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- To train the medical professionals in doctor-patient relationship, communication skills, record maintenance and prevention of litigations.
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**Editorial :**

# **Patient litigation not linked to money charged**

**Dr Pankaj Garg**

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**Keywords :**

Conduct of physician; communication; concern; transparency; litigation

The modern day medical practice is full of challenges. With increasing distrust between the physician and the patients, it is pertinent that the traits needed in a physician to maximize the trust should be emphasized. Incidentally, unlike commonly assumed, the increasing litigation rate by the patients is not much related to money or even expertise of the physician. It is more related to three cardinal traits (3 C's) in a physician- Concern, Clarity (transparency) and Communication.

India is the largest democracy in the world coupled with the oldest traditions. Charaka, the renowned Indian physician practiced medicine in 3rd century BC and Sushruta had developed innovative surgical techniques for general, gastrointestinal and plastic surgery in as early as 6th century BC [1,2]. Conventionally in India, the relation between doctor-patient had been that of charity. The doctor used to treat the 'suffering' patient assuming it as his duty to serve humanity, and monetary benefits were secondary. The non-affording patients were treated free or at subsidized rates. In return, doctors were given immense respect and the status of 'next to God'. This system continued for several centuries till the things started to change three decades back.

With massive progress in health sciences and medical equipment, the physician was just one of the players in providing quality healthcare. The latest equipment and technology became as

pertinent as the skills of the doctor.

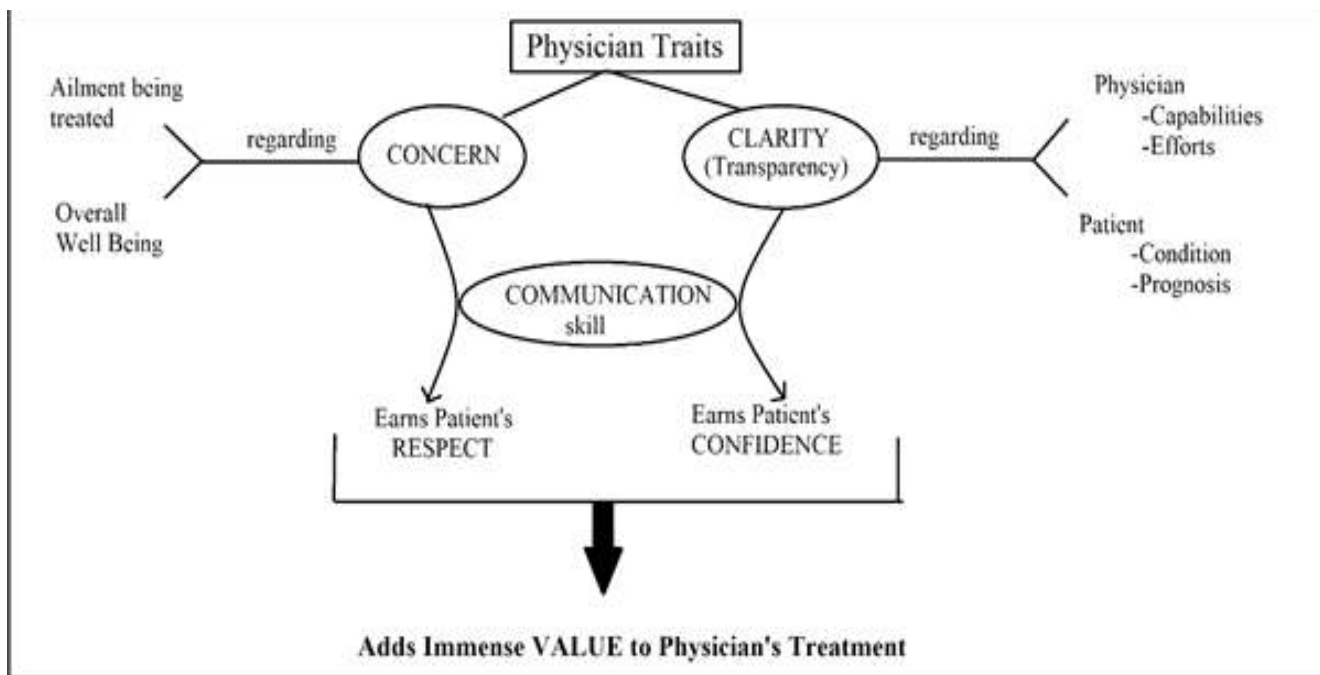
The mushrooming of private health sector especially after 1990 brought world class health facilities to India. But it came with a price. The big companies started investing heavily in private healthcare. They needed to thrive and naturally the charges became the primary focus of providing medical treatment. The model slowly changed from 'service' model to a 'consumer' model. With this came the expected problems of mistrust and litigations. As the private healthcare sector in India increased from minimal in 1990 to about \$100 billion today, the mistrust (between doctor-patient) and the litigation rate increased at a much more faster rate. Money factor had quickly changed the whole dynamics of healthcare in India.

Amidst this crucial transition, I started my medical schooling in New Delhi in 1990 and the independent medical practice in private sector in north India in early 2001. I was quite aware of the changing scenario in healthcare in the country. The confusing question before me was "How to strike optimum balance between charging money and minimizing the risk of litigation?". I was narrated this rule by my seniors "If the money is charged, then litigation is inevitable and should be expected". But this rule was proved wrong. After two decades of experience, I realized that the litigation by the patient was rarely related to the money charged or even to the expertise of the physician. If three C's – Concern, Clarity and Communication- are taken care of, then a majority of mistrust and litigation issues can be prevented.

