU have been studied. The majority of lawsuits involved the ED and of these, the majority involved delayed treatment and therefore presumably related to misdiagnosis.

One study found a rate of 20% of misdiagnosis in the ICU. Other studies have found that it is relatively common for serious conditions such as acute myocardial infarction (heart attack), stroke, pulmonary embolism, meningitis, or appendicitis to be misdiagnosed in emergency care[6]. For example, non-typical presentations such as a young person or a woman having a heart attack are less likely to be correctly diagnosed. Furthermore, a normal ECG test alone does not rule out a heart attack, and some physicians rely too heavily on this test.

These misdiagnosis rates are likely to be higher than the overall health care misdiagnosis rate because of

the time-critical and serious nature of the diagnosis under these crisis conditions.

Misdiagnosis and biopsy: Pathology slide tests involve a workup of a sample onto a slide and then a manual viewing by a pathologist, or more commonly a technician. They are commonly used to identify abnormal cells, such as in cancers. This inherently human process has a clear risk of error and can lead to misdiagnosis.

Malpractice cases and misdiagnosis

Another interesting fact is that a large proportion of malpractice cases are based on misdiagnosis or delayed treatment of serious conditions.

Davenport (2000) lists the top five malpractice-risk conditions in order of prevalence as myocardial infarction, breast cancer, appendicitis, lung cancer and colon cancer, and notes that almost all suits are cases of misdiagnosis or mismanaged diagnostic tests leading to delayed treatment[7].

Myocardial infarction and appendicitis are likely to be related to emergency department visits, whereas the three litigation-prone types of cancers are more common in general physician work.

Ultrasound

When a radiologist does an ultrasound, no matter how careful he or she is, there are certain anomalies which are not seen or are difficult to be seen, for example- missing part of finger, or baby with extra thumb. "Some defects are not always seen even if they are present. So, normally we will put a disclaimer in the report that though no anomalies are seen on this scan at this time - that does not mean that there is no anomaly. But the court usually does not accept this disclaimer,"

The types of medico legal issues occurring in the field of ultrasound are mainly related to misinterpretations and misdiagnosis. This occurs mainly in obstetric scans for fetal anomalies. "This often happens because patients come at wrong gestational age for scanning and fail to realize the limitations of this technique".

Precautions

What exactly is the degree of control a doctor has over his patient? Kindly ponder over these aspects:

- A patient may show up very late in course of illness.
- Patient may come without any record whatsoever of treatment already taken.
- Patient may be hiding facts from the doctor.
- Patient may question the probable diagnosis, drugs prescribed, their role, side-effects, cost, interaction etc. and may avoid taking the prescribed medicine.
- After the consumer (patient) leaves the doctor's clinic with the prescription, can a doctor control subsequent actions ?
- Will all the prescribed medicines be purchased?
- Will prescribed doses be administered at correct intervals?
- Will the full course of treatment be taken?
- What if patient takes treatment for only 2 days instead of 5?
- Will other precautions advised be taken?
- Can the doctor control follow-up of patient?
- Patient may not come at all or come according to convenience.
- Doctor does not know he has improved/ deteriorated / gone elsewhere. Follow-up, which is cardinal component of medical management is entirely beyond the control of the doctor.
- Irregular treatment in tubercular patients, rheumatic heart disease, epileptics etc. is well known.

Patient may comply with doctor's prescription but concomitantly use Homeopathic, Ayurvedic or Unani medicines, the interactions of which are not known. Patient may resort to magic / faith healing. How can a doctor control this? A case of jaundice is advised certain tests, precautions and medicines. Patient may not bother about these and after leaving doctor's clinic may go for "Jhara" (Magic healing). In case of deterioration, how can a doctor's service be held deficient? Some patients refuse investigations without which at times correct management is not possible.

Whenever a patient feels that he is not getting well with the treatment of a doctor/ hospital he is free to leave any moment or to consult any other doctor. Most private hospitals permit consultation with any doctor the patient / attendants wish to. They can always question the rationale of treatment, progress of illness during the course of treatment.

A doctor does not guarantee a diagnosis. It may be a provisional diagnosis or a differential diagnosis on which the treatment may be based. A doctor never guarantees a cure. He makes his best efforts because he knows that much more than anything else, his professional reputation is at stake.

Some Do's

- Mention qualifications on prescription. Qualifications mean recognized degrees / diplomas as regulated by the Indian Medical Degrees Act, 1916 as amended from time to time.
- Mention of scholarships / training / membership / awards which are not qualifications should be avoided.
- Always mention date and timing of the consultation.
- Mention age, sex, weight (if child).
- In complicated cases record precisely history of illness and substantial physical findings on your prescription.
- If the patient / attendants are erring on any count (history not reliable, refusing investigations, refusing admission) make a note of it or seek written refusal preferably in local language with proper witness.
- Mention the condition of patient in specific /objective terms. Avoid vague / non-specific terminology.
- Record history of drug allergy.
- Write name of drugs clearly. Use correct dosages (by revising knowledge periodically) and mention clearly method and interval of administration. Here one must use local or sign language. Do not forget writing precautions like Ast./p.c./a.c./locally/with milk/h.s. etc.
- If a drug is a poison (e.g., certain local applications), warn in writing.
- Mention additional precautions e.g., food, rest, avoidance of certain drugs, allergens, alcohol, smoking etc. if indicated.
- Mention whether prognosis explained. If necessary take a signature of patient / attendant, after explaining the prognosis in written local language.
- In case of any deviation from standard care, mention reasons.
- Specifically mention review, SOS /or follow-up schedule.
- Mention if patient /attendant are / is under effect of alcohol / drugs.
- In case a particular drug / equipment is not available, make a note.
- Mention where the patient should contact in case of your non-availability / emergency.
- Keep updating your knowledge. Read again what you think you already know. You will be in for surprises.
- Routinely advice X-rays in injury to bones /joints.
- Make a diagnosis check list
- Make a list of commonly not diagnosed diseases
- Read rare case reports
- Multiple system checker (one should stress upon having double checks in place and verify it properly).

Some Don'ts

- Do not hesitate to discuss the case with your colleagues/seniors.
- Do not hesitate to discuss the case with patients / attendants.
- Do not write Ayurvedic formulations.
- Do not allow substitutions.
- For goodness sake do not examine a patient if you are sick, exhausted, under effect of alcohol.

- Never talk loose of your colleagues, despite intense professional rivalry. Never criticize your brother in profession.
- The patient /attendants may incite you to say/do something. They may seek your comments on the other doctor's treatment. There is always a polite way to set aside their queries. Remember if you had seen the case from start you would done the same. If your colleague has made error of judgment regarding diagnosis or treatment, you never know under what circumstances this happened.
- Do not adopt experimental method in treatment. If there is some rationale do it only after informed consent.

Once you understand the Duties and Obligations of Doctors carefully and apply them religiously in your day to day practice, you are safe.

There are certain protocols that need to be followed, Ensuring adequate follow up and documentation: There are some simple and effective steps you can take in your practice to ensure adequate follow up and documentation:

Document all recommendations for diagnostic procedures in a diary system.

