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Journal of Indian Medico Legal And Ethics Association

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# Journal of Indian Medico Legal And Ethics Association

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# **Indian Medico Legal And Ethics Association**

Aims & Objectives

- To promote, support and conduct research related to medico-legal, ethical and quality care issues in the field of medicine.
- To help, guide, co-ordinate, co-operate and provide expert opinion to the government agencies, NGO, any semi-government, voluntary, government agencies, legal bodies / institutions and judiciary in deciding settled or unsettled laws or application of laws / rules related to medico-legal or ethical issues.
- To train the medical professionals in doctor-patient relationship, communication skills, record maintenance and prevention of litigations.
- To promote and support the community members and individuals in amicable settlements of the disputes related to patient care, management and treatment.
- To provide specialized training in related issues during undergraduate or postgraduate education.
- To organize conferences, national meets, CME, updates, symposia etc related to these issues.
- 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.

### **Editorial:**

# **Reforms in Medical Education**

\*Dr. Satish Tiwari \*\* Dr. Sushma Pande

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**Key words :** Exit examination, Ghost faculty, Ethical issues, Medical councils, Medical Education Commission, Crosspathy, Gurukul Medical Education.

### Introduction:

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

### **Privatization of Medical Education**

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

### The Medical Council Regulations:

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

According to chapter, 1.4.2 Physicians shall display as suffix to their names only recognized medical degrees or such certificates/diplomas and memberships/honors which confer professional knowledge or recognizes any exemplary qualification/ achievements. This regulation is very ambiguous because the word "or" for the certificates/ diplomas and honors etc doesn't apply to MCI recognized achievements only. Similarly, according to chapter 7.20 A Physician shall not claim to be specialist unless he has a special qualification in that branch(3). Here again the regulations are ambiguous regarding whether the qualifications should be MCI recognized or any qualifications. The effect of these ambiguous regulations or guidelines is that there are many organizations, institutes or bodies who are running unrecognized courses and cheating the students, parents, peoples and the communities. The State Medical Councils which were formed to look in the matters of state wise registration of medical

\* Professor of Pediatrics, Founder President, Indian Medico-legal and Ethics Association Email : drsatishtiwari@gmail.com \*\* Professor of Physiology, Dr. P.D.M.M.C., Amravati., Editor in Chief, JIMLEA. graduates are recognizing such (MCI unrecognized) qualifications for practicing in a particular state only. This is not only creating a confusion in the minds of medical graduates, but it also raises the very vital issue regarding the powers of the various councils as far as regulation of medical education is concerned. There is need to tackle this paradox since MCI is the highest body as far as regulation of medical education is concerned. Hence, if MCI doesn't recognize a particular course or qualification, the various state medical councils can't over rule these MCI guidelines and recognize these courses in their respective states. If a proper decision in not taken on this issue, it will create a chaos in the future because in India we have more than thirty states and each and every state can frame own guidelines and regulations for medical education in their states. So, there has to be a highest regulatory body whose decision shall prevail in case any controversy or ambiguity arises.

### **Role of Regulatory Bodies :**

The regulatory bodies like medical and dental councils have been formed with the aim of regulating the medical education and practice of medicine in different systems. But, recently the health ministry had discussed the option of scrapping the MCI, which has been shrouded in controversy in recent years, altogether(4). The Medical Council of India, often in the news for controversial approvals and corruption, is set to be replaced by a Medical Education Commission that will have three independent wings to oversee curriculum, accreditation of colleges and medical ethics. The new commission could be run by eminent persons from the medical field, who will be allowed to continue their professional commitments. The scandal-hit MCI will be a thing of past as the panel, has sought a detailed overhaul of the medical education regulator that aims to bridge shortages of skilled health workers and address a major hurdle in meeting growing quality health care needs. In past, various private medical colleges mushroomed all over India defying all the prescribed MCI norms. Many institutions are conferring unrecognized degrees, diplomas, certificates etc. and thus cheating the highest regulatory body of India. Cheating of Medical Councils has become a norm rather than exception.

The unethical practice is ignored and guilty doctors remain undetected and unpunished by otherwise highly qualified, resourceful and powerful medical bodies.

### The Present Scenario:

The medical education system has totally failed on cost-effective and input-output analysis. These industries can produce only commercially sound but morally weak graduates. Our health system needs "Barefoot doctors" (as experimented in China) who will serve the masses and not the classes(5). The emphasis is changing from health care for the people to health care by the people.

The teaching faculties in private institutions are mostly part-time, 'daily wage earners', fixed salaried, 'transient teachers' or the so called "Ghost faculties" are substandard and frustrated individuals willing to 'sort things out' as per the need of the management. The Oversight Committee appointed by the Supreme Court to oversee the functioning of the Medical Council of India (MCI) seems to have started cracking the whip. This has been a long-standing demand of those calling for greater transparency to help fight the rampant practice of 'ghost' faculty at medical colleges during inspection by MCI teams and the practice of the same professor being shown as faculty at several colleges(6).

Most of the teachers in clinical specialties who have well-established private practices, hardly find time to teach. Serious teaching and research have been affected badly. The few who are enthusiastic are disheartened by uncongenial atmosphere.

Associated with this, the commercialization of medical education has further deteriorated the already "rotten system". The important issue is whether the higher education shall be the right of a citizen? Should Government nationalize and act as a watch-guard in controlling the corruption and financial mismanagement in running the private institutions of "political heavy-weights"? Are we going to produce ethically and morally motivated graduates from these "Money spinning educational factories"? The long felt need is that the Government should enact a legislation to provide equal opportunities for higher/professional education to the poorest of the poor citizens. Regretting that some "privilege remains unchanged" even after 68 years of independence, the Supreme Court held that national interest requires doing away with all forms of reservation in institutions of higher education, and urged the Centre to take effective steps "objectively". A bench of Justices noted that despite several reminders to the central and state governments to make merit the primary criteria for super-specialty courses, the ground reality remains that reservation often holds sway over merit(7). While dealing with the issue of reservation in super-specialty courses in medical institutions, the court had said "there should really be no reservation" since it is in the general interest for improving the standard of higher education, and thereby improving the quality of available medical services. It also referred to a body of judgments, asking government authorities to abstain from relaxing the eligibility criteria basing it on various kinds of reservation since it would defeat the very object of imparting the best possible training to selected meritorious candidates.

### **Cross-pathy vs. Integration:**

The crosspathy is one of the highly debated and hottest issues at present. Many state governments are allowing AYUSH doctors to practice modern medicine in their states. The Medical Universities have also asked for Ayurvedic and Homeopathic OPDs in the medical colleges. The Central government is also promoting AYUSH by having a separate department or ministry for them. The modern medicine doctors see this as unlawful, harmful to the society as the AYUSH doctors are "half baked" and not adequately trained in medicines used in allopathy. They are protesting this at various levels. The authorities say that as modern medicine doctors are not giving their services in rural areas, the only option with government is to allow modern medicine practice through AYUSH doctors.

One of the suggestions on the issue is to, integrate the different systems and have a common undergraduate degree. This means that the undergraduate Ayurvedic and Homeopathic courses shall be scrapped or abolished. Some are also of the opinion that the graduates in Dental sciences shall be allowed to do condensed MBBS course. So, one of the option is that at undergraduate level there should be only MBBS or BBMS (Bachelor of Basic Medical Sciences) where the students shall be taught about some of the common medicines from allopathy, ayurvedic, homeopathy and dental science etc. The specialization in ayurvedic, homeopathy or dentistry shall be during post graduation i.e. there should be MD, MS in ayurveda, homeopathy etc as we have in Pediatrics, Medicine, Surgery, Orthopaedics etc. The undergraduates can practice all the system of medicine, but those who are MD Avurveda or Homeopathy shall practice only their specialty. In the present scenario this seems to be one of the most practical solutions for the present controversy regarding crosspathy or integration of medical sciences.