Concern regarding the patient and his health is of cardinal importance. It is something which

doesn't need to be spoken. If it's there, patient will automatically come to know and vice-versa. It's preferable to have concern not only for the ailment which the physician is treating but also for the overall wellbeing of the patient (Figure-1).

expertise. When the physician has clearly conveyed his shortcomings (in expertise, experience or logistics etc) before initiating the treatment, then the patient develops confidence that the physician is not concealing anything. Then even if the treatment



**Figure-1: Traits required in a modern day physician**

Empathy for the patient cannot be substituted or eliminated from the physician's arsenal. Though this demands extra effort physically and mentally on the physician's part but it is a cardinal reason which makes medical profession different and more respected than all other professions. Concern is a double edged sword. Having concern for the patient helps to earn respect while lack of the same erodes all respect rapidly.

Clarity or transparency is conveying clearly to the patient about treating physician's capability and efforts and patient's condition and prognosis at all times. This is paramount to earn patient's confidence. This honesty on physician's part even helps to circumvent any deficiency in physician's

does not lead to the expected outcome, the chances of patient going for the litigation become quite low. There is a saying “You might be as intelligent as Einstein, but never underestimate the intellect of the person in front of you”. If the physician is honest, the patient will understand it and if the physician is dishonest, then the patient will definitely know of it. Therefore, clarity may at times be less beneficial in short-term but is extremely beneficial in the long-term building of reputation of the physician and in preventing litigation.

Thirdly, communication is a basic fundamental trait required in the physician for a good physician-patient relationship. Good communication is key to enforce the first two traits- concern and clarity. If the physician has both the

first two traits but falters in communicating them, then their presence goes futile. Therefore, communication is a skill that is mandatory for every physician to develop.

It is not difficult to understand why patients' dissatisfaction and litigation are not about money. For example if a patient is charged Rs.100 for a treatment and he feels that he got services from the physician worth Rs.125, then he would be satisfied. However, if a patient spends Rs. 50 on the same treatment worth Rs. 100 but feels that he got services worth just Rs. 30, then he would be dissatisfied and would be a potential litigant. Therefore, rather than the amount of money, it's the value the physician provide to the patient is what matters. The above three physician's traits, especially concern, has no objective monetary value but add immense subjective and psychological value to the treatment. Their adequate presence raises the patients satisfaction to an altogether new level and hence decreases the chances of litigation proportionately.

Therefore, these three traits- concern, clarity and communication- in the physician are

cornerstone to build physicians' reputation, boost physician-patient relationship and prevent potential litigations. Presence of these three traits can compensate for money factor or some deficiency in physician's expertise. On the other hand, absence of even one of these traits immensely increases the patient dissatisfaction rate even in presence of great expertise and minimal money charged.

Unfortunately, these three cardinal skills are not being taught actively in medical schools in most parts of the world. Their inclusion in theory as well as practical classes in the medical schools is paramount to build a long-term harmonious physician-patient relationship in the society.

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## **Recommendations: IMS Act- Appraisal and Recommendations in improving breastfeeding in India**

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\*\*\*\*\*Dr Shailesh Jagtap \*\*\*\*\*Dr Digant Shastri**

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### **Keywords:**

Breastfeeding, monitoring of IMS Act Violations, Health care system, Media, Professional organizations.

### **Abstract:**

There is still large gap between optimal breastfeeding rates and current rates. The intents of IMS Act were to improve the nutritional status of children by promoting, protecting and supporting breastfeeding. Unfortunately, the impact of the Act was far from satisfactory. The loopholes are easily exploited by multinationals and manufacturers of infant milk substitutes. There are many inadequacies, which hamper the long-term achievements of the Act. The violation continues directly or indirectly. It is our moral and ethical responsibility to remove misconception and taboos. The absence of strict vigilance has badly failed in achieving the aims, objectives of the Act. Clear standard protocols and guidelines need to be developed. There is a need to create certified lactation management professionals. So as to prevent continued violations, there should be monitoring with more vigilance by District level authorities. Media should highlight the problems of continued violations of the Act.

### **Background :**

Breastfeeding trends have shown improvement over the years. However, there is still large gap between optimal breastfeeding rates and current rates. As Infant Milk Substitute (IMS) Act was implemented, some of the producers of these products have developed innovative means to bypass the act [in spirit]

although they may withstand legal scrutiny. Suboptimal breastfeeding rates despite mammoth efforts on the part of NGOs and Government of India and the efforts to bypass the act by some of the manufacturers of formula milk need a review to develop future strategies and actions to further support, promote and protect breastfeeding.

With improving breastfeeding trends and upcoming newer modalities in breastfeeding field like banked human milk and increasing availability and use of breastfeeding related equipment like pumps, nipple shields, etc.; there is increasing promotional use of internet media and violations of IMS Act. The newer and newer modes of violation of IMS Act by IMS producers in form of dummy institutions etc are very obvious. There is an urgent need of appraisal for discussing the impact of them amongst the experts and stakeholders supporting, promoting and protecting the breastfeeding.