If the patient does not present for the procedure within a reasonable period of time, make reasonable efforts to contact the patient to find out why he or she did not attend; document the steps you have taken to contact the patient.

Keep a register of outgoing pathology samples and incoming reports, particularly those involving biopsy of tissue or cytology.

Ensure your practice has an effective system to follow up with patients who are given referrals to attend a specialist, and to ensure you thoroughly advise patients of the risk of adverse outcomes if they do not attend the specialist. This is particularly important when the condition for which the patient has been referred is potentially serious. This applies to diagnostic procedures as well.

Thorough documentation should include information on what you and your patient have discussed and the rationale for the proposed management plan.

If you consider that a patient has misunderstood a recommendation or the seriousness of the condition, try to confirm the patient's comprehension before the end of the consultation.

The importance of good record-keeping

Diagnosis-related claims usually focus on the medical decisions taken which caused the delay, and whether those decisions were justified. The single most important issue is the close analysis of all of the factors that led to the delay in diagnosis, beginning with the medical record. Detailed, consistent notes can be very helpful if those decisions have to be defended.

Role of Patient in preventing Medical Mistakes[8]

A patient can do a lot to prevent mistakes in their medical care. They generally can spend a lot more time examining the situation than over-worked medical advisors often can. There are several basic strategies to cut down mistakes overall:

- Get educated
- Get involved
- Ask questions
- Tell your doctor everything
- Research past records

Preventing a Misdiagnosis

There are a lot of things that a patient can do to avoid or reduce the risk of a wrong diagnosis:

- See a doctor
- See a specialist
- Get a second opinion
- Ask for a diagnosis
- Ask questions
- Repeat laboratory or pathology tests
- Repeat the same test
- Different tests
- Different brand of the same tests

- Read test documentation
- Research the disease

Misdiagnosis and autopsy studies

One useful way to detect misdiagnosis is to perform an autopsy, and then compare the original diagnosis with that found at autopsy. Various studies have found major differences, with discrepancy rates as high as 40% in the Medical ICU (CHEST, February 2001). This rate of 40% in the ICU is undoubtedly higher than the rate for general medicine because of the difficult and often multi-factorial nature of serious ICU cases.

Unfortunately, autopsy rates are declining for various reasons and the opportunity to measure misdiagnosis in this way is reduced.

A practical example of a common condition

Ectopic - A physical examination might have helped, but often would not have revealed an ectopic. Ectopic pregnancies are small and often not palpable during physical exam. Tenderness may not always be present. Ultrasound often has variable appearances

Rahul Sinha and others V/s Dr A Mitra and others

The instant case was an operated case of uterine cancer, whereby the CT scan report stated that everything was normal with the patient and there was no trace of cancer, which subsequently turned out to be recurrence of cancer.

The National Commission while dismissing the appeal against the radiologist (Dr Mitra), for wrong report of the CT scan, observed that it is prudent on part of the attending physician to have a careful look at the medical history of the patient before prescribing treatment on the basis of a scan report. Relying totally on the impression of the radiologist in such cases is not correct, particularly when the medical history does create a suspicion of malignancy.

Summary

Diagnoses are not as easy as patients would think, or lawyers would like to make judges believe. No doctor goes to work wanting to make a wrong decision.

Most of the claims / complaints concerning negligence in general practice are often based on allegations of missed diagnosis. In general practice, many of these claims often involve a failure in the practice's systems of documentation & follow up. Another common factor is poor communication between the doctor and patient, or the doctor and other health professionals. It is useful to ensure that the doctor receives consultant findings and lab results; adequate follow-up occurs; doctor-patient communications are well documented.

One of the most effective ways to minimize the risk of missed diagnosis is to develop mechanisms that ensure that communication between care givers themselves & patients is effective.

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Request for Contributing articles

All the members, reviewers, well wishers are requested to contribute articles, case reports, happenings, original studies, research publications as per the guidelines for the authors published in this journal.

Quacks of India and the Law

Dr. Pradip I . Martin
President, Association of Physicians of Surat 2012-13
Surat, Gurat, Mob.: 919426104471
e-mail: healinghandshospital@yahoo.co.in

Definition: "Quack" derives from the 17th century word "quacksalver", in turn from the Dutch word kwakzalver (hawker of salve). Both "quack" and "kwak" originate from the Middle Dutch quacken (to brag or boast). Quacksalvers would appear in town markets offering cure-alls in bottles to anyone gullible to part with their money.

Who is a 'Quack'? "A person who does not have knowledge of a particular system of medicine but practices in that system and a mere pretender of medical knowledge or skills." (Supreme Court of India) AIR 1996 SC 2011 Poonam Verma Vs Aswin Patel. The Oxford Dictionary defines a quack as "a person who pretends to have medical skill or knowledge". The FDA defines health fraud as "the promotion, for profit, of a medical remedy known to be false or unproven." Rough estimates by Indian Medical Association: 300,000 non-qualified practitioners in India. These include: Compounders, Ward boys, Nurses, Lab Technicians, Pharmacists, Dental hygienists, Traditional birth attendants (Dais), Multi Purpose Health Workers Etc.

What is Quackery: As a survey declares "the number of quacks in our country exceeds the number of doctors. Even if one quack causes the death of one patient in one year due to wrong diagnosis and treatment, nearly 95,000 silent murders take place across the country".

It is said that judgments about individual methods should be based on whether or not there is scientific evidence of effectiveness. However, quackery is not confined to charlatans exploiting their victims but also extends to the sale of inappropriate products, or even manufacturers advertising specious products. Lately quackery has been on the rise especially in the rural areas. A survey conducted by AIIMS showed that 93% of the Delhi slum dwellers depend on over 50,000 quacks for medical treatment in Delhi. Organ-trading has been illegal since 1994. But India has done little to curb its "quacks". "They take acute patients and make them chronic," says Dr Kohli, citing quacks who misdiagnose, prescribe steroids as pick-me-ups, mix their own remedies and buy cheap, out-of-date antibiotics. Their most common error is prescribing and selling antibiotics unnecessarily. Sandeep Guleria, a professor at AIIMS in Delhi, says quacks have helped cause the high levels of drug resistance in India.

Quackery in the news

Pakistan also facing problem: Lahore, Sept 11: quacks were doing business openly in the province and playing with patients' lives in the name of medical treatment.

NEW DELHI: Deaths from heart attack and paralysis can only be avoided if the treatment is started within 60 to 90 minutes. Can a quack diagnose the same in the short time? The Delhi Medical Association condemned government's stand of deferring the Anti-quackery Bill in 2003 which was first introduced in 1998. India's private health business is booming, importing flashy technology to serve a growing middle class and foreign "medical tourists". But the public health system remains skeletal. There are only 60 doctors for every 100,000 people in India, compared with 257 per 100,000 in America.