### Time for "Gurukul Medical Education"

The big hospitals exist in splendid isolation in the community, acquiring the euphemism "an ivory tower of diseases". Medicine will continue to evolve so long as man's quest for better health continues. But the important issue that arises is that, should we continue with commercialization of medical education? or should we go back to simplified and basic methods of teaching medical sciences? Should there be centralization of medical education and that too in the hands of capitalist or the process should be decentralized in the benefit of common layman in the community. This is the time to review our errors and accomplishments. Can this be included in "Millennium development goals"? The government of India along with Medical Council of India is planning to start medical colleges to educate rural students and deploy them there to provide basic health care to villagers(8). Many villagers rely on indigenous systems of medicine. The doctors taught in villages or small towns (Taluka places) might prefer to work in that area following the footsteps of their "Guru". Thus it can solve the problem of mal-distribution of doctors in remote areas. This means that technical advances in health services are not going to fulfill the dreams of Indian population as well. We are going to provide services to classes at the expense of masses. This trend can't be cost-effective in developing countries like India. What we need is health care for the people that too preferably by the

people. This can be achieved only if we have more health care personals (including qualified medical graduates) catering to the needs of community including rural community.

There are many good academicians who are engaged in private practice. Because of their busy schedule, they are unable to keep pace with technical advances in medical sciences. Teaching liabilities may encourage them to update their knowledge by reading and attending CME, Workshops and Panel discussions etc. There is no paucity of good, morally strong medical teachers (Gurus) even in present era. In fact, the postgraduate medical education is completed under a guide (Guru)(9). Then, what is the harm if, undergraduate candidates are also taught by the Guru? Why we should not allow them to select the shishya from the community and train them for this noble profession? Can Indian method of Gurukul teaching solve this problem of commercialization? The graduates taught in Gurukul can be examined, evaluated by an authorized agency (as we are doing for undergraduate students from overseas universities) and subsequently trained for latest advances in medical sciences at specialty hospitals (Government or Corporate) with minimum expenses and as per the need. In this manner, there are more chances of producing morally strong and qualified graduates. Thus we can achieve the concept of "health care for the people and health care by the people".

### The "Exit examination":

Armed with recommendations from the Medical Council of India (MCI) and the Parliamentary standing committee on health and family welfare, the Centre is considering instituting an exit examination for MBBS students passing out of government and private medical colleges. All students would have to clear the test before they can start practising medicine, as well as to get admission in postgraduate medical courses(10). The proposal to conduct an "Exit examination" is to bridge the gap in any discrepancies in conducting regular examinations in properly equipped medical colleges or ill-equipped medical colleges. It is discussed that a student who passes out from illequipped medical college may be qualitatively poor graduate and his competency and practical

knowledge may be questionable. But, there are many who believe that it is not a particular institute which decides the quality of graduates, but, there are many other reasons. The quality of students, teachers and facilities vary from intra-institute to inter-institute. Hence, it is neither advisable nor recommended to increase the burden (of an extra examination) on the students, on the infrastructure or the resources of the country.

### **Conclusion:**

'Reform' is the buzz word. Not only in medical system but also in other aspects of life and education we need this very urgently especially in context of our prevailing attitude towards health care and physician's accountability. Major reforms are needed in the administration and administrators of the medical colleges(11). Patient care is given more importance than education. Recent resurgence of opinions, views and suggestions in these social medias for the demand of 'Reform' and single entrance test indicates that the time is just right. If we work together and talk in the same language we can achieve our goal. In the current scenario, academic committee of MCI or Medical Education Commission has a prime responsibility for medical reforms in UG/PG education.

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# Perspective -Conspiracy of Silence: Violation of Human Rights during Polio Eradication

Dr. Yash Paul

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**Key words :** Human rights, Oral polio Vaccine, VAPP, IPV, Compensation for polio, Punishment for refusal.

Polio eradication program in India was started in 1995, though belatedly last polio case by wild polio virus was reported on 13th January 2011, it is a great achievement. We all should acknowledge and appreciate the tiring but selfless hard work by millions of citizens in administering Oral Polio Vaccine (OPV) to millions of under five children time and again. We should also acknowledge the role played by the World Health Organization (WHO) and the contributions made by many national and international donors specially Melinda Gates Trust and Rotary International. Indian Academy of Pediatrics (IAP) also participated in this national project. During this program some wrongs were done which should not be overlooked, so that such incidences may not occur in future.

In 1988 the World Health Assembly, during its 41st meeting passed resolution 28, (WHA-41.28) declaring that "World Health Organization (WHO) takes initiative for global eradication of polio exclusively by OPV". The scientific information regarding OPV available at that point of time i.e. 1988 was as following:

- 1. It can cause paralysis in vaccine recipients. It is called vaccine associated paralytic poliomyelitis (VAPP), which in fact is polio disease caused by OPV. It occurs because polio vaccine viruses sometimes back-mutate and reacquire property to cause disease.
- 2. Secondary spread of these mutant neurovirulent vaccine polioviruses can cause VAPP in close contacts ie. some persons may develop disease without taking OPV themselves.
- 3. Some children, especially from tropical and developing countries, show poor response to

OPV and may develop polio disease by wild polioviruses despite taking many doses of OPV. India qualifies on both kinds.

But, the cost factor and ease of administration, as it is given by mouth were important reasons for choosing OPV.

A move in the direction of providing the WHO with more oversight and regulatory power was taken on 23 May 2005 with the revision of International Health Regulations (IHRs), thereby signaling remarkably increased willingness by member states and the organization itself to assert WHO authority not only in coping with emergent, serious communicable disease threats and outbreaks, but also in establishing a firmer international legal basis for international scientific cooperation towards that end(1). Thus, Government of India was expected to participate in this global polio eradication program. But, the Government cannot absolve itself of its responsibility regarding welfare and safety of the children.

It is presumed that pre-launch evaluation of every program is done regarding feasibility, acceptability and relative benefits and harms which would accrue from a program. Such evaluation must have been done for global polio eradication program.

There is also a need for periodic ongoing evaluation of program to assess if the program is providing high benefits. In case it is found that less benefits or more harm is occurring, honest re-evaluation of the whole program should be done; and if needed the program be suspended for some time or even abandoned. Last polio case by wild polio virus was reported on 13th January 2011. No attempts were made by the experts to find reasons for failure and delay in polio eradication. People were blamed that they were not participating in the program i.e. not letting their children be administered OPV drops

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during the Pulse Polio Program.

National Polio Surveillance Project is presently the only agency in the country which collects data for children upto 15 years of age regarding polio cases in India. National Polio Surveillance Project (NPSP) classifies polio cases in following groups:

- 1. Polio cases caused by wild polio viruses, these are called confirmed polio cases.
- 2. Polio cases caused by mutant vaccine viruses in OPV called VAPP cases.
- 3. Polio cases where it could not be determined whether polio was caused by wild polio viruses or by vaccine polio viruses contained in OPV are called polio compatible cases.
- 4. In case mutations in vaccine viruses contained in OPV progress further, these behave like wild polio viruses in capacity to spread and cause disease. These are called vaccine derived polio viruses (VDPVs) cases.

We would like to take up the issues of human rights violations which occurred during polio eradication campaign in India.

# 1. Polio disease caused by OPV is not considered polio disease.

An enquiry instituted by WHO having Albert Sabin the maker of OPV and other 34 international experts concluded that OPV can cause paralytic polio disease (2). An acute flaccid paralysis (AFP) case who fulfills all the clinical criteria (parameters) to be labeled as a case of poliomyelitis, where no wild poliovirus is detected in two adequate samples of fecal matter, but vaccine poliovirus is detected should be considered a case of vaccine associated paralytic poliomyelitis (VAPP). Simply put, it is a case of polio disease caused by OPV. It is pertinent to state that enquiry was instituted by WHO and published in year 1976 in Bulletin of WHO.

In India those children who develop polio disease by OPV are not considered polio cases, which is not only unethical but unscientific also. In July 2013 issue of Indian Pediatrics, in section 'News in brief' under subhead 'Polio in Maharashtra' it was stated: A(n) 11 month old child has been confirmed to have vaccine derived polio virus (VDPV) in the Beed district of Maharashtra on June 1st 2013. This is the third case of VDPV since March 2012 and the first in Maharashtra. There is a suspicion of underlying immunodeficiency in the child since he has been suffering from prolonged bouts of illness. India will not forfeit the polio free label because of this since VDPV is not enumerated in wild polio numbers (3).