With this background, during the world breastfeeding week 2019 a workshop was organized by IYCF Chapter of Indian Academy of Pediatrics and Alive and Thrive on 6th August 2019 at New Delhi. Stake-holders interested in promoting and protecting breastfeeding were invited. Day long discussion in form of lectures and panel discussion was carried out. The essence of the meeting's Appraisal and Recommendations are presented here.

### **Importance of Breastfeeding :**

Breastfeeding is the natural way to feed newborn babies. The World Health Organization (WHO) recommends exclusive breastfeeding for

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first six months of life and continued breastfeeding till two years [1]. Academic bodies like Indian Academy of Pediatrics [2], American Academy of Pediatrics [3] and several other organizations endorse these recommendations. In addition to providing natural and nutritionally most appropriate milk for newborn, breastfeeding is associated with reduced gastrointestinal and respiratory infections. These benefits last till long after cessation of breastfeeding. It is observed even in developed countries with clean environment [4]. Moreover, breastfed babies were found to have lower blood pressure, lower total cholesterol, less obesity/overweight and type II diabetes mellitus and higher performance on intelligence scales [5]. On some of these parameters impact was as much as that of targeted interventions in adults [5]. Thus, the emphasis of breastfeeding and its promotion and protection is justified.

#### **Status of Breastfeeding in India :**

Exclusive breastfeeding rates in India have been low. Prelacteal feeds were common and continued to remain regular and frequent in many communities [6,7]. Analysis of data from National Family Health Survey 2005-06 and 2015-16 showed improvement in exclusive breastfeeding rates from 46% to 55% and early initiation of breastfeeding from 23% to 42%. Prelacteal feeding rates showed sharp reduction from 57% to 21% [8]. Data from the Bihar study is similar at 55% for exclusive breastfeeding and 26% for prelacteal feeding [6], whereas an urban settlement from Vellore showed a poor exclusive breastfeeding rate of 22.1% at four months and 1.1% at six months [7]. Lower breastfeeding rates in urban India continue to be a cause for concern.

As compared to 2006, gains were made in the EIBF (Early initiation of breastfeeding) rates across all socio-economic groups, with poorest and marginalized being the biggest beneficiaries. However, wide inter-district variations exist with

rates being lower than the national average in 291 out of 637 districts with percentages ranging from 13.3% to 89%. Uttar Pradesh replaced Bihar as the worst performing state. Initiation of breastfeeding in C-section deliveries remained suboptimal at 35% and with the private hospitals performing worse than the public health facilities [9].

#### **Impact of not Breastfeeding**

A new tool has been developed to assess the cost of not breastfeeding [10]. The global impact of not breastfeeding is estimated to be 595379 under-five deaths annually, 98243 maternal deaths annually due to breast and ovarian cancer and type II diabetes mellitus. The economic burden of these mortalities and still greater degree of morbidity is estimated to be 1.1 billion dollars/annum. Still greater losses are estimated due to loss of future productivity and cognitive development. Aggregate of these losses are estimated to be 343.1 billion US dollars/annum. This is equivalent to 0.7% of gross national income of the Governments across the world [10]. Unfortunately, the India specific data from the same tool is not calculated.

#### **The IMS Act: Purpose and Objective**

The Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1992 was brought in 1993 and was amended in 2003 to strengthen it further [11]. The primary objective of this Act is to promote, support and protect breastfeeding. The Act prevents all promotional activities for Infant Milk Substitutes, not only by manufacturers and distributors or their representatives but also by retailers, healthcare workers and anyone else.

The statement of objective as presented in parliament is *Inappropriate feeding practices lead to infant malnutrition, morbidity and mortality in our children. Promotion of infant milk substitutes and related products like feeding bottles and teats do constitute a health hazard. Promotion of infant milk substitutes and related*

*products has been more extensive and pervasive than the dissemination of information concerning the advantages of mother's milk and breastfeeding and contributes to decline in breastfeeding. In the absence of strong interventions designed to protect, promote and support breastfeeding, this decline can assume dangerous proportions subjecting millions of infants to greater risks of infections, malnutrition and death....."*

### **The IMS Act: Is it working?**

The effectiveness of IMS Act is evident from the improvement observed in exclusive breastfeeding rates across the country [8]. The annual report of Nestle India Ltd [12], which holds the largest market share and tries to promote itself through Nestle Nutrition Foundation shows a growth of 4.7% over last year, including other products like dairy whitener, condensed milk, UHT (ultra- high temperature) processed milk, yoghurt, maternal and infant formula, baby food, health care nutrition, is also an evidence of the effectiveness of the IMS Act.

In contrast, the market research report [13] shows that China, where there is no such Act and a country which till recently had a one child norm, accounts for 30% share of infant formula market. Similar trends are seen in many other countries (Fig 1 and 2) where trends in growth of Infant Milk Substitutes are far greater than India. This shows the efficacy of IMS Act in protecting and promoting breastfeeding. However, a lot of ground need to be covered considering that within South-East Asian region Democratic People's Republic of Korea achieved an exclusive breastfeeding rate of 89% [14].

### **Recommendations for Improvement**

The recommendations arising out of workshop can be grouped for:

- a. Health Care Systems
- b. Professional Bodies
- c. Media

### **Solutions within Health Care Systems**

1. Accelerating capacity building for

managers/facility administrators and providers to promote, support and protect breastfeeding including increasing awareness on provisions of the Act.