Man who produced 50,000 fake doctors: 25 July 2011. The 90-year-old conman Balwant Rai Arora was arrested at 80, undeterred by a jail sentence of 4 years, has churned out fake medical degrees in near industrial quantities becoming, arguably, the single biggest operator of his kind in the country, producing at least 50,000 fake doctors in Delhi and the NCR over the last 15 years - since 1995 (1). Some 'degrees' like the basics of allopathic medicine and surgery – BAMS have been invented by him. The Medical Council of India (MCI) does not recognize any degree by this name. Arora reportedly issued medical degrees of MBBS, Bachelor of Unani Medicine & Sciences (BUMS), Bachelor of Dental Surgery (BDS), Bachelor of Ayurvedic Medicine & Surgery (BAMS), Registered Medical Practitioner (RMP) and MD. The number of 'degrees' given out by Arora's fake institute so far is more than five times the number of MBBS degrees that four of Delhi's top medical institutes

would have given out in 15 years. The AIIMS has 50 MBBS seats, Maulana Azad Medical College (MAMC) has 250 MBBS seats, the University College of Medical Sciences (UCMS) has 150 MBBS seats and Lady Harding Medical College (LHMC) has 150 MBBS seats. "There are no doctors in the rural areas so they need some persons to help them. I am doing no crime". Said Arora, a winner of " Who is Who of the year 1998" by American Biographical Institute (ABI) Inc. " ABI sells medical degrees and awards in the US which is not acceptable in India,"

Number of Medical College Admissions (Annual) Number of colleges

	Allopathy	Ayurveda	Unani	Siddha	Homeopathy	Naturopathy	Total
India	28,928	10,220	1,595	320	13,035	385	54,483
No. of Colleges	262	225	38	6	182	10	723
Delhi	560	40	90	0	100	0	790
No. of Colleges	5	1	2	0	2	0	10

Quack doctors invaded not only in slum clinics but they can be spotted in nursing homes and some of the major hospitals in Delhi like Max Balaji Hospital, Dharamshila Cancer Hospital, Batra Hospital, Rockland Hospital, Mata Chanan Devi, Sant Parmanand, Sunder Lal Jain, Sri Action Balaji Medical Instititute, Jeevan Mala, Ayushman, Shanti Mukund, Deepak Memorial and Jeevan Anmol Hospitals, from a report of Delhi Medical Council of May 2010. Most of these caught in private hospitals were working as assistants to senior doctors or as RMO. In emergency they are the only doctors in night shifts. The number of registered MBBS doctors in New Delhi is around 40,000 which are sufficient to treat 1.75 crore residents of the national capital. However, each day there is a large influx of patients in the capital from adjoining states, and as a result the registered doctors prove insufficient.

Non-registered clinics rising in Delhi: Presently, the number of non-registered nursing homes is higher than registered ones. There are 600 registered nursing homes in Delhi, whereas the number of non-registered surpasses 1000. In search for cheap medical treatment patients end up visiting fake doctors because government-run clinics are too far away and the queues too long. In many rural areas, there are no clinics. Quacks give high power anti-biotic to the patients which provide instant relief. Quacks are least bothered about the harmful effects of such anti-biotic.

Delhi Medical Council orders shut down of 2 Clinics after quack injection of heavy dose of antibiotics kills 2 kids in Delhi.

Madras High court warns against use of 'Dr.' without valid medical degree in the tug-of-war between physicians and physiotherapists over the use of the prefix ' Dr '. Physiotherapists come under the allied health sciences category. CHENNAI February 24, 2010.

Tamil Nadu: "There are nearly 30,000 quacks in Tamil Nadu. The number of quacks is high in rural areas and most of them have studied only up to class V or VI. There are persons who have studied other systems of medicine but practice allopathy. Quacks are common in fields related to sexual problems, infertility, and abortions which could be very dangerous. At present, if a quack does get arrested, he/she get away with a fine of Rs. 500 or Rs. 1,000 in the absence of a separate law. Woman dies after getting treatment from quack Dindigul, Tamil Nadu, Jan 2012.

Police told to file report on quacks: CHENNAI: The Madras High Court had specifically prevented Vijaya Kumar and his relatives to practice either in Siddha or Ayurveda who cheated a woman for Rs four lakh.

Cops launch crackdown on quacks, open helpline: September 22, 2011 CHENNAI: The Tamil Nadu police have launched a special drive to crack down on quackery and arrested nearly 50 people in four districts on charges of quackery and cheating. Seeking to involve the public in the hunt, the police have opened helplines. Oragadam police arrested S S Murugan, a priest, who owns a clinic and an unlicensed pharmacy, in abortion of eight months pregnant woman.

Most doctors in urban India are not MBBS: August 3, 2013 MUMBAI: Largest chunk of doctors in the country do not hold the MBBS degree, a basic prerequisite to practice modern medicine (allopathy). Instead, they have degrees of alternative medicine like ayurveda or homeopathy, but they may still be prescribing a significant portion of allopathic medicines.

Gujarat: Health at peril - Ahmedabad: March 2012.

Deputy health officer Dr Tejas Shah says 21 fake doctors traced had fake degrees. A few doctors had diploma and bachelor's degree in homeopathy but were practicing allopathy, which is not allowed. There are 50-odd quacks in the city whose names have been submitted to the police by the association and strict action should be taken against them." Quacks on the prowl in the remote areas , VADODARA, January 27, 2004: more than ten bogus medical practitioners have been identified in Karjan-Palej stretch.

Crack down on quacks: HUBLI: Karnataka Ayurvedic and Unani Practitioners' Board (KAUPB). According to a preliminary survey conducted by KAUPB, there are around 80-100 quacks in each district, and their number is more in villages. With 250-300 quacks, Belgaum tops the list in the state and is followed by Koppal, Raichur, Bidar and Yadgir. The reluctance of government doctors to work in rural areas and backward districts is said to be the main reason for the rise in their number.

A medical degree for Rs 17,000! : December 27, 2001 Bangalore: Over 80,000 quacks in Karnataka have got their medical certificates from fake medical colleges. While quacks are spread out over the state, they can be found in large numbers in Bangalore.

Where is Filipino 'faith healer' now? January 18, 2005. BANGALORE: Even doctors agree that faith can heal. The Benny Hinn episode, which is still unraveling itself in Bangalore, is mired in a controversy in Karnataka. In August 2002, a controversy rocked Bangalore when Reverend Alex N. Orbito, a Filipino, claimed to have the powers to heal any disease under the sun with his 'psychic surgery' methods.

Quacks make merry as government flounders-Bangalore: 25 fake doctors, most of them from Bangalore, have been arrested and FIRs filed against them by Venkataramiah, registrar of the Ayurveda, Yoga, Unani, Siddha and Homeopathy (AYUSH) Practitioners' Board, authorized by the government to inspect and file cases against fake medical practitioners. Most of them have only passed the SSLC or PUC exams. With work experience as ward boy or nurse in nursing homes and using fake medical certificates of Indian Multipurpose Medical Welfare Society, Indian Board of Alternative Medicines (affiliated to the UN!), International Association of Educator for World Peace and Rural Medical Practitioners Association of India. They have been running clinics and nursing homes for years." The majority of these quacks practiced allopathy. Interestingly, on verification of the transfer certificate of Vidwan exam one quack was declared Vidwan at the age of 13! Another candidate Nagesh Chilale's Government High School, Rajajinagar record shows March 1976 as last year and surprisingly the Andhra Ayurveda Parishad certified him Vidwan in November 1975. The Lokayukta report also states that most of these certified doctors have only passed high school or SSLC. Mr. Venkataramiah was transferred to be medical officer at a district hospital. With such a government system, how can we check fake doctors?" said Venkataramiah. The AYUSH Practitioners Board also accused the police for not cooperating with them during the investigation and in filing the FIR report.