In the March 1999 issue of Indian Pediatrics the author had stated: In our enthusiasm to eradicate Poliomyelitis, perhaps we are over-looking the fact that Oral Polio Vaccine has some relative and some definite contraindications. It should not be administered to a child with immunodeficiency and also to a child who is in close contact of a person with immunodeficiency. Such children should be administered Inactivated Polio Vaccine (IPV) (4). In year 2013 IPV was available, still the above mentioned child was administered OPV, who developed polio disease but would not be considered a polio case.

It is necessary to provide information regarding 'Polio Compatible' cases. As stated earlier any child upto the age of 15 years who develops weakness in any part of body is reported to NPSP as a case of acute flaccid paralysis (AFP). Surveillance Medical Officer (SMO) of NPSP of that area examines the child, collects all information and obtains two samples of fecal matter within two weeks of onset of paralysis. In case both stools are negative for wild polio viruses and vaccine polio viruses, or fecal matter could not be collected but after excluding other causes of paralysis like Guillain Barre Syndrome, Transverse Myelitis etc., the child fulfils all the parameters to be labeled as polio case, it is classified as 'Polio Compatible' case.

It can be seen in Table 1 that number of Polio Compatible cases has been high. There may be lack of medical facilities in urban slums and rural areas, parents may not take the affected child to medical facilities, but may approach a 'faith-healer' or take the child to places of worship for blessings of gods. Thus such a case may come to notice of NPSP quite late.

It is great irony that VAPP cases are not mentioned in case classification by NPSP, there is no column for VAPP cases. VAPP cases are discarded as nonpolio cases, and 'polio compatible' and VDPV cases are not counted as polio cases as has already been stated.

### 2. Compensation for Polio cases

In any mass public health program some participants may not derive benefits due to some reasons, but, harm should not occur to any participant. The fact that OPV may cause polio disease in some children was not disclosed to the people so that parents may not refuse to administer OPV to their children. Question arises: Was it a justifiable policy decision? Answer is: It was not only right policy, but, it was necessary also. It is a harsh reality that there is low vaccine coverage in India, many children do not receive any or complete doses of different vaccines during the childhood. In case, had this information been made public, many parents would have refused to administer OPV.

However, if it is indeed to be accepted that the benefits of polio eradication outweigh the withholding of information about the risks of harm, then at the very least, an adequate compensation scheme should have been formulated. Natural justice demands this (5). But, instead of providing some mechanism to provide compensation to these children who develop polio disease by OPV the Government of India punished the families who refused OPV administration to their children.

The Governments give compensation to affected persons or their families following accidents and calamities. Every person who develops harm due to failure of a drug or adverse drug reaction is entitled for damages for drug trial volunteers or cases depending on phase of trial and compensation from Pharma industry or medical personnel or the hospitals. Why should the children who have been harmed by OPV and affected by life long disability be deprived of any legitimate compensation on the ground that this polio eradication program was part of a global program under aegis of WHO?

On 22nd December, 2005 the author had presented a memorandum to the then Health Minister, Government of India, with copies to the Secretary, Ministry of Health & Family Welfare and the then Member of Parliament from Jaipur, but received no communication from any one. On 20th May 2013, the author had sent a memorandum regarding compensation to polio cases to Shri Ghulam Nabi Azad, the then Health Minister, Government of India, but did not receive any acknowledgement or response. On 5th August 2013, the author sent similar memorandum to the Secretary, National Human Rights Commission, New Delhi. A letter from the National Human Rights Commission dated 30th August, 2013, reference No. 1977/20/0/2013 was received informing that the memorandum has been forwarded to the Ministry

of Health, Government of India, but received no further response from the Ministry of Health, Government of India or the National Human Rights Commission.

On 6th October 2014, the author sent a petition to the Council of State (Rajya Sabha), Parliament House for consideration of compensation to those children who had developed polio disease during the polio eradication program. A letter from Ministry of Health and Family Welfare; Ref. No. Z-33011/03/2014-LLSV dated 13th February, 2015 was received. It stated: "Under the Public health system established in India, all types of Acute Flaccid Paralysis Cases, whether polio or nonpolio, are provided free medical care at all health facilities including corrective surgery, regular physiotherapy and rehabilitation."

It is a right idea to provide above mentioned facilities to all people with disability because of polio disease or other reasons. Disability in persons due to non-polio conditions include congenital anomalies (birth defects), birth injury, neonatal asphyxia, neonatal infections, Kernicterus and many more reasons in a newborn baby which may result in permanent disability. Such disabilities can occur later also because of brain infections, brain injury, accidents etc. During the polio eradication program every case of polio disease, vaccine related or wild polio case, who has developed disability, it is because he/she had participated in polio eradication program so rightfully deserves appropriate compassion and compensation, and such children should not be labeled as 'price paid' for the national program.

### Why Compensation?

- 1. Every child who has not been administered OPV drops or IPV injection may not develop polio disease. The child may not be infected by wild poliovirus or if infected may not develop paralytic disease.
- 2. Any child who has received age appropriate number of OPV doses should not develop polio disease. During the Polio Eradication Program many children had developed polio disease even after taking many doses of OPV as can be seen in Table 2.
- 3. No child should develop polio disease because of OPV. Many children had developed polio disease classified as VAPP cases or VDPV cases. Both are not considered polio cases in

India. Number of VAPP cases has never been displayed by National Polio Surveillance Project (NPSP) on its website www.npspindia.org

This means that many children had developed polio disease because either OPV caused the disease or failed to provide protection against the disease.

### Who is eligible for Compensation?

Pulse polio immunization program was started in India on 2nd October 1995. As no proper records of vaccination are maintained, every child living in India and born on or after 2nd October 1995, should be presumed to have received OPV doses during every pulse polio round. Thus, any child who was born on or after 2nd October, 1995, and has developed residual paralysis due to wild polio virus or vaccine polio virus should be entitled for compensation.

### 3. Punishment for Refusing OPV Administration

Hindustan Times dated August 14, 2007 carried news with caption 'Refuse polio drops, lose power and ration cards'. It stated: "In what appears to be a first in Uttar Pradesh, the polio drive is sending a clear message to the people: refusing polio drops will cost them dear. At least two people in the district have had their ration cards cancelled and the power supply to their homes cut for saying no to the immunization of their children." Is penalizing for refusing OPV administration lawful and ethical? The answer is: It is unlawful and unethical.

Immunization against particular disease(s) is compulsory in a number of countries. Punishment for non-compliance include; fines or imprisonment for the parents and refusal of school admission for the children. Compulsory immunization could be justified on the grounds that it promotes the overall health of the population, the common good. This argument cannot be applied to make OPV administration compulsory because it may cause paralysis in some children, and on the other hand it may fail to provide protection to some children who may develop paralytic disease by despite taking many doses of vaccine.

On September 3, 2007 the author had sent a Memorandum to the National Human Rights Commission, New Delhi, salient points are stated here:

OPV administration has not been declared

compulsory. People or the parents of children have a right to refuse a vaccine which has been mandated as compulsory, they have to give reasons for refusal and would be responsible for any harm occurred to them or their family members because of nonvaccination. In the above instances OPV was being forced and penalty imposed for non-cooperation.

A child may not develop polio disease even if the child has not received any polio vaccine. On the other hand a child may develop polio disease despite taking many doses of OPV, because either OPV had failed to protect the child or had actually caused polio disease (VAPP). It can be seen in Table 2 that 2004 onwards percentage of polio cases who had taken more than 7 doses of OPV increased. No caring society and welfare government should condone FORCED administration of OPV which is neither very safe nor very effective, the facts which are known to the experts all over the world.

Through this memorandum following remedies are sought from the commission:

- 1. Forfeited ration cards be returned and the electric power connections be restored to the affected house-holds.
- 2. Appropriate actions be taken against those who in their misguided over enthusiasm have caused inconvenience and hardships to these families.

The complaint was placed before the Commission on October 8, 2007. Commission in its letter dated October 10, 2007 forwarded the complaint to the Secretary, Dept. of Health and Family Welfare, Govt. of Uttar Pradesh, Lucknow. Copy of this letter was sent to the author on March 26, 2008, ie 5½ months later. Reminders were sent to the commission on 23rd April 2008 and 26th May 2008 to know about the status of the case, but there was no response.