2. Clear standard protocols and guideline need to be developed if at all there is need for provision of substitutes in rare situations based on the type of facility. This should include on a) use of human milk in facilities with HMB (Human Milk Bank), b) and in case of no HMB then what are the indications for the provision of substitute, what should be given, how should it be given and consent (written) from the relatives or the patients etc.
3. There is a need to create certified lactation management professionals who will help mothers and prospective mothers during antenatal period.
4. Making Lactation management training as part of Undergraduate Medical and Nursing courses, Home Science, Dietetics and Nutrition, etc; PG training in Pediatrics, Community Medicine and Obstetrics and Gynecology and Neonatology super-specialty training.
5. Changing behavior by addressing most critical low points for adherence e.g. acceptance of sponsorships, gifts, distribution of samples. There should be clear cut directives to Facility administrators, professional association members and the health care providers on the sponsorship norms (with clearly stating the clause of conflict of interest) for any academic event to be planned.
6. Improvement in Monitoring Systems: Designated senior official at state level in the system to monitor implementation / adherence. There is need for formation of committees for monitoring the adherence to provisions of IMS act at various level i.e. Facility level, District level, State level and National level. The IMS Act implementation

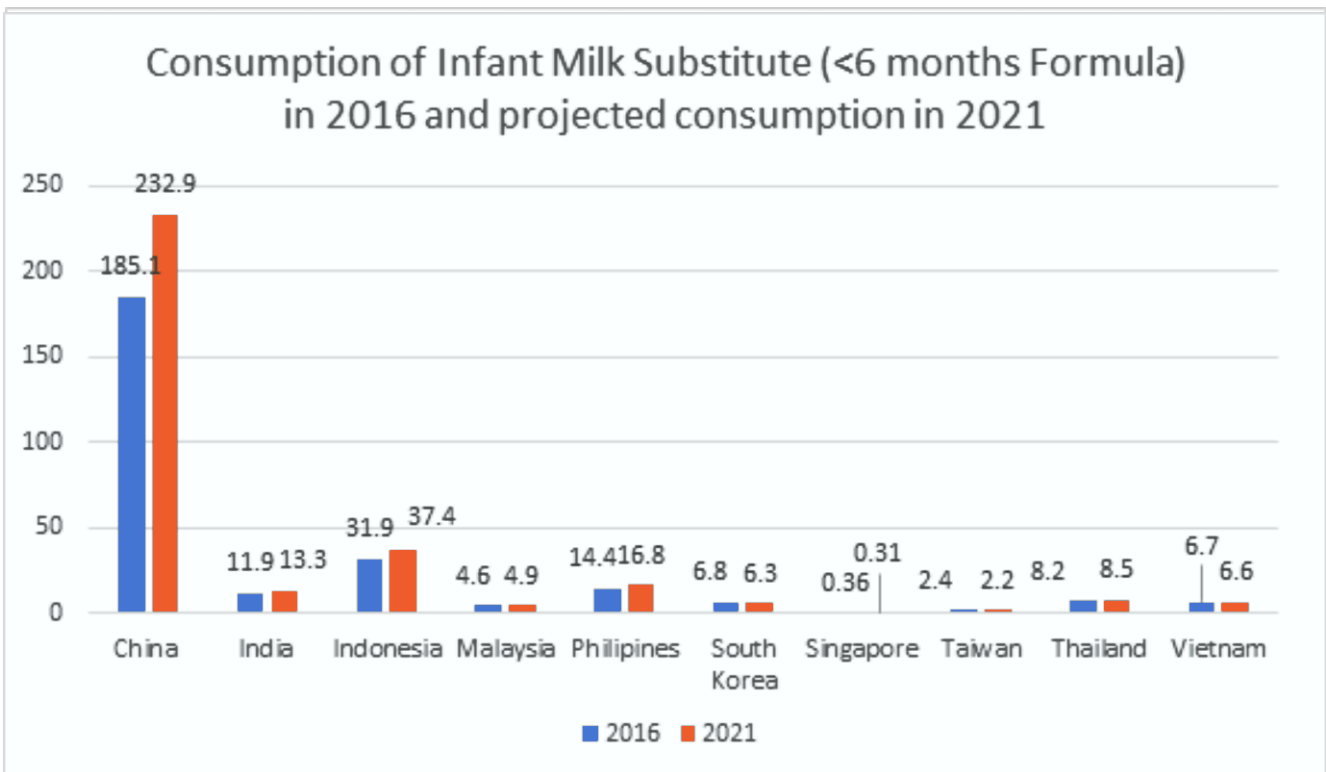


Fig 1: Consumption pattern of < 6 month formula Infant Milk Substitutes in some countries