'Eye surgeons' blind man: November 12, 2003. BANGALORE: Quackery has cost a 35-year-old man his vision. Two "eye surgeons" forcibly poured a plant's sap into the man's eye to treat discoloration, damaging the cornea completely, which have been booked for violation of the Indian Medical Council Act 1950 and Karnataka Ayurveda and Unani Practitioners and Medical Practitioners Miscellaneous Provisions Act, 1961.

Jail waiting for quacks: November 15, 2003 & June 9, 2004. BANGALORE: Complete cure for HIV/AIDS, arthritis and cancer... Reduce obesity in four days... Epilepsy and fistula cure without surgery... Henceforth, "doctors" claiming such magic remedies will be jailed. The health department will invoke the penal clauses of the Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954 and prosecute such doctors. "The number of people starting clinics claiming immediate cure for HIV/AIDS and other diseases is on the rise. Most of them are quacks, which get fake certificates from other states and practice here. On an average, IMA's anti-quackery cell here gets three complaints everyday on fake doctors or quacks. IMA says there are over 75,000 quacks in Karnataka. In 2004 BANGALORE IMA has found in a survey: there are over 5,000 fake MBBS / MD degree holders practicing in posh clinics across Bangalore. And it is brazenly done: the

'quacks' flash their allopathic 'degrees' on their nameplates.

Andhra has 1.5 lakh quack doctors: Mar 28, 2003, Nearly 10,000 such persons operate in Hyderabad and surrounding areas. Such people prefix 'Dr' to their names, examine patients, issue prescriptions and refer patients to qualified doctors. Unless the AP Private Medical Care Establishment (Registration and Regularization) Act 2002 comes into force, these nursing homes and clinics run by unqualified practitioners will thrive.

40,000 quacks in Kerala: THIRUVANANTHA-PURAM, 2004. IMA state branch reports 40,000 quacks practicing modern medicine across the state, especially in villages, equal to 40,000 registered allopathic practitioners in the state.

A survey shows 9,465 quacks in Punjab. May 14, 2003. FEROZEPUR: With government hospitals and dispensaries in rural areas facing shortage of doctors, quacks are having a field day in villages in collusion with the health department officials and local police.

Health dept caught on 'wrong foot' : March 23, 2003. CHANDIGARH: On the occasion of World Tuberculosis (TB) Day, UT health department finds itself caught on the 'wrong foot'. Its decision to sign a Memorandum of Understanding (MoU) with the National Integrated Medical Association (NIMA), the apex organization of graduates in integrated system of medicine, to check the spread of TB here has sparked off a major controversy. Drawing references to the guidelines laid down by the Supreme Court, the Chandigarh branch of IMA has come down heavily on the health department alleging that they are "promoting quackery" risking the lives of thousands.

KOLKATA, 1 lakh and still quacking, June 9, 2004: The medics blame it on the old culprit, "lax monitoring". West Bengal, home to some of the finest doctors in the country, also has an estimated one lakh quacks practicing for years, an estimate diagnosed as "conservative" by the IMA's national president, Sudipto Roy.

KANPUR July 27, 2009. Court refuses bail to Anil Kumar Sachan, posed himself as a doctor accused of manufacturing and selling fake medicine.

Quacks back in business: February 11, 2009. KANPUR: Falling prey to a quack and losing lives has become prevalent in the urban and rural pockets. Interestingly, the health department launched a campaign to curb the menace of quackery in the past few months. But due to the absence of will and determination of the enforcement machinery, coupled with the influence wielded by unqualified and unregistered practitioners, the drive simply went up in smoke and the quacks are back into business.

Electro-homeopathy clinics to be sealed: March 2012 KANPUR: order of Allahabad High Court. "Unrecognized system of medicine which is nothing but quackery" Court dismissed a petition filed by New Delhi-based Indian Electro Homeopathy Medical Council,"

NAGPUR May 13, 2009. The IMA, Nagpur, declared that Dr Patil is a quack claiming to treat even diseases like cancer through his bio-transmission therapy.

Health department to probe quackery: May 23, 2012. NASHIK: The district health office (DHO) suspected 288 quacks, administering allopathic treatment.

November 18, 2012. IMA reports over thousand quacks spread over 333 panchayats of Gaya district practicing medicine in a clandestine manner.

Use of allopathic drugs proves expensive for AYUSH doctors : March 5, 2013. LUCKNOW: As many as 15 of the 40 doctors, accused of prescribing allopathic medicines as the base for the 'powders' and 'tincture tonics' nabbed by the health team were qualified AYUSH doctors -- four ayurvedic, five unani and six homeopaths. They were involved in 'malpractice', which amounts to quackery.

Why quacks thrive?

Why quacks thrive: Bangalore, December 2012. According to the Karnataka Ayurveda and Unani Practitioners Board, there are at least 10,000 illegal medical practitioners in the city. Quacks thrive due to shortage of doctors and their skewed distribution across the State. For more than six crore people in the State, there are only around one lakh doctors. It takes at least five hours to conduct an inspection and raid teams are sometimes verbally and physically abused. They don't have staff for this task.

Government failure: Admitting that the steps taken by the Health Department are "inadequate", Prabhu Chandra, District Health Officer (Bangalore Urban), said that only three raids have been conducted over

the past three months. The Health Department was busy carrying out "development work" and did not have manpower for the task of carrying out raids".

No manpower: Additional Commissioner of Police (Law and Order) T. Suneel Kumar said that although the police have suo moto powers to conduct inquiries, they don't have the manpower. Once the raids are conducted, the documents and certificates seized are sent for verification to the institutions that could be located anywhere in the country. "By the time we receive [the feedback] the person concerned disappears. Though we have suo moto powers to investigate, we cannot [take someone into custody] unless we have concrete proof to book him under the appropriate sections," he said. He called for greater participation by the Health Department to tackle the menace.

Procedural Delay: On an average, Delhi Medical Council (DMC) receives around 350 complaints about quacks annually. In their monthly meeting, DMC initiates action on six to seven complaints. Due to the slow rate of action against fake doctors, several complaints have been pending for past many years. This is one of the major reasons behind the increasing number of quacks in the capital. There are only four doctors in the anti-quackery cell of DMC, set up to control fake doctors. These four doctors are not given any additional payment for the task. They have been assigned the task of formulating policies and initiating action against quacks. The committee does not have its own network and no additional staff has been allotted to them.