Author raised this issue with Medico-legal group of Indian Academy of Pediatrics regarding: (i) Can the parents or caretakers of the children upto 5 years of age be penalized by the local authority or prosecuted in the court of law if they refuse administration of OPV during Pulse Polio Immunization?(ii) Can such punitive action be taken against a doctor who does not administer OPV to those children who have received IPV to avoid any risk of VAPP in close immunecompromised contacts? (6). The medico-legal experts of the group stated: All the national health programs need to have persuasive tone and should never have coercive tenure. Coercion may arrogate with fundamental right enshrined in Article 21 of Constitution of India (7). Many doctors carry the impression that if they say any thing against OPV or some aspects of polio eradication program they will be punished by the government.

On 20th January 2014, the World Health Organization (WHO) declared India polio free country. After some time NPSP not only stopped updating polio data on its website www.npspindia.org; but also removed the past data from its website.

# The Government has no information regarding polio cases:

As stated above NPSP had removed data regarding polio cases, the author sought information from The Ministry of Health & Family Welfare regarding number of cases of vaccine associated paralytic poliomyelitis (VAPP), polio compatible cases and cases with VDPVs which had occurred between 1st January 2011 and 31st December 2015. The author received a Letter Ref. No. Z.33013/02/2016-Imm. Government of India, Ministry of Health & Family Welfare Immunization Division which stated: Please refer to your RTI application dated 10.02.2016 seeking information under RTI Act, 2005. In this regard, it is informed that no data on polio compatible case / cases with VAPPs is maintained by this Ministry. The data on polio compatible case / cases with VAPPs is maintained by WHO and uploaded on their website from time to time".

Through this letter the Government has admitted that it has no information regarding these cases. But, surprisingly the Government is not aware of the fact that WHO (NPSP) has not only stopped updating the data regarding polio cases, but, has removed the past data also.

Deafening silence observed by Indian Academy of Pediatrics, Government of India and National

	1998	1999	2000	2001	2002	2003	2004	2005	2006
Virologically Confirmed	1934	1126	265	269	1600	225	136	66	676
Compatible Cases	2286	1680	362	286	681	370	361	397	494
VDPVs									
	2007	2008	2009	2010	2011	2012	2013	2014	
Virologically Confirmed	874	559	741	42	1	0	0	0	
Compatible Cases	447	538	473	190	54	31	23	0	
VDPVs			21	5	7	1	5	2	

TABLE No. 1: Number of polio cases for year 1998 - 2014

\* Presently no data regarding polio cases is being displayed on NPSP Website.

TABLE No. 2 : Number of OPV doses received by polio cases, 1998-2009

OPV Doses	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
0 Dose	15	14	14	9 16	14	4	0	3	1	1	1	
1 - 3 doses	47	45	28	31 41	35	11	11	10	3	3	4	
4 - 7 doses	32	34	35	41	33	34	41 44	22	12	18	18	
>7 dose	7	8	23	18	11	17	44 45	65	85	78 77		

Source: www.npspindia.org, accessed on 27th July, 2009.

Human Rights Commission on occurrence of human rights violation of children and their parents during polio eradication program is beyond any comprehension.

# How shall Indian Academy of Pediatrics justify its stand on following two issues?

- 1. India is a polio free country. Last polio case by wild polio virus was reported on 13th January 2011, but polio cases caused by OPV have been reported even after 13th January 2011, and as OPV is to be administered till year 2018, some more case of polio disease caused by OPV may occur in future also. It can be said that India had become wild polio free after 13th January 2011, but not polio free country.
- 2. Compensation for polio cases. During the polio eradication program many children had developed paralytic polio disease because in some children OPV administered had failed to provide protection and in some children administered OPV had caused paralytic polio disease. But these children have not been given any compensation.

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# Review Article : Legal Issues faced by the Hospitals

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**Key words :** Legal issues in hospitals, Injury reports, Court Summons, Court Warrent.

The medical profession is a noble profession. Apart from routine clinical cases, a doctor comes across certain Medico legal problems at one time or the other during their profession. Healthcare providers and facilities own a legal duty of care to their patients. In a recent judgment(1). Hon'ble National Commission has observed that, due to the changing scenario of medical advancement and expectation of the patients/ people, it's legitimately expected by the patients or their attendants that the doctor or hospital need to be accountable to a certain degree. If the hospital claims to have super specialty facilities and high cost of treatment; there will be higher expectations of treatment and care.

Often, it is a challenge for doctors to deal with multiple patients around the same time as well as keep the patients' attendants in loop at every step, especially in cases of emergency where every minute counts. When a patient comes in a critical condition, the doctor is responsible for his/ her treatment. The patient attendants are often anxious and tense and expect that doctor would speak to them at length at the same time.

The Indian health care industry is undergoing rapid expansion and in order to survive in the Healthcare market, have competitive edge and growth; hospitals today are training and continuously updating themselves on current issues, challenges and effective methods of Hospital Administration. One of these aspects is legal issues related to health care. Hospital Administrator should be aware about various laws, regulations, policies, procedures, reports required to be submitted in relation to legal issues and various returns to be filed in relation to licensing requirements. Hospital being a very complex system, legal issues in relation to health care is also complex in nature. This article attempts to summarize legal issues in hospitals under following three categories, based on working experience of the hospital.

- A. Legal Issues to be dealt with on day to day basis
- B. Legal Issues to be dealt with as and when they arise.
- C. Statutory and Regulatory licensing requirement.
- A) Legal Issues to be dealt with on day to day basis:
  - 1. Injury Reports required by Police / Public Prosecutor / Court.
  - 2. Court Summons and Warrant of Arrest.
  - 3. Correction of Name and Details.
  - 4. Health Insurance claims processing

### **Injury Reports:**

Reporting of Medico legal Cases are the responsibility of all doctors working in any hospitals in the country. After examination and stabilization of Medico Legal Case, doctors are required to inform police, write Injury report/MLC Report for Court of Law describing injury and the final opinion on the nature of Injury. The injuries are classified as "Simple" or "Grievous" or "Dangerous to life" or "Not Dangerous to life". Injury Report plays a vital role in Charges labeled Case and Section on accused totally depends on the Nature of Injury (Final Opinion by Treating Doctor) (2).

When Police Authority/Court asks for Injury Report from hospital, it is duty of the hospital to provide the same, based on available hospital records. Injury Report is initially prepared on the basis of the medical record prepared by the initial treating doctor and if he is not sure regarding the nature of Injury then final opinion regarding nature of injury is given by Specialist Doctors. A doctor

\* Manager- Medical Records & Compliance, Tata Main Hospital, Jamshedpur. \*\*Head Consultant & HOD Pediatrics, , Tata Main Hospital, Jamshedpur. drmishras@gmail.com who has not examined the patient should not write injury Report in usual circumstances. A sample of injury Report format see Annexure-I.

**In Absence of Treating Doctor:** If Dr. X has left the hospital and Police Authority/Court asks for Injury report of a patient treated by him, it is duty of hospital to provide injury report to concerned police authority/Court. In this situation, any doctor who was posted along with Dr. X in Hospital on that particular date in the same shift can write injury reports of patients mentioning in remarks column "For Dr. X, at present not posted in the Hospital" based on available hospital record. If that doctor is also not available then HOD or Unit Head can write Injury Report.

### **Court Summons:**

Court Summons is an order by Court of Law to appear in person at a given Court, on date and time specified by the Court. Summon is received by hospital for doctors/Hospital Staff. It is responsibility of Hospital Administrator to provide the system to comply with the order of Honorable Court and to produce their witness before Court of Law.

If Summon is received for Doctor/Hospital Staff and that particular person is on leave or for an emergency reason is not able to attend Court, same have to be informed to Court with prayer to schedule next date for appearance before court of Law.

If Summon is received for Doctor/Hospital Staff and concerned person is no longer in service of hospital then same have to be informed to Court. Where the current address of the person is available with the hospital, same should be informed to the Court.

### **Court Warrant of Arrest:**

Chapter five of the Code of Criminal Procedure, 1973 deals with the arrest of persons. If Doctors/Hospital Staffs do not obey the direction of Court (Compliance of Court Summons), Court may issue the Warrant of Arrest to police for production of concerned person before court of Law for their witness in a particular case where (s)he had treated the M-L case. Compliance to Court Order is the responsibility of concerned Police Station and Police official are authorized to arrest the doctor/hospital staff.