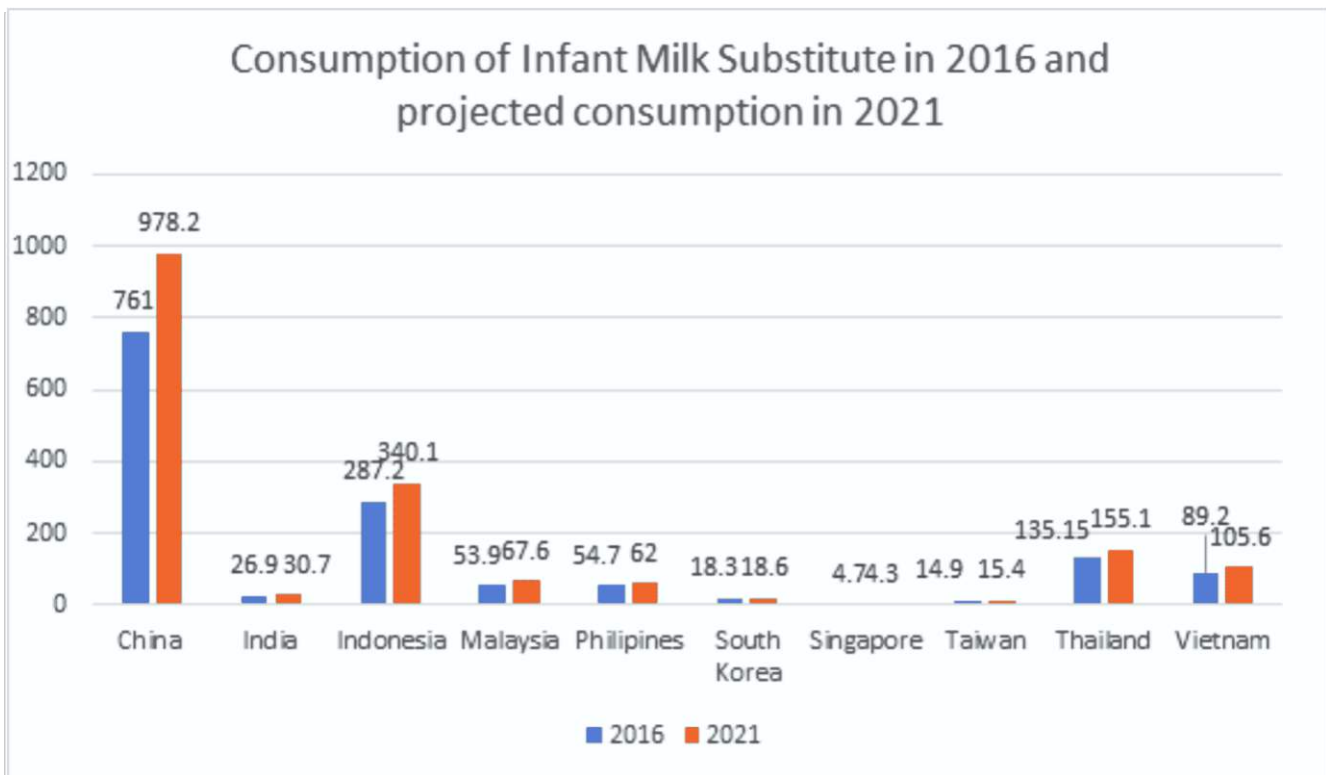


Fig 2: Consumption pattern of Total formula Infant Milk Substitutes in some countries

committee to review the status of adherence on regular frequency (quarterly/half yearly) and provide details/report to the higher level committee. The committee to comprise members from Government System, Professional bodies, Media, Civil Society Organizations, Community Members etc.

7. Dedicated funding for monitoring adherence through government involving partner organizations.
8. Develop a ready reckoner on IMS for different section of stakeholders.
9. Inclusion of adherence to optimal breastfeeding practices and compliance to IMS Act as criteria for quality certification/ accreditation of hospitals.

#### **Additional recommendations for inclusion in IMS Act amendment**

1. There is need to stop availability of feeding bottles as they compound the dangers of breastmilk substitute. Various stake-holders should convince the law makers or government to look in to this issue at the earliest. Never show a feeding bottle or its icon in lieu of breastfeeding, or baby being fed with bottle, in any kind of public place like transport systems e.g. airports or railways or alike.
2. There is urgent need for prohibition and monitoring promotion and sales of IMS products especially on online media.
3. Upcoming issues to be addressed and included in IMS act, like production and promotion of banked human milk in different forms and breastfeeding related equipments like breast pumps, nipple shields, etc. which bear an impact on breastfeeding.

#### **Professional Bodies**

1. Professional bodies should develop joint action plan for promoting, supporting and protecting breastfeeding and improving awareness about the IMS Act.

2. Professional bodies like IAP, FOGSI, IAPSM, IMA, HMBA, IMLEA and others can provide training platforms and faculties for such programs.
3. Prepare curriculum for various future service providers specially lactation management professionals, human milk banks, neonatal units, nutrition centers, dieticians etc and include accurate and adequate content on Infant Young Child Feeding (IYCF) and the IMS Act.
4. Ensure that all service delivery points are using updated protocols with accurate content on IYCF and IMS Act.
5. Provide an internal platform for anonymous reporting of violation of IMS Act by its members.

#### **Media**

1. Ensuring mothers and families receive accurate information on the benefits of breastfeeding and optimal infant and young child nutrition.
2. Make breastfeeding a new normal by in-depth reporting on the benefits of breastfeeding and adverse effects of breast milk substitutes.
3. Being a leader in upholding the IMS Act by not publishing advertisements in violation of the Act.
4. Media should highlight the problems with bottle-feeding and should never show a bottle or its icon or baby being fed with bottle in lieu of breastfeeding in any kind of program including entertainment programs.