Easy let off for culprits: In the absence of strict rules, the confidence level of quacks has been on a rise. In the last three years not even a single doctor has faced complete punishment because they are easily granted bail. As per DMC quacks will be sentenced to a three-year jail or will be fined for Rs 20,000 or both. Central Government had made an Act in 1956, which awards two years of imprisonment or Rs 2,000 fine or both. To check quacks the government does not have its own network.

Community hostility: Usually, raids are conducted by the Police Department and the District Health Officer or the District Ayush Officer. The local community opposes such action against the "unauthorised practitioners". In one instance in Tumkur district, member who opposed the raid says: "There was nobody to save my son at midnight and this doctor helped him."

Number of Registered Medical Practitioners (Government & Private) 2006

	Allopathy	Ayurveda	Unani	Siddha	Homeopathy	Naturopathy	Total
India	668131	443634	46230	17560	216858	541	1392954
% of Total	48	32	3	1.2	15	0.03	
Delhi	38311	2264	1049	0	3026	0	44650
% of total	89	5	2.3	0	6.7	0	

Source: Medical Council of India & Central Council of Indian Medicine / Homeopathy / Dept. of AYUSH, MOHFW/ GOI (One doctor per 1,689 populations in India). Almost per 2000 people there is 1 allopathic doctor. And per 1000 people there is 1 doctor of any pathy. Thus there is need of 24, 41, 569 allopathic doctors in India and if we take total no. of doctors of all category of 13,92,954 then still we need another 17,16,746 doctors of any kind for health care need of India to match to western standards.

Factors Contributing to Quackery

System Level: Large population leading to high demands in Health / Medical care, Inadequate infrastructure, health care delivery & qualified / trained human resources, Lack of coordination among various stakeholders, Poor monitoring & vigilance on a regular basis. Long & tedious Law enforcement procedures

Individual Level: Lack of awareness & consciousness among general public, Self Medication, Counter prescription, Shortcut to quick & easy money on the part of 'quacks'.

Measures to Control Quackery: Improving & strengthening the Health Infrastructure & facilities, Improving the public health delivery system, outreach & coverage, Increasing public awareness and consciousness, Reporting quackery & malpractices, Ensured implementation of the Acts / Rules, Active participation of Medical & Health Professional Bodies /Associations. Launch of National Rural Health Mission (NRHM) by honorable Prime Minister of India, 12 April 2005 - for improving health infrastructure, facilities & ensuring service delivery up to the remotest areas in India. Ensuring

efficient functioning of various Medical Councils & implementation of the relevant Acts / Rules. Enhancement of health budgets. Strengthening health human resources with Public Private Partnership & Capacity Building. User friendly website that shares information on Indian good practices & innovations in health services management. REMOVAL OF AMBIGUITY OF LAW FOR QUACKERY.

Indian Medical Association and any other Specialty organization i.e. Association of Physicians of India – API, FOGSI –Federation of Gynecological Societies of India, etc. should see that they do not entertain or allow NON MBBS doctors to attend any of their conferences, CMEs. In fact the Specialists and Super Specialist MUST STOP DELIVERING LECTURES to Organizations of MIXED DOCTORS where there are doctors of all system of medicine are gathered. We have in Surat such local doctors' clubs and area wise doctors association over and above IMA and others. In addition specialists MUST STOP WORKING OR DOING ANY OPERATION AND PROCEDURES in any hospital run by such NON MBBS doctors owned and run hospitals.

IMA must act as POLITICAL LOBBYIST and not simply lick the soles of politicians as they often do in Gujarat. All specialist association should focus on CME and other social activities but PRIME FOCUS OF IMA MUST BE ASKING AND GETTING RIGHTS OF QUALIFIED DOCTORS of modern scientific medicine, like subsidy or concessional rates of electricity, water, telephone, gas supply, bio medical waste disposal charges and municipal taxes for private small nursing homes or hospitals of less than 50 beds, run and owned by qualified doctors of modern scientific medicine, at par with charitable trust owned hospitals across India.

Actions taken so far: Delhi April 2011, MCI prepares a paper on quackery to send to Union Health Ministry. Medical Services Strikes by Karnataka branches of Indian Medical Association in 2001 for 2 days for passing Anti Quackery Act and banning permission to new medical colleges at least for next five years in Karnataka.

Judiciary's Wrong Interpretation

Goa medical council flayed for calling qualified doctors quacks. October 10, 2008. MARGAO: The Goa Board of Indian System of Medicine and Homeopathy (GBISM&H) has asked the Goa Medical Council to render an unconditional apology to the qualified doctors they referred to as quacks.

Traditional doctors get a breather from high court: February 12, 2011 CHENNAI: The police cannot initiate action against registered practitioners of Indian medicine for prescribing allopathic medicines, the Madras high court ruled on Friday on the writ petitions filed by the Tamil Nadu Siddha Medical Graduates Association.

Latest judgment of Allahabad High Court dated 11-5-2012. If an Ayurvedic, Unani, Siddha or homeopathic person practice allopathic medicines his / her clinic should not only be sealed but also an FIR should also be lodged.

Scoring System for Risk of Medico-Legal or Negligence Case

Dr. Satish Tiwari
M.D (Ped), L.L.B., FIAP, IBCLC
Professor of Pediatrics, Amravati
Founder President, IMLEA
E-mail: drsatishtiwari@gmail.com

The beginning of the third millennium has brought us at the doorstep of information and technology era. But these technological advances are not without their inherent drawbacks. The cut throat competition in modern society has resulted in deterioration of moral and human values. The age old doctor-patient relationship is no exception to these negative changes in the society. As the relationship of faith and trust is changing into a buyer-seller relationship, it is the average man who is at the risk of maximum suffering[1]. Since the patient is paying money and going for "doctor shopping"; his expectations are soaring and the end result is naturally frustration if something unexpected happens. The legal cases related to negligence or deficiency in service has increased tremendously in last few years between the patient, relatives and the medical practitioners. ***The Supreme Court in; CA no. 3541 of 2002, Martin F. D'Souza v Mohd. Ishfaq*** has observed that "The medical profession is a noble profession and it should not be brought down to the level of a simple business or commerce. The truth of the matter, sadly, is that today in India many doctors (though not all) have become totally money-minded, and have forgotten their Hippocratic Oath. Since most people in India are poor the consequence is that for them proper medical treatment is next to impossible, and hence they have to rely on quacks. This is a disgrace to a noble profession. The law is a watchdog, and not a bloodhound, and as long as doctors do their duty with reasonable care they will not be held liable even if their treatment was unsuccessful. While this Court has no sympathy for doctors who are negligent, it must also be said that **frivolous complaints against doctors have increased by leaps and bounds in our country particularly after the medical profession was placed within the purview of the CPA.**"

Herewith we have developed a scoring system to assess the risk of Medico-legal cases in your day-to–day practice. The scoring will help the individual practitioner in assessing the risk of having an allegation of negligence while caring for patient. The scoring is based on six different vital issues, criteria or situation, which one has to face daily as far as the legally safe and ethical practice of medicine is concerned.