In such situation Police Officials considering the

status of medical profession, provide the details of case and help the hospital administrator to take a fresh date and request for recall of the order from court without arresting concerned person.

### Correction of name and details of patient:

When an error is made in a medical record entry, the original entry must not be obliterated, and the inaccurate information should be accessible. The reason for correction should be documented, and the correct entry must be dated and signed by the person making the revision. There should be an authorized person by hospitals to make changes in patient's identification details based on documentary proof. Details of the documentary proof should be entered in hospital records for future reference.

- It is advisable to ask for proper documentary evidence (e.g. court Affidavit/Court Order).
- In police cases/ Medico-legal cases however no correction/addition should be made after discharge of patient from Hospital as the information has already been sent to police.

### Health Insurance claims processing:

Today's environment of hospitals is favorable to health insurance schemes. The health insurance market is very wide and demanding in India. With increasing cost of treatment both in rural and urban places, availing health facilities have become unaffordable to poor and lower middle class of society. So people are bound to take health insurance policies to get the quality treatment at affordable cost. Demands and functioning of health insurance in hospital, the role of administrator has become vital to manage the insurance related function and redressal of insurance related queries by Insurance company/TPAs or by patient himself. Hospital administrator must know that, Health insurance claims are legal documents which contain valuable public health data as well as sensitive personal information which must be kept confidential. Health insurance are also under purview of Consumer Protection Act, so insurance related queries /issues should always be given priority by hospital management and it is advisable to engage knowledgeable person for dealing with the insurance related issues in the hospital.

# Processing of Reimbursement claims of Govt. Employees:

Apart from health insurance facilities, various

Government employees like CRPF, BSNL, BSF, Income-Tax Department etc have their own processes to get treatment through reimbursement system based of government guidelines. For reimbursement usually Government employees comes along with the Certificate-A (For OPD Treatment) along with the concerned hospital documents and Certificate-B (For Indoor treatment) along with concern document in hospital. Hospital management should authorize a person for filling up concerned Government claim forms based on hospital documents for employee / dependents of various Government Employees.

# B) Legal Issues to be dealt with as and when they arise:

- 1. Enquiries by various Law Enforcement Agencies (CID, CBI, Police Authorities etc.), Civil Surgeon, Human Rights Commission enquiries etc.
- 2. Information under RTI Act.
- 3. Legal Notices.
- 4. Law and Order problems related to hospital itself.
- 5. Domestic Enquiries.
- 6. Missing Indoor Case Sheet
- 7. Cases against hospitals in Legal Fora

Any enquires like, Human Rights Commission Enquiry, CBI Enquiry, Police Enquiry, Enquiries held on directive of Dy. Commissioner / Civil Surgeon; Domestic Enquires etc. are being addressed and facilitated by Hospital Administrator in any hospital. It is duty of hospital administrator to conduct or facilitate such enquiries in consultation with legal expert.

### Missing Indoor Case Sheet:

There are no known guidelines available regarding missing indoor case sheets. However hospital shall develop their own procedure considering potential legal and consumer issues attracting untoward attention. A simple way to practice it is as follows: As soon as any missing case sheet of patient is noticed in the ward by sister/doctor, the same should be brought to the notice of sister In-charge, Nursing Superintendent by sister on duty and to Unit Head by doctor on duty.

A thorough Physical check of ward and stores of the ward will be carried out over the next 24 to 48 hours. When all above measures have failed to

locate the missing case sheet, intimation is to be given to Hospital Administrator and Medical Record Officer who will intimate the local police station about missing case sheet and a copy of the police intimation will be kept in medical records section for future. It may be useful in situations like-Insurance claim, Enquires, Legal fora etc. Sample format for information letter to Police Station in case of missing Indoor patient's record see Annexure-II.

### Cases against hospitals in Legal Fora:

Legal notices of various courts mentioning the case details are received by Hospital. The same should be replied to Honorable Court after taking help from concerned doctors, other domain experts and medico legal experts. Every Hospital should have liasoning with medico legal experts. Large hospitals should have their own Legal department in the hospital .Usually legal personnel takes charge of the case, and after interactions with doctors and hospital management they take forward the legal notices.

In this era of deteriorating doctor patient relationship, the legal cases are going to increase. But we can minimize such cases by attending all patients carefully with standard medical practice. Doctor-patient communication or nurses-patients communication also plays a vital role in preventing cases. So it is advisable to communicate with the patient and document same after explaining the condition. Also documents related to all cases should be maintained properly. Hospital authority should make a system where issues related to bills should be properly explained and informed at the time of admission or even before admission. Hospital staff should be properly trained and adequately experienced to deal with situation where legal issues may arise. Hospital authority must display the list of services available in the hospital along with empanelled insurance companies.

# C) Statutory and Regulatory licensing requirement:

Hospital shall fulfill all the statuary requirements and comply with all the regulations issued by local bodies of State and Union of India. Hospital shall have copy of these regulations/acts. List of statuary and regulatory compliances is given in many guidelines .The following Statutory / Regulatory requirements are commonly applicable to hospital in India(3).

# I. Statutory and Regulatory Requirements Related to the Commissioning of Hospital

The laws are to ensure that the hospital facilities are created and started as per laid down legal guidelines and also to ensure that the hospital has minimum infrastructure for their customers. Compliance of these laws is subject to periodic inspection through appropriate authorities(3).

- 1. Building Permit under Building Bye-Laws 1983
- 2. NOC from Chief Fire Officer
- 3. Atomic Energy Regulatory Body Approvals (AERB)
- 4. The Clinical Establishments (Registration and Regulation) Act, 2010
- 5. The Urban Land (Ceiling and Regulation) Act. 1976

### II. Statutory and Regulatory Requirements Related to Practice of Medical Profession

The following laws are to ensure that the hospital staffs are qualified and authorized to perform their job within specific limits of competence in accordance with standard codes of conduct and ethics(3,4).

- 1. Indian Medical Council Act, 1956
- 2. Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002
- 3. Indian Nursing Council Act, 1947
- 4. Dentists Act, 1948
- 5. Registration of Medical Professionals with National/State Medical Councils

### III. Statutory and Regulatory Requirements Related to Drugs and Medication

The following laws are to control and monitor the usage of drugs, chemicals, blood, blood products and prevent misuse(3).

- 1. Drugs and Cosmetics Act, 1940
- 2. Pharmacy Act. 1948
- 3. License under the blood storage Act, 1994
- 4. Narcotics and Psychotropic Substances Act, and Licenses.

### IV. Statutory and Regulatory Requirements Related to Patient Care

These are the laws for setting standards of medical profession practice. They deal with management of medico legal problems, emergencies, dead bodies etc. and also guidelines on how to avoid medical negligence(3).

- 1. Medical Termination of Pregnancy Act, 1971
- 2. Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act. 1994
- 3. Registration of Births and Deaths Act. 1969
- 4. Transplantation of Human Organs Act. 1994
- 5. The Mental Health Act, 1987
- 6. Consumer Protection Act, 1986
- 7. Indian Evidence Act, 1872 (Disclosure of Privileged / Confidential Patient Related Information Before a Court of Law)
- 8. Laws of Contract, Section 13 (For Consent)

### V. Statutory and Regulatory Requirements Related to Environment

Environmental laws pertain to issues of concern to the environment and protecting natural resources. Environmental laws also have relevance to product/service design in the form of emission control, environmentally friendly materials, and energy-efficient electronic devices(3).

- 1. Bio-medical Waste Management Rules, 2016
- 2. Air (Prevention and Control of Pollution) Act. 1981 and License
- 3. Noise Pollution (Regulation and Control) Rules 2000
- 4. Environment Protection Act. 1986
- 5. Prohibition of Smoking in Public Places Rules, 2008

### VI.Statutory and Regulatory Requirements Related to Patient Safety

A patient is coming to a hospital is already compromised/challenged either physically and/or mentally. It is duty of health care providers to identify and recognize these and manage the patient accordingly. Over the period of time, certain focus and enactments have come into force, to officially safe guard the interest of the patient as regard his/her various safety issues are concerned. These Statutory and Regulatory requirements may be directly applicable for patient safety or may be indirectly linked to the patient(3).