#### **Conclusions**

The IMS Act was enacted with the aim to promote, protect and support breastfeeding. Judicious use of Infant milk substitute is not banned under IMS Act. The aim is to prevent indiscriminate, unscientific overuse of artificial milk and related ill-effects. It is our moral responsibility to monitor the violations of the Act and report it to appropriate authorities so that the

optimal nutrition of the child is taken care of. Proper and optimal nutrition in infancy is one of the major strategies to prevent malnutrition related mortality and morbidity in our future generation. We hope these recommendations and appraisal will help us in achieving the aims and objectives of the IMS Act not only in words but also in spirit.

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**Case Law :**

## **Mediclaim in Fibroids and Infertility**

**Dr. Vivekanshu Verma**

*Received for publication : 10 Aug. 2019 Peer review : 10 Jan. 2020 Accepted for publication : 20 Jan. 2020*

**Keywords:**

myomectomy, Insurance cover, Gynecologist, Fibroid

The core question, which falls for consideration in below case, is, as to whether, the Patient underwent treatment for infertility or any disease arising therefrom or not.

**Infertility is** standard permanent exclusion in Mediclaim coverage by some companies.

Temporary exclusions for 2yrs- As per exclusion clause in mediclaim policies, Unless the Insured female has Continuous Coverage in excess of 2yrs, expenses on treatment of the following Gynecological Illnesses are not payable: dilatation and curettage (D and C); hysterectomy for menorrhagia or fibromyoma or prolapse of uterus unless necessitated by malignancy; myomectomy for fibroids; surgery of genito urinary system unless necessitated by malignancy.

**Case details:**

A 35 years old non-diabetic, normotensive female patient, who bought that mediclaim policy 6 month ago, consulted to Gynecologist in OPD with H/o heavy bleeding during menses and lower abdominal pain, and inability to conceive after 1 year of marriage.

Gynecologist advised admission for further management with provisional diagnosis- Dysmenorrhea and infertility under evaluation. Pre-authorization form for cashless facility was sent to the Mediclaim Company by patient, as per the policy conditions, prior to the admission for the treatment of primary infertility for 1 year with provisional diagnosis of Fibroid Uterus from Ivy Super-Speciality Health Care, Mohali with estimated cost of Rs.85000/-.

Mediclaim Company refused mediclaim on ground that treatment for infertility is excluded from Mediclaims. And treatment for Fibroids is covered under Mediclaim only if, fibroids occurred after waiting period for 2yrs after buying mediclaim policy.

Patient's lawyer told that patient took mediclaim policy, in the year 2009, which was being renewed annually. Prior to this the patient was insured with some other Insurance Company.

Patient suffered severe abdominal pain, and heavy bleeding during the menses, due to which, she got admitted in emergency under Gynecologist in empanelled Hospital by paying cash. USG- showed large postero-superior fibroid uterus (9x10 cm) present in the post wall of uterus. Gynecologist advised Myomectomy and, as such, she underwent diagnostic Laparoscopy and Myomectomy of the fibroid and not any treatment for infertility.

Patient spent Rs.73,510/- on the treatment and, thereafter, lodged a claim, for payment of the said amount, which was refused, on the ground, that the hospitalization was related to the treatment of infertility, which was excluded under the policy.

Insurance lawyer argued that in discharge summary, the patient was diagnosed for primary infertility and fibroid uterus.

Patient's lawyer replied that USG reported heterogeneously echogenic discrete lesion size 8.6 x 6.6 cm; in posterior wall of uterus displacing endometrial cavity anteriorly s/o fibroid, for which patient was operated through Myomectomy and postoperatively, the patient was managed with antibiotics, analgesics anti-inflammatory medicines along-with other supportive treatment. The clinical findings and the treatment provided are distinguishable.

Clearly, as per the discharge summary, the treatment taken by the patient was for fibroid uterus, and the same was covered under the terms and conditions of the policy.

Myoma is an ailment in female because of which there is excessive bleeding. A person taking treatment for myoma could be covered under the policy conditions. Insurance lawyer argued that in the present case, the patient had infertility because of the myoma.

When she was diagnosed for myoma, myomectomy was done to treat the infertility. Sterility, treatment whether to effect or to treat infertility; any fertility, sub-fertility or assisted conception procedure; surrogate or vicarious pregnancy; birth control, contraceptive supplies or services including complications arising due to supplying services was excluded permanently.

Patient was well informed, at the time of filling the proposal form while buying policy about exclusion of fertility treatment.

When the grievance of the patient was not redressed, left with no alternative, a complaint under Section 12 of the Consumer Protection Act, 1986 was filed in consumer forum.

State Consumer Forum observed that –“No doubt, the patient was suffering from infertility, but the evidence, on record, particularly, the

findings in discharge Summary clearly indicate that she was having large fibroid in uterus, for which patient was operated through myomectomy.

However, a waiting period of 2 years will not apply if the insured person was insured continuously and without interruption for at least 2 years under any other Indian insurers individual health insurance policy for the reimbursement of medical costs for inpatient treatment in a hospital, and she establishes to our satisfaction that she was unaware of and had not taken any advice or medication for such illness or treatment.”

State Forum ordered Mediclaim company to pay to patient- Hospital bills of Rs.73,510/-; Rs.20,000/- as compensation, for mental agony and physical harassment; Rs.10,000 as cost of litigation.

**Conclusion:**

Gynecologists' meticulous documentation and lawyer's proper representation of facts helped in procuring Mediclaim for genuine patient.

**Reference:**

Chandigarh Consumer Disputes Redressal Commission in case of Kirti vs Apollo Munich Health Insurance on 28 November, 2013 <https://indiankanoon.org/doc/131724784/> Accessed on 6 August 2019.