Criteria	**Score**				
	1	2	3	4	5
Access to Medico-Legal Consultant (Help & Guidance)	All possible help	Written help/ guidance	Discussed	No guidance	No help
Behavior (Communication skills)	Communication with proper skills	Communication with relatives	Communication with "So called Social worker"	With patient but not with relatives	No communication
Consent	Informed	Written	Implied	Blanket	Not taken
Dr-Patient Relationship	Excellent	Good	Average	Poor	Very poor
Expertise in the field	Proper qualification/ experience	No experience	No qualification	Crosspathy	Quacks
Facts /Documentation	Clear, Correct Comphrehensive, Chronological	Record of other colleagues	Improper	Manipulated	Not available

The scoring or grading can be interpreted, analyzed and calculated as follows:

High risk – if the score is 25 – 30

Moderate risk – if the score is 19 – 24

Average risk – if the score is 13 – 18

Minimal risk – if the score is 7 - 12

Negligible risk – if the score is < 7

Limitations of this scoring:

Though the care has been taken to consider various issues related with day-to–day practice, but there may be many other factors which predispose to allegations of medical negligence. The "No risk" group is not there as it is very difficult and practically impossible to learn and acquire all the skills with complete competency or perfection. The laws are interpreted and analyzed differently by different people / experts including legal experts. The scoring may change after provocation of / by the patient, relatives or "So called social workers".

The benefit / outcome:

It is expected that those who want minimum stress or crisis in their practice should follow these parameters very meticulously / judiciously. This scoring may not give full or complete protection against medical malpractice / negligence cases but will definitely indemnify in the hours of crisis.

In, ***Kusum Sharma V. Batra Hospital (S C 10th Feb. 2010)*** the hon, Supreme Court has agreed that, a professional deserves total protection. The Indian Penal Code has taken care to ensure that people who act in good faith should not be punished. Sections 88, 92 and 370 of the Indian Penal Code give adequate protection to the professional and particularly medical professionals.

References:

1) Tiwari SK, Baldwa M. Doctors & Criminal Law, Indian Pediatr 2002; 39:1119-1125

Landmark Judgments

CASE – 1

Contributed by:
Dr Sudhir Mishra
HOD, Pediatrics, Tata Main Hospital, Jamshedpur
Email: drmishras@gmail.com

Jai Prakash Mehta Vs Dr B N Rai

Judgment of National Consumer Dispute Redressal Commission, New Delhi

Lessons from the Judgment

Background

Mr. Jai Prakash Mehta suffered from electric burn injury during the course of his work as a contract laborer in Bihar on 26th June 1998. He was taken for treatment to one Dr. Sanjay Singh who did not take up the case after giving preliminary care (this being a medicolegal case) because of which he approached Dr. B N Rai.

Dr. Rai apparently advised an X Ray of the part and later prescribed some medicines and later again on 5th July 1998. Mr Mehta was referred to IMS BHU for treatment on 12th July 1998. At IMS BHU, he was found to have gangrene of the hand because of which amputation was performed.

Mr. Mehta approached District Forum and later state forum where his appeal was dismissed. Therefore he filed his appeal as revision petition before National Consumer Dispute redressal commission.

Argument of the Petitioner

Counsel for petitioner argued that this is a case of res ipsa loquitor (where facts speak for themselves) as the loss of limb due to gangrene is obvious and that Mr Mehta was being treated by Dr. Rai, who is an ENT specialist, for about two weeks prior to referral.

Defense of Dr. Rai

Dr. Rai took many defenses. First he suggested that the court (National commission) has no jurisdiction as the case was being examined by the labour court. This was not agreed by the court citing supremem court judgment e.g. Karnataka Power Transmission Corporation Vs. Ashok Iron Works (P) Ltd. [(2009) 3 SCC 240], Arvind Mills Ltd. Vs. Associated Roadways [(2004) 11 SCC 545], which ruled that the remedy under the Consumer Protection Act, 1986 is an additional remedy available to the consumer and not in derogation to any other law for the time being in force.

Second, Dr. Rai denied having seen and treated Mr. Mehta on 26th June 1998 citing no evidence. Here the prescription filed by in front of state commission and records of Shanti X Ray Clinic (where it was recorded as x ray was done on reference from Dr. Rai). Court also said that it is untenable as to how Dr. Rai could deny the previous part of his prescription.

Third defense taken was that previous doctor who had seen (Dr. Sanjay Singh) gave some injection which may have caused gangrene. Court ruled that wet gangrene is a known complication of electric burns which are not treated properly.

Learning

1. It does not help to deny having seen and advised/ treated a patient, just because he may not have a prescription.
2. It does not help to try and pull another doctor in the case, who is not considered as negligent by the petitioner.
3. It does not help to challenge the jurisdiction of the court without adequate grounds.
4. Treating a patient belonging to another specialty, it is generally accepted that the competence of the doctor will not be adequate so as to take a rational decision as the court observed "Respondent No.1/Doctor being an ENT specialist did not prima facie possess the medical skills to treat a serious burn injury but which he continued to treat for over two weeks"

CASE – 2

Spring Meadows Hospital & another v Harjol Ahluwalia through K.S. Ahluwalia & Another [(1998) 4 SCC 39] Date of Decision: 25/03/1998

A child was admitted to the appellant hospital with the diagnosis of typhoid. Allegedly Inj Chloroquine was given intravenously following which the child developed sudden cardiac arrest and collapsed . Resident doctor diagnosed cardiac arrest and attempted manual resuscitation. Anaesthetist arrived within half an hour and started the procedure of manual respiration .Senior Paediatrician also arrived on the scene and helped but here was no improvement in child's condition. The child was shifted to the AIIMS(All India Institute of Medical sciences). The doctors at the AlIMS informed the parents that the child's condition was critical and even if the child survived he would live only in a vegetative state due to irreversible damage to the brain. Later, the child was discharged from AIIMS and again admitted to the appellant hospital.

The outcome : The National Commission decided that the child had suffered cardiac arrest because of IV injection of an excessive dose of a drug and that there was considerable delay in reviving the heart, which led to brain damage. The Commission decided that that there was clear dereliction of duty on the part of the nurse and that the hospital was negligent in employing an unqualified person as nurse and entrusting the child to her care. It also held that the resident doctor was negligent since he failed to follow the instruction of the Senior Paediatrician that the injection should be administered by a doctor. The Commission held that since the resident doctor and nurse were employees of the appellant hospital, the latter was Iiable and awarded compensation of Rs 12 .51akh to the chiId and of Rs.5 lakh to the parents for acute mental agony.

Appellent Defence : An objection was filed by the appellant before the commission taking the stand that since no payment was made so as such the complainant was not a consumer within the definition of 'Consumer' in the Consumer Protection Act, 1986. It was argued that that there has been no deficiency or negligence in service on the part of the doctors of the hospital and the negligence, if any, is on the part of the nurse who misread the prescription. It was also argued that immediate steps were taken by doctors, and hospital authorities had summoned three specialists to examine the patient. It was further stated that although the patient was taken to the All India Institute of Medical Sciences by the parents for better treatment ,the patient was admitted in the appellant hospital on compassionate grounds after the discharge from AIIMS ,and full treatment was provided to the patient without any payment and at no point of time there had been any negligence on the part of the doctors attending the minor child in the hospital. It was also urged that in any event the liability to pay compensation would be that of the insurer.