- 1. Food Safety and Standards Act, 2006.
- 2. The Indian Explosives Act, 1884 and Explosives Rules, 2008
- 3. The Disaster Management Act, 2005
- 4. The Protection of Human Rights Act, 1993
- 5. Hazardous Waste (Management, Handling and Trans-boundary Movement) Rules 2008
- 6. The Atomic Energy (Radiation Protection) Rules, 2004

# VII. Statutory and Regulatory Requirements related to Human Resource in Hospital

These are the laws applicable to govern significant aspects of labor relations and human resource management and system of grievances and dispute(3).

- 1. Information Technology Act, 200
- 2. Factories Act. 1948 (for Laundry)
- 3. Employees provident Fund Act. 1952
- 4. Maternity Benefit Act. 1961
- 5. Payment of Gratuity Act, 1972
- 6. Persons with Disability Act, 1995
- 7. Protection of Human Rights Act, 1995
- 8. Insurance Act. 1938
- 9. Public Provident Fund Act. 1968

# VIII. Statutory and Regulatory Requirements related to Hospital Business

These are the laws applicable to hospital in relation to its business nature(3).

- 1. CopyrightAct. 1982
- 2. Gift Tax Act, 1958
- 3. Cable Television Network (Regulations) AmendmentAct,2011
- 4. Foreign Exchange Management Act, 1999
- 5. Insurance Act, 1938
- 6. Vehicle Registration Certificates for Ambulances
- 7. Income Tax Act. 1961

### **Monitoring of Statutory and Regulatory Compliances**(6):

Compliance to all applicable Statutory and Regulatory requirements of hospital is ongoing process which requires a system to monitor all the compliances related to concerned laws. Hospital administrator must establish a system and also assign competent personnel for monitoring of all legal compliances related to hospital. In the era of computerization, many legal experts' agencies are providing consulting services with IT solution to meet such monitoring requirements. Hospitals may take their services for establishing a monitoring compliance IT tool in hospitals. A sample of comprehensive tracking formats of Statutory and Regulatory compliances are as below, which hospital authority can use for monitoring of Statutory and Regulatory compliances in the hospital.

Sl. no.	Statutory and Regulatory Requirements Photocopy)	Document Description	Issuing Authority	Responsibility of Tracking	Tracking Link	Document Validity (Original /	Document Location	Remarks , (If any)
1								
2								
3								
4								
5								

All the above Statutory and Regulatory requirements are not applicable to all hospital. It totally depends upon the size and nature of hospitals. Individual hospital needs to identify the applicability of these requirements based on their functioning. It is responsibility of hospital administrator(s) to understand and know the requirement related to their hospitals.

### Annexure-I

Sample of Injury Report/ MLC Report

### ..... (Name of Hospital with Address) Injury Report/ MLC Report

Date : ..... Time of Examination: .....

### To, The Officer Incharge .....Police Station

	Name of Person Examined Age
2.	Identification Marks
3.	Father's/Husband's Name
4.	Address

5. Name and Address of the person accompanying the patient .....

### 6. Type and Size of Injury:

Type of Injury	Part of Body Involved	Size of Injury in Inches		iches
		Length	Breadth	Depth

7. Weapon used to inflict injury/cause .....

- 8. Age of Injury .....
- 9. Nature of Injury .....
- 10. Remarks. (If any).....

Signature of Doctor
Name of Doctor
Designation
Regn. No

### **Annexure-II**

Sample of information letter to Police Station for Missing Indoor Case Sheet

### To,

The officer In-charge, ......Police Station City ..... State.....

### Sir,

S. No.	Name of patient	IPNO	Date of Admission	Date of Discharge	Date of Death
1.					
2.					
3.					
4.					
5.					

This is for your information and necessary action please.

Hospital Administrator

 (Name of Hospital)
 (City)
 (State)

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## **Recent Judgment**

### Dr. Alka Kuthe

Received for publication : 12 Dec. 2016 Peer review : 20 Dec. 2016 Accepted for publication : 30 Dec. 2016

**Key words :** Anembryonic pregnancy, Blighted ovum.

First Appeal No. 800 of 2015 (Against Order Dated 07/08/2015 Complaint No. 138/2009 of State Commission Maharashtra)

Madhumita Poddar and Mr. Sudeep Kumar Saha, Versus Dr. Ranjana V. Dhanu, Ms. Sancha Fernandes and Lilavti Hospital Mumbai- Dated: 28 Oct 2016

### Order

"An anembryonic pregnancy (often called "blighted ovum") occurs during early stages of pregnancy when a fertilized egg implants in uterus, but an embryo fails to develop. Only the placenta and membranes develop – fooling the body into believing, it is still pregnant. The pregnancy hormones are still being produced which prevent a miscarriage. In other words, it is a pregnancy loss that happens in very early pregnancy".

### The brief facts are:

1) Complainant, Smt. Madhumita Poddar wife of Sudeep Kumar Saha went to Dr. Ranjana Dhanu for her complaints of nausea with severe cramp in lower abdomen on 12.7.2008. Dr. Dhanu examined her and conducted Urine Pregnancy Test (UPT). The report was negative. Therefore she concluded that complainant was not pregnant and diagnosed it as Premenstrual Syndrome (PMS) for which she prescribed certain medicines, but after that also the patient continued to have symptoms of pregnancy. Tablet 'Deviry' for PMS was advised on telephone but menstrual cycle did not start. Patient went back to Hyderabad on 21.7.2008 on her employment. Her pregnancy symptoms and uneasiness further continued. Therefore, on 24.7.2008, she visited Vikram Hospital, Hyderabad and underwent Serum Beta HCG test which

confirmed pregnancy of 4 weeks. On 25.7.2008, the complainants consulted Dr. Priyamvada Reddy of Apollo Hospital, wherein the patient was advised Pelvis USG. After seeing the report of USG, Dr. Reddy asked the patient to stop medicines immediately with the idea that they may cause irreparable damage to the fetus. On 27.7.2008 the couple went to their hometown Kolkata and consulted different doctors, namely, Dr. Ratnabali Chakraborty and thereafter Dr. Ranjit Chakraborty wherein pelvic USG was repeated and the report was twin pregnancy. Due to confused state of mind and because of knowing the horrifying effects of medicines prescribed by Dr Dhanu, the patient again consulted another specialist Dr. Kalyani Mukherji at Kolkata who also advised medical termination of pregnancy (MTP). The patient took another opinion from Dr. Geetasree Mukherji, who also advised the same. The patient got admitted in AMRI Hospital, Kolkata wherein Dr. Gitasree Mukherji performed MTP on 8.8.2008.

2) Claiming the above to be deficiency in service, the complainants filed complaint before Maharashtra State Consumer disputes Redressal Commission, Mumbai for a total compensation of Rs. 1 Crore.

3) The State Commission after considering the pleas and evidence dismissed the complaint. Therefore, aggrieved by the impugned order of State Commission, the complainant preferred the first appeal before National Commission.

4) The Senior counsel for the complainant vehemently argued the matter. As per his arguments, the dates of the prescriptions revealed that the submission made in the written version by Dr Dhanu as "the patient was under her continuous treatment" was false. The prescription dated

Practising Obstetrician, Amravati. Email : alkakuthe@yahoo.com

12.7.2008 clearly depicted the diagnosis as PMS ++, Dr. Dhanu did not advise confirmatory test for pregnancy or -HCG level. On the contrary, she prescribed several medicines which had teratogenic effect on the embryo.

5) The counsel submitted that, because of persistent symptoms of pregnancy, she underwent blood test for Beta HCG at Vikram Diagnostics which revealed pregnancy of four weeks. On 25.7.2008 Dr. Priyamvada Reddy of Apollo Hyderabad, advised pelvic USG and suggested to stop medicines immediately because, those drugs are prohibited during early pregnancy and may cause damage to the fetus.

On 28.7.2008, they consulted Dr. Chakraborti of Woodland Hospital Calcutta wherein, the USG confirmed twin pregnancy. The patient had strong apprehension and fear about risk in continuation of pregnancy because of consumption of medicines though was not willing for idea of abortion; therefore, she again consulted Dr. Kalyani Mukherjee and Dr. Geetasree Mukherji who also advised MTP. Therefore, on8.8.2008, Dr. Geetasree Mukherji performed MTP. Because of entire developments, the complainant could not join her duty for 1 <sup>1</sup>/<sub>2</sub> months and her husband was also kept away from his job.