## Perspective : Self-medication: Medical negligence

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### Keywords :

Glycoside, Fenugreek, Cardiotoxicity, Bradyarrhythmia, Pacemaker, Digital watch, Digitalis, Activated Charcoal

### Abstract :

Ingestion of naturally occurring cardiac glycosides as various over the counter products having fenugreek seeds produces a clinical picture very similar to that of digitalis poisoning. The main life-threatening clinical manifestation is cardiac toxicity. Apart from its critical toxicological profile, many studies have also documented its beneficial effects, creating false sense of security in general public about safety of consuming fenugreek seeds, just like any other herbal household remedy. We are reporting an interesting case of medical emergency associated with food supplement toxicity by consuming fenugreek seeds powder in excessive overdose, resulting in fatal life threatening cardiotoxicity, hinted on right time by digital wrist watch with inbuilt ECG monitor by alarm, fortunately worn by the patient herself, which led to urgent admission in our emergency.

### Introduction:

In the recent times, the problem of food safety is gaining importance in developed and developing countries. Major causes that are responsible for food toxicity include poor knowledge, self-medication of over the counter products, malpractice during their preparation, the presence of bacteria, toxins or allergens in the food, and cross-contamination with harmful organisms.

### Common Botanical Emergencies :

- Injury : Physical/ chemical/ thermal/ mechanical
- Intoxication: Alcohol-ferment fruits/substance abuse leaves of coca, flowers of Opium/Toxic Plants
- Ischemia : Acute Myocardial infarction, Brain Stroke- Chronic Cannabis abuse
- Illnesses - oriental starfruit -Acute kidney injury
- Infections : Bacterial, Viral, Parasites infested fruits eaten
- Immunological disorders: insect bites and stings

while handling plants, Plant allergy, Food allergies, Drug allergies, anaphylaxis

- Insanity : Mania, Psychosis- cannabis.

Many short-term (nausea, vomiting, weakness, diarrhea, mild fever and headache) and long-term (kidney failure, brain and nerve damage) health hazards may result from exposure to food toxicants. Therefore, efforts are being taken by various government and regulatory agencies such as World Health Organization, International Program on Chemical Safety, US Food and Drug Administration, US Environmental Protection Agency, Agency for Toxic Substances and Disease Registry, European Chemicals Agency, etc. to publish evidences based on peer-reviewed scientific literature related to health assessments of chemicals[1,2]. Fenugreek (*Trigonella foenum graecum* L., family: Fabaceae) is one of the most promising traditional medicinal plants cultivated widely in India, Egypt, and Middle Eastern countries[3]. Its leaves and seeds have been extensively used as medicine, spice, and vegetable in various pharmaceutical, nutraceutical, and functional food industries[4]. Apart from its toxicological profile, many studies have also documented its beneficial effects[5]. It may create confusion among the public regarding the safety of fenugreek seeds-based healthcare products, creating false sense of security in general public about safety of consuming fenugreek seeds, just like any other herbal household remedy. We are reporting an interesting case of medical emergency associated with food supplement toxicity by consuming fenugreek seeds powder in excessive overdose, resulting in fatal life threatening Cardiotoxicity.

### Case Report:

Interesting case of medical emergency associated with food supplement toxicity by consuming fenugreek seeds and Smart-watch device at her wrist (Figure1). 49 years old diabetic, hypertensive female, with history of sudden syncope in bathroom at 8:00 am with altered mental

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status since then. Patient's husband narrated history of consumption of fenugreek seeds 10-15 grams at early morning, for controlling diabetes by self-medication without any expert advice. Patient's husband communicated with ECG in iPhone 5 on her wrist- alarming bradycardia, and was advised to shift to hospital, as soon as possible.



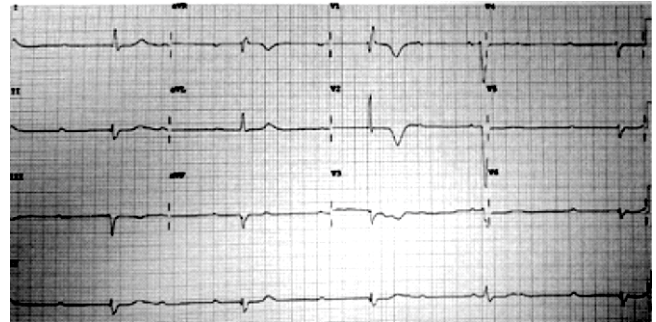
**Figure 1 : Digital watch(Apple I Watch-5), with inbuilt ECG monitor, has helped this patient on fenugreek overdose, in alarming bradycardia**

Patient was shifted in drowsy disoriented state in ambulance. Bedside ECG reported- Complete Heart Block (Figure 2).

**ER assessment- ABCD approach:**

On arrival in Medanta Hospital Emergency department, patient was in altered mental status. pupils bilaterally equal, 3mm and reactive. Airway was patent, moving all four limbs on verbal stimuli. Breathing rate was 20/min with SPO<sub>2</sub> = 98% on room air, Circulation- peripheral pulses were palpable, HR= 30/min. BP=90/50 mmHg. Temp- Afebrile, Chest – Bilaterally air entry present, Cardio Vascular System examination – S1,S2 normal. Per Abdomen – soft, non-tender. Disability –Moving all four limbs. Bilaterally equal pupils (2mm) but reactive, Plantar were bilaterally flexors. No injury or injection marks noted. Random Blood Sugar was 325mg/dl. ABG reported lactic acidosis with component of metabolic acidosis. Patient's

husband communicated with past history of normal Coronary Angiography in recent health check-up and normal Echocardiography (Echo), reported EF= 55%, No regional wall motion abnormality (RWMA) report of one month ago.