Miss Bina Matthew, the nurse who injected the Lariago injection ,party No.2, filed her objection that she was a qualified nurse and had exercised all diligence and care in discharging her duties. It was further stated that the patient was under the treatment of Dr. Bhutani who had the duty to decide the course treatment and as nurse she was only working under her control and direction. She also stated that as the patent was already taking lariago syrup and when the doctor advised that injection should be given she thought that the same lariago injection to be given and it was the duty of the duty of the doctor to give the injection and take all care.

Supreme court stand : In the appeal of the hospital, the supreme Court observed that because the Consumer Protection Act was a beneficial legislation intended to confer speedier remedy on consumers, its provisions should receive a liberal construction. The Court rejected the appeal of the hospital that the child's parents were not covered within the definition of consumers in s. 2(1)(d) of the Act and thus ,could not be awarded compensation separately. It held that when a child was admitted to a hospital by his parents and the child was treated by a doctor, the parents would come within the definition of consumer .and the child would also be a consumer under the inclusive part of the definition, being a beneficiary of such services. Therefore, both the parents and the child would be 'consumer' and would be awarded compensation.

Medico-legal News

Contributed by:
Dr. Prabuddh Sheel Mittal
Consultant Obstetrician & Gynecologist
Executive Editor, JIMLEA
Email: prabhu.mittal@rediffmail.com

Majority of Malpractice Claims Against Primary Care Doctors Linked With Missed Diagnosis and Drug Errors

A new study published in the online edition of the journal BMJ Open reports that majority of malpractice cases brought against primary care doctors are made up of missed diagnoses of diseases, such as cancer, meningitis or heart disease, and drug errors.

The risk of litigation has not been given a great deal of attention in primary care, say the authors. But with most healthcare contacts taking place in primary care, it is important to characterise the causes and types of claims arising from these encounters, they add. They carried out an extensive trawl 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. And 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 unsuccessful, with only one third of US claims and half of UK claims ending up in a pay-out. But while the number of claims brought against US doctors has remained fairly stable over the past two decades, those brought against Australian and UK GPs have been rising.

The authors acknowledge that it may be difficult to generalise their findings as the term 'primary care' does not mean the same thing in all the countries studied, and none of the healthcare systems is the same. Using legal claims as a proxy for adverse events also has its limitations, they add. But they point out that the threat of litigation can result in "defensive medicine" and over diagnosis and treatment, and that doctors who find themselves on the end of a malpractice claim, often find the process very distressing.

http://www.medindia.net/news
(July 21, 2013 at 11:46 PM)

Family of Girl Who Received Glue Injection Gets £2.8 Million Compensation

The family of a 10-year old girl whose brain was injected with glue during treatment at London's Great Ormond Street Hospital will receive £2.8 million as compensation from the hospital. The payment has been approved by Judge William Birtles at London's High Court with the girl, Maisha Najeeb, being paid £383,000 a year until she turns 19 after which she will

be receiving £423,000 per year for as long as she lives. Maisha was ten years old when she underwent an operation at the Great Ormond Street Hospital For Children NHS Trust and instead of having a dye injected into an artery in her brain, doctors accidentally injected glue leaving her with permanent brain damage. The court heard that absence of labels on the syringes meant that doctors accidentally used the one filled with glue rather than the dye. "We can't wind the clock back. We hope there are now systems and procedures in place to ensure such a tragic mistake cannot be made again", the trust's lawyer Nick Block said.

http://www.medindia.net/news
(January 28, 2014 at 9:47 PM)

High court asks police to make sure no quacks practice in Delhi

The Delhi High Court has directed the city police to ensure that "no quacks are allowed to practice" in the national capital, saying that it affects the fundamental right to life of people. A division bench of Justice P.K. Bhasin and Justice J.R. Midha also expressed concern over the functioning of anti-quackery cell, saying it has not carried out inspections and is making excuse of the non-availability of a government vehicle.

'This appears to be a very shocking state of affairs of the anti-quackery cell,' it said. In its order last week, the bench asked the Additional Solicitor General (ASG) Sidharth Luthra, appearing for Delhi Police that fundamental right of people to get protection of life from unprofessional practitioners or quacks be looked into. 'Additional solicitor general shall also look into all aspects to ensure that no quacks are allowed to practice as it affects the very fundamental right to life of citizens under article 21 of the constitution,' the court said. During the hearing, the court also took into note a report filed by Delhi government's health department on the functioning of the anti-quackery cell. The report accompanied with a chart stated the number of complaints received during 2012-2013 on the issue of quacks in the city. 'The table indicated that in west and north west district, the inspections were not carried out in respect of the majority of the complaints due to the non-availability of a government vehicle. This appears to be a very shocking state of affairs of the anti-quackery cell,' the bench said in its order.

The court was hearing an appeal filed by a man, convicted of causing the death of a woman during an illegal abortion. The man who was a compounder in the clinic had been sentenced to five years imprisonment for causing death of a woman by an act intended to cause miscarriage. Dealing with the appeal, the court decided to take the issue of quacks prevailing in the city. The bench also asked police to convene a meeting of the officials from its department, Delhi government, the Medical Council of India, the Medical Council of Delhi, the Central Council of Indian Medicine and other stakeholders to discuss the issue. Filing a report, ASG Luthra also submitted a status report that under the Delhi Medical Council Act, police has registered 10 cases in the month of January 2014. It also said that under the DMC Act, all doctors were required to display their registration numbers on a board outside clinics. Earlier while ordering inspections, the court had observed that police could consider concentrating on the areas with populations of the poor as the quacks tend to dupe those people.

http://health.india.com/news
(February 21, 2014 at 11:52 am)

Doctors' Rights

Dr. Archana Tiwari
MBBS, MS
Consultant Gynecologist & Obstetrician
Apex Hospital,Gwalior
Email: archana_mukul@yahoo.co.in

Doctors don't just have duties; they also have some rights.....

- A doctor has a right to turn away a patient before starting treatment but he should provide minimal basic care especially in an emergency situation.
- He has a right to select the drugs from wide range of options available, allowed by drug licensing authority of his country.
- A doctor can also select the investigations and method of treatment depending upon various factors.
- He/she has right to obtain a written refusal in case the patient does not want to do as advised.
- If the doctor, for some reasons cannot continue to look after the patient, he/she can delegate the rights/powers to look after the patient to properly trained colleagues, usually with the willingness of patient. However, a better alternative for the practitioners is to start group practice so that one of the regular consultants is always available.
- A doctor can decide regarding visits, fees to be charged and maintenance of the patient's record including its secrecy in certain specific situations.
- To equal treatment and equal benefit of the law in all applications by and dealings with government, the private sector and others.
- Doctors have the right not to be harassed. They have a right to have his/her life protected which includes the right not to be placed in disproportional life-threatening situations.
- To freedom and security of the person which includes the right to physical autonomy and the right to be free from violence.
- To freedom of religion, belief and opinion which includes the right of doctor to act in accordance with their beliefs.
- To freedom of expression which includes the right to express themselves and their opinions without victimisation.
- Doctors have the right to work in an environment that is not hostile in terms of sex, gender, sexual orientation or (presumed) race or ethnicity.
- To an environment that is not harmful to their health or wellbeing, including appropriate management of stressful situations and supervision/ assistance of junior doctors.
- To access to information held by the state and/or private institutions.
- Not to be arrested, detained or accused unlawfully. Doctors have the right not to be forced to take part in any unlawful (bodily) search or seizure and have the right to enquire as to the status of the subject brought to them, as well as the legislation in terms of which this is done.