6) Learned counsel, Mr. Rohit Sharma argued on behalf of Lilawati Hospital (OP 3) and submitted that the doctors are working in OP 3 on consultation basis during different time slots. No laboratory investigations of patient were performed in the hospital. Therefore, in the instant case, there will not be any liability upon the OP 3.

7) On behalf of Dr. (Ms.) Ranjana Dhanu, learned counsel Dr. G. N. Shenoy vehemently argued that this is the case of misconception of the facts and misleading pleadings in the complaint. He initially explained few medical terminologies pertaining to different types of pregnancies like normal, abnormal, the ectopic and anembryonic pregnancy . Also thrown light upon "Viable and Non-viable pregnancy". He further submitted that the patient was a known case of irregular periods and was under treatment of OP 1. The patient approached OP 1 on 12.7.2008. The OP 1 examined the patient and gave her prescription with a diagnosis as a case of PMS++ her LMP was 9.6.2008.

In the same prescription, OP 1 advised for 8) repeat urine test after 7 days. He further submitted that the patient purchased only single dose of Forcan 150 mg. The Chemist Shop cash bill of OP 3, revealed the correctness of submission. HCG report which was performed at Vikram Diagnostics, revealed -HCG level 3840.10 mlU/ml. which was much less than normal level(13860-19600 mIU/ml at 5-6weeks). It was because of an abnormal/ anembryonic pregnancy and not because of Dr Dhanus prescription. The Pregnancy Fetus scan (USG) report, clearly showed an early uterine gestation corresponding to less than 5 weeks and further repeat scan which was advised after 2 weeks for viability showed no evidence of yolk sac and fetal pole.

9) On 27.7.2008, patient went to Kolkata and consulted Dr. Ranjit Chakraborty on 28.7.2008 at Woodland Hospital, wherein Trans Vaginal USG (TVS) was performed which revealed "Anteverted gravid uterus with intra uterine two small gestation sacs of 3 to 4 weeks stage. No obvious fetal pole or volk sac was seen. Finally patient consulted Dr. Kalyani Mukherjee and Dr. Geetasree Mukherji at AMRI Hospital who advised MTP and, on 8.8.2008, Dr. Geetasree Mukherji performed MTP. The counsel for Dr Dhanu finally in nutshell submitted that patient took consultation with doctors in Hyderabad and Kolkatta and she had knowledge of non-viable pregnancy. She left with only choice for MTP either by medication or by D & C. Therefore, the patient on her own wish opted for termination of abnormal pregnancy. As such, it would have automatically got aborted as a natural course.

10) Various medical records like prescriptions, receipts, USG and laboratory investigations clearly showed that Dr Dhanu diagnosed her as PID (Pelvic Inflammatory disease), UTI, Endomet- riosis and PMS (Premenstrual syndrome) and had advised serum-HCG, prolactin, CBC, urine and culture sensitivity and medications in the said prescription. Thus, it proved that the patient was under periodic/regular consultation since July, 2007. Vikram Laboratory which conducted blood tests clearly showed that the patient was referred by Dr. Ranjana Dhanu. 11) The counsel for OP1 brought important point to note that, as per the last menstrual date, laboratory and USG investigations, which patient underwent in Hyderabad and Kolkata ,it was proved that it was anembryonic pregnancy. The prescription of Dr. P. Reddy clearly recorded that " she (patient) does not want to continue pregnancy". Also, the prescription of Woodland Medical Centre, Kolkata given by Dr. Ranjit Chakrabotry, expressed the doubt about fetal viability and advised the patient for termination of pregnancy (MTP) either by Medical Method or by surgical intervention by D & C.

12) The Commission while delivering the order stated that, it appears that the complainants misunderstood the facts about pregnancy. The multiple consultations with doctors in Hyderabad and Kolkata after the initial prescription of Dr Dhanu reveal that the complainant was in dilemma and confusion. The complaint was filed on wrong premise to mislead to the court. They tried to make brick without straw.

13) As per literature, the medicines prescribed by Dr Dhanu as per clinical acumen are not harmful to the patient and are routinely advised in early pregnancy or in the cases of PMS. The side effects or the alleged teratogenic effect would not be obvious by a single dose. Those medicines directly will not cause for an anembryonic pregnancy. The various investigations clearly proved that it was an anembryonic pregnancy which is a form of a failed early pregnancy (blighted ovum). Therefore, Dr Dhanu did not deviate from the standard obstetric practice and no deficiency in service was found.

14) National Commission did not find any merit in the instant appeal, which would need any interference in the well-reasoned order of the State Commission. Hence, the appeal was dismissed.

### **Conclusion:**

The appeal was dismissed by the National Consumer Disputes Redressal Commission but the take home message from above mentioned facts for the gynecologists specially is to go for ultrasonography without fail in doubtful cases, before prescribing hormones and not to rely on urine pregnancy test simply which many a times not reliable, Serum beta HCG is better option.

This write-up is based on Judgment from National Consumer Disputes Redressal Commission New Delhi. It was delivered by Hon'ble Member Dr. S. M. Kantikar with the presiding member Hon'ble Justice Shri Ajit Bharihoke.

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# **Contribution in JIMLEA**

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# **Medico Legal News**

**Dr. Anil Lohar** 

# Negligence: Doc to pay son for mother's death during C-section

New Delhi, A doctor at a reputed private hospital in south Delhi has been directed by state consumer commission to pay Rs 15 lakh compensation to the son of a woman, who died at the age of 22 due to negligence during her cesarean operation in 1993.

The state commission bench, presided by its member N P Kaushik, directed doctor Sadhna Kala to pay the amount to the deceased woman's son Deepanshu Mishra and other family members including her father Uday Kant Jha and husband Uma Shanker Mishra.

"Facts speak for themselves. I am, therefore, left with no option but to hold that it was the negligence on the part of Sadhna Kala that led to the death of a 22-year-old, hale and hearty young girl," the bench said.

According to the complaint filed by Jha, his daughter Anjana Mishra was admitted to Moolchand Khairati Ram Hospital here, on April 12, 1993, for delivery.

The complainant alleged that the doctor performed C-section operation, due to certain complexity it resulted in profuse bleeding.

It further alleged that the condition of the young mother got worse during the following days and she was kept on artificial breathing. She was diagnosed with jaundice after the bleeding due to which her liver stopped functioning.

It said the doctor consulted other experts about the woman's health but on April 22, 1993, she passed away.

The doctor had denied negligence on her part and said a healthy baby was born on April 12, 1993.

She had also submitted that jaundice was in a preclinical stage and there were no apparent outward symptoms which could have been noticed by the doctor.

**Source :** http://health. economictimes. indiatimes. com/ news/ 01dec2016

# 'One of the Worst Cases of Medical Negligence in India'

Human rights commission asks state to initiate action against 3 doctors for being 'negligent'.

Eight years after a couple from Bhiwandi lost their baby during delivery at the Thane Civil Hospital, the state human rights commission has now asked the Maharashtra government to initiate disciplinary action against three doctors for being "negligent".

It is, however, a case of justice delayed, justice denied. One of the three civic doctors named in the commission's report has already fled the country.

The human rights commission order, which was received by the couple, Haresh and Preeti Patil, three days ago, terms their ordeal as "one of the worst cases of medical negligence in the country", and directs the state to pay the couple a Rs 5-lakh compensation with 12% interest per annum from the time of filing the complaint.

The report names gynaecologists Dr Anuradha Nandpurkar -- in whose care Preeti was admitted after she went into labour – and Dr S Shinde, besides Dr (Mrs) Nagarkar, the then in-charge of the labour ward at the Thane Civil Hospital.

The police complaint filed by the couple said that Preeti went into labour on April 30, 2008, and was rushed to the Thane Civil Hospital where Dr Nandpurkar advised delivery by a Cesarean section. The complaint said that Preeti, then aged just 19, was left unattended for the next four hours, as Nandpurkar allegedly went off to attend to patients at her private clinic.

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"In the meantime, the baby got stuck during labour and choked to death. Nandapurkar rushed back to the hospital but it was too late. My wife is fortunate to have survived the ordeal," Haresh Patil said in his complaint.