**Figure 2 : Bedside ECG reported- Complete Heart Block**

**Point of Care in ER: utilising “5G” technology for bedside diagnosis:-**

- Glucose= 325mg/dl
- Gas analysis -ABG- Metabolic acidosis, Lactates= 4.9
- Graphs -ECG- Complete Heart Block
- USG- 2D ECHO showed akinetic anterior septum, IVS, apex, mid anterior wall, mid inferior wall, left ventricular ejection fraction- 25%. Dilated LA (4.2cm), Dilated LV (5.5/4.7cm).
- Radiography- CT scan-No intracranial Bleed/infarct. MRI & MR venography- No abnormality detected

**Emergency Treatment:**

Patient underwent temporary transcutaneous pace-making by Defibrillation electric pads in ER. 50gm of Activated Charcoal was administered for gastric decontamination. Inotropic support was started and acidosis corrected with sodium bicarbonate infusion.

**Course in Hospital:**

Patient was admitted in Heart Command and investigated further. Two sets of Cardiac enzymes – consecutive tests 6 hours apart, were within normal limits. Patient underwent temporary pacemaker implantation. The procedure was uncomplicated and well tolerated. Neurology

review was taken. In view of persistent severe left ventricular ejection function suspected due to fenugreek toxicity, Patient underwent implantation of Cardiac Resynchronization Therapy (CRT) Defibrillator (D) for patients with heart failure. The CRT-D combo device monitored the heart's rhythm, detected irregularities and corrected them with electrical impulses. Patient showed improvement with given medications and discharged in stable condition after 7 days of hospital stay with CRT-D device insitu, and warned to not attempt self-medication again. The fenugreek seeds brought by patient's husband were chemically identified and verified by Expert Botanists at Biodiversity Unit, Devlilal Botanical Park, Gurugram.

#### **Case Discussion:**

The diagnosis of fenugreek related cardiotoxicity was made, as diagnosis of exclusion, after thorough medical investigations and continuous monitoring to rule out other medical causes of sudden illness. Although the patient's mortality was prevented by timely intervention, but the permanent morbidity of severe left ventricular dysfunction, could not be cured completely, and patient became life-time dependant on CRT-D combo device, for preventing future episodes of cardiac dysrhythmia. Thus we prevented one medicolegal case of alleged medical negligence, by proving beforehand, patient's negligence in self-medication with cardiotoxic fenugreek seeds. Fenugreek (*Trigonella foenum graecum*), have toxic adverse effects, besides, several medicinal pharmaceutical and nutraceutical properties. Ouzir M et al (2016) reported that consumption of fenugreek induced some serious toxicological side effects, especially neurobehavioral and neuropathological side effects [6]. Various pharmacologically active compounds with different concentrations have been isolated from fenugreek seeds such as: Alkaloids, flavonoids, tannin like phenolic compounds, polyphenols, steroids, saponins, free amino acids, unusual amino acid 4-hydroxyisoleucine, lipids, phospholipids, mucilaginous fibers, vitamins, and minerals, some functions of these active compounds are known, but many still unknown

[7]. Different over the counter herbal dosage forms of fenugreek seeds are available these days as a herbal drug store for medical uses in the treatment of: bronchitis, abscess, diabetes, hypercholesterolemia, and as a protective drug for liver against lipid accumulation, and for kidney against diabetic nephropathy[8,9]. Due to it's documented historical and traditional use as a spice and medicinal herb in various parts of the world, fenugreek has been granted "generally recognized as safe" (GRAS) status by the U.S. food and drug Administration.

The latest term for drugs, medications, toxins, venoms, antidotes, toxic plant products, toxic animal products, alcohol intoxication is Xenobiotics[10]. Indian society of Toxicology Life Support (ISTOLS). Course teaches Toxicodromal approach for: Toxic Plants, Venomous bites and stings, Drugs of Abuse and withdrawals, Medication overdose and intoxication. (Figure 3) Toxicodromes: symptoms and signs in specific poison affecting vital organs, either stimulating or suppressing their function, thus resulting in pattern of clinical features, which can be controlled by its antagonists. We utilize five senses for Identification and Investigation:

- See: Identify the poison/ toxin/ animal/ plant/ intoxication
- Smell: the noxious/fruity/ropy/pungent odour
- Touch: Simulated victims /Snakes/ Spiders/Scorpions
- Hear: Sounds of venomous animals (Rattle snakes), moaning
- Test (Never try to Taste): Chemical Analysis of poison

Autonomic control on vital organs by stimulating/ suppressing by secreting chemical messengers- adrenaline, acetylcholine etc. Fatal poisons compromises the autonomic control on vital organs – Heart, Lung, Brain.

**Different Toxic Plants** – principle of toxicity is irritation to the different vital organs:

- Brain irritants & stimulants- Dhatura, Cannabis, tobacco, Strychnos, Hemlock, Castor,
- Cardiac irritants & stimulants- Atropa, Dhatura, Belladonna