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

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

		Annual Fee for Individual	**Annual Fee for Hospitals Establishment**
1	Physician / doctors with OPD Practice	Rs. 60 / lakh	Rs. 340 / lakh + Re. 1 / OPD Pt + Rs. 5 / IPD Pt + 7.5 % of basic premium + Service Tax 10.3 % on the Total
2	Physician / doctors with Indoor Practice	Rs. 115 / lakh	
3	Physician / doctors with Indoor Practice of Surgeon	Rs. 230 / lakh	
4	Physician / doctors with superspecialty, Anesthetist etc	Rs. 340 / lakh	
5	• **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.		

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

List of Members
Professional Assistance Scheme
(PAS) IMLEA

Name	*Place*	*Speciality*
Dr. Dinesh B Thakare	Amravati	Pathologist
Dr. Satish K Tiwari	Amravati	Pediatrician
Dr. Rajendra W. Baitule	Amravati	Orthopedic
Dr. Usha S tiwari	Amravati	Hospi/N.Home
Dr. Yogesh R Zanwar	Amravati	Dermatologist
Dr. Ramawatar R. Soni	Amravati	Pathologist
Dr. Rajendra R. Borkar	Wardha	Pediatrician
Dr. Alka V. Kuthe	Amravati	Ob.&Gyn.
Dr. Vijay M Kuthe	Amravati	Orthopedic
Dr. Neelima M Ardak	Amravati	Ob.&Gyn.
Dr. Vinita B Yadav	Gurgaon	Ob.&Gyn.
Dr. Balraj Yadav	Gurgaon	Pediatrician
Dr Kiran Borkar	Wardha	Ob & Gyn
Dr Bhupesh Bhond	Amravati	Pediatrician
Dr R K Maheshwari	Barmer	Pediatrician
Dr Jayant Shah	Nandurbar	Pediatrician
Dr Kesavulu	Hindupur AP	Pediatrician
Dr Ashim Kr Ghosh	Burdwan WB	Pediatrician
Dr Apurva Kale	Amravati	Pediatrician
Dr Asit Guin	Jabalpur	Physician
Dr Sanjeev Borade	Amravati	Ob & Gyn
Dr Prashant Gahukar	Amravati	Pathologist

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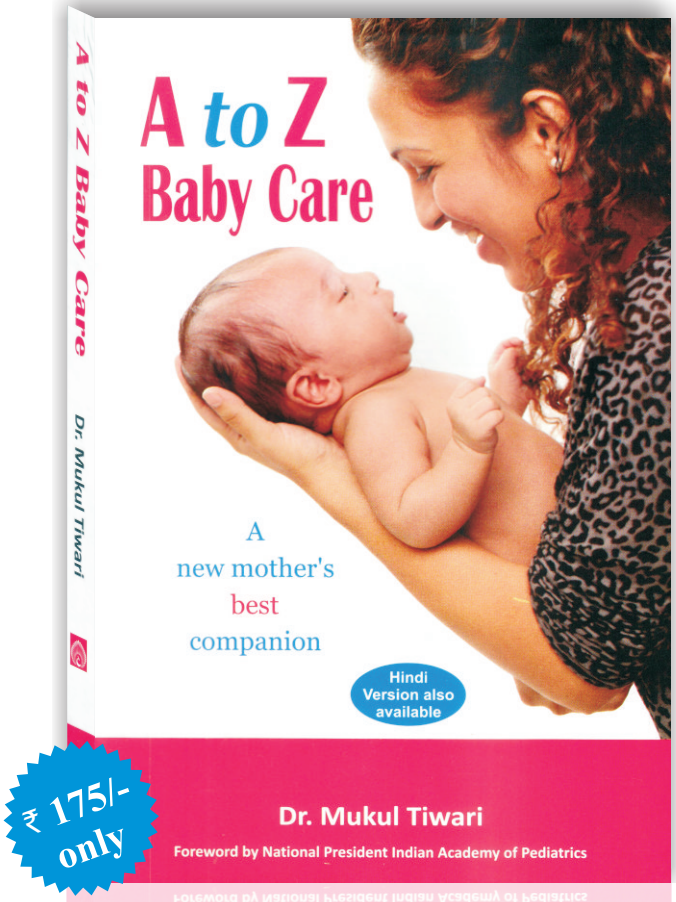

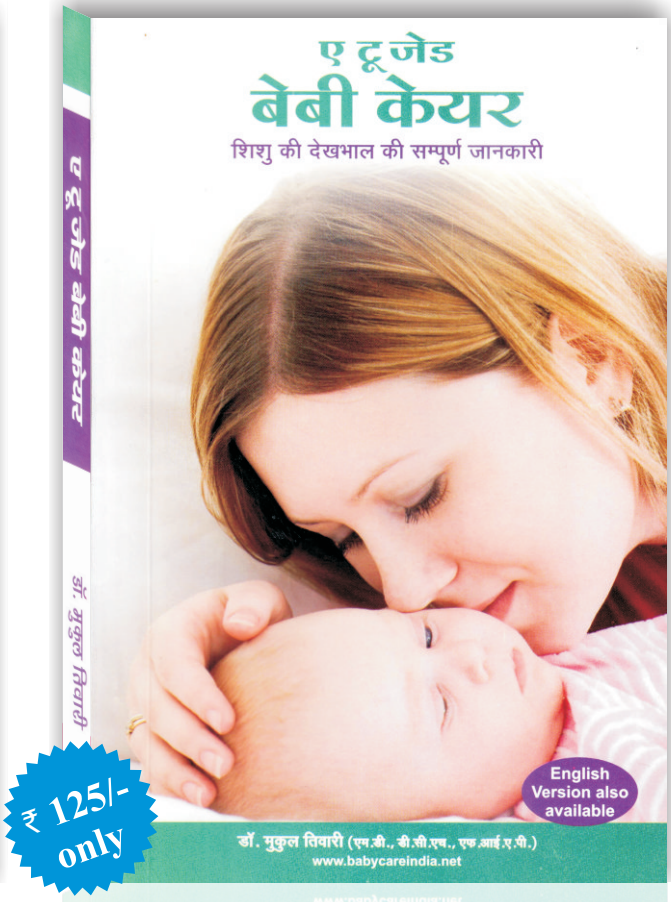

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