After the complaint was filed at the Thane Nagar Police Station and a post-mortem was conducted at JJ Hospital, the state government formed a committee to probe the matter, but nothing came of it. The couple were helped by an NGO called Madat, which hired advocate Anuradha Pardeshi to argue the case before the state human rights commission.

"The case dragged on as there was nobody to head the commission for some time. The hearing restarted only two years ago," said Shashi Agarwal from the NGO. In its order, the commission has also made several recommendations, such as training staff at government and civic-run hospitals to handle such emergencies, and filling up vacant posts.

Advocate Pardeshi called the commission's order a "landmark judgment". "Hopefully now, we will see a massive change in the way patients are treated at government and civic run centres," she said.

**Source:** http://mumbaimirror. indiatimes.com/ mumbai/crime/ 22 Nov 2016

# Fortis Doctors fined over Rs.23.5 Lakh for Negligence

Fortis Seshadripuram doctors asked to cough up Rs 23.5 lakh as surgery was conducted despite absence of a cardiac care centre, which led to the death of 45-yr-old lady principal of a school

The Karnataka State Consumer Disputes Redressal Commission has ordered two surgeons and an anaesthetist of Fortis Hospital, Seshadripuram, to pay up a total of Rs 23.54 lakh as compensation to the husband and children of a 45-year-old school principal. She died on February 11, 2010, allegedly due to negligence of the doctors after a surgery at the hospital.

The commission held that despite "no cardiac care centre" present at the hospital the doctors still ventured to conduct a surgery on K Vidya Prasad, school principal of Regency Public School, Vidyaranyapura. And this was done although there was a "pre-operative cardiac risk factor involved" in her case.

The commission arrived at its decision that there was negligence involved as the doctors "acted in haste in conducting surgery, that too when the opinion given with regard to the cardiac risk factor was involved in the case".

However, another doctor and a neurosurgeon who were consultants for the surgery were let off as they were not part of the decision-making process.

HNM Prasad, an advocate at High Court of Karnataka, and his two minor children, approached the Consumer Forum in 2011. The complainants had alleged medical negligence on the part of the hospital and its doctors who conducted the surgery on her.

Vidya, who was then working as the principal of Regency Public School, Vidyaranyapura, was suffering from lower back pain and was found to have 'intervertebral disc prolapse', or 'slip disc'.

She had a surgery for the problem at the Columbia Asia Referral Hospital in October 2009. When her problem relapsed a few months later, she approached Dr. P. K. Raju who advised another surgery stating that the earlier surgery was a failure.

On his advice, she was admitted to Fortis Hospital and the surgery was conducted on February 11, 2010.

Prasad in his complaint claimed that after the surgery at 11.30 am, he was informed it was a "success", and that his wife would be shifted to the ward shortly.

But by 12.45 pm, Vidya was not responding to treatment, and the doctor allegedly told Prasad that "only God can save her" as there was no pace-maker facility in the hospital. She died before she could be shifted to another hospital.

Awarding the compensation to be paid by the hospital and the doctors, the commission said, "On account of untimely death of the victim, the complainants being her husband and children are entitled to be compensated for the same though no amount of money can adequately compensate the loss of a person."

The commission calculated the compensation amount by applying the method employed under the Motor Vehicles Act for accident cases.

### Past Case :

Fortis Hospital is not new to facing action over negligence cases. In September 2011, the licence of Fortis Hospital on Bannerghatta Road was cancelled by the commissioner of health, family welfare & ayush services after negligence by the doctors had caused the death of a retired Indian Army Major's wife.

The licence cancellation had followed a detailed investigation by then Lokayukta Justice N Santosh Hegde, which had found negligence to be the cause of her death. The probe had confirmed that the surgery involving transplant of the lady's pancreas was carried out despite the hospital having no licence to perform transplantations.

The retired Major had appealed to the Lokayukta after his wife's death in May 2010 – just three months after alleged negligence had claimed the life of K Vidya Prasad, the principal of Regency Public School, Vidyalranyapura, in its Seshadripuram branch.

**Source :** http://bangaloremirror.indiatimes.com/01 Nov 2016

### Health secretary, hospital director get notices in a case of cancer patient wrongly diagnosed as pregnant

New Delhi: Taking suo motu cognizance of a media report about a young woman who was wrongly diagnosed as pregnant and after eight months was again diagnosed and told that instead of being pregnant she was having a tumour, the National Human Rights Commission (NHRC) has issued notices to Health Secretary, Tamil Nadu and Director, Kasturi Bai Government General Maternity Hospital, Chennai calling for reports within two weeks.

"The Commission has been receiving from time to time numerous complaints of medical negligence in primary health centres and government health centres all over the country. However, the incident reported in the "Dinamalar" and Thinathanthi, Tamil newspapers dated 23.11.2016, is classic, which goes to the core of the medical negligence on the part of hospital, the doctors etc," NHRC said in its order dated November 24. According to news reports, 28-year-old Hasina, wife of Amir Ali, resident of Kannagi Nagar, Rajiv Gandhi Road, Tamil Nadu went to Kasturi Bai Government General Maternity Hospital for pregnancy check-up in April 2016. She was checked and was diagnosed as pregnant. She visited the hospital frequently for review. She was informed that the tentative delivery will be after eight months and expected date of delivery would be on 8th November 2016. She was put under necessary medication required to take care of the development of healthy and normal child and she expected delivery in due course after a period of eight months, which she did not experience.

As the woman did not develop any delivery pain in spite of the date elapsed, she went to the hospital, where a scanning was done. The scanning report showed a baby. She came back home and suddenly on 21st Nov 2016, she developed severe pain. She was again rushed to the hospital where a fresh scan was done. She was informed that she was not pregnant and there was only a small tumour.

In its order the NHRC said, "If the contents appeared in the reports are true, it would amount to serious violation of human rights of a lady. Firstly, the lady was diagnosed positively as to her pregnancy when factually she was not pregnant. There was either a wrong diagnose or misdiagnosis. It appears that right from the month of April 2016 she had been regularly visiting the hospital for her review and surprisingly for all these eight months she was medicated for her pregnancy."

"The Commission fails to understand how the doctors had failed to notice even the physical growth of the baby for the eight months let alone from the physical appearance of the lady. The above facts show a total callous attitude in the diagnosis of a lady, who was not only given a positive report for the pregnancy but was also made to consume a number of medicines during the period of eight months," added the NHRC.

**Source:** http://www.indiamedicaltimes.com/ 2016 / 11/ 30 By IMT News Bureau



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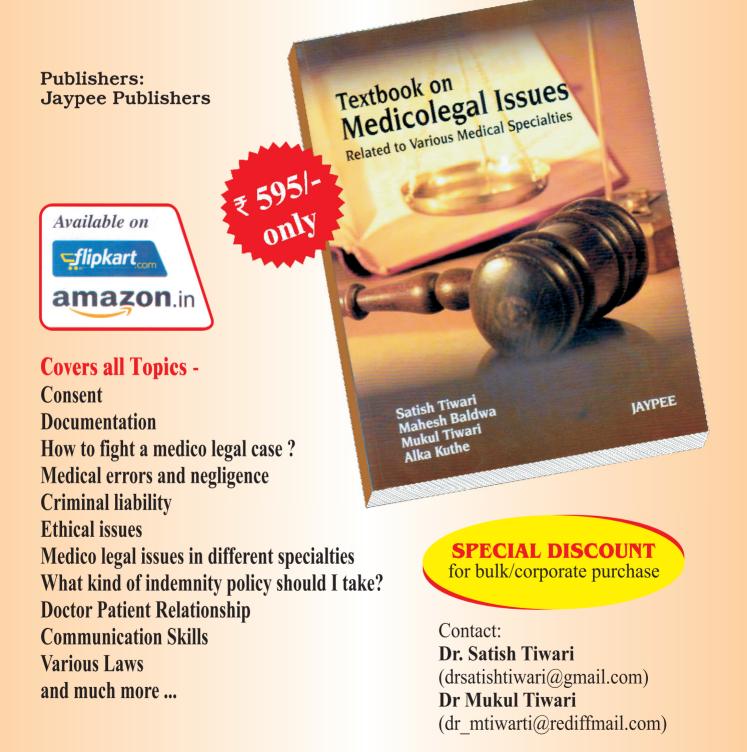
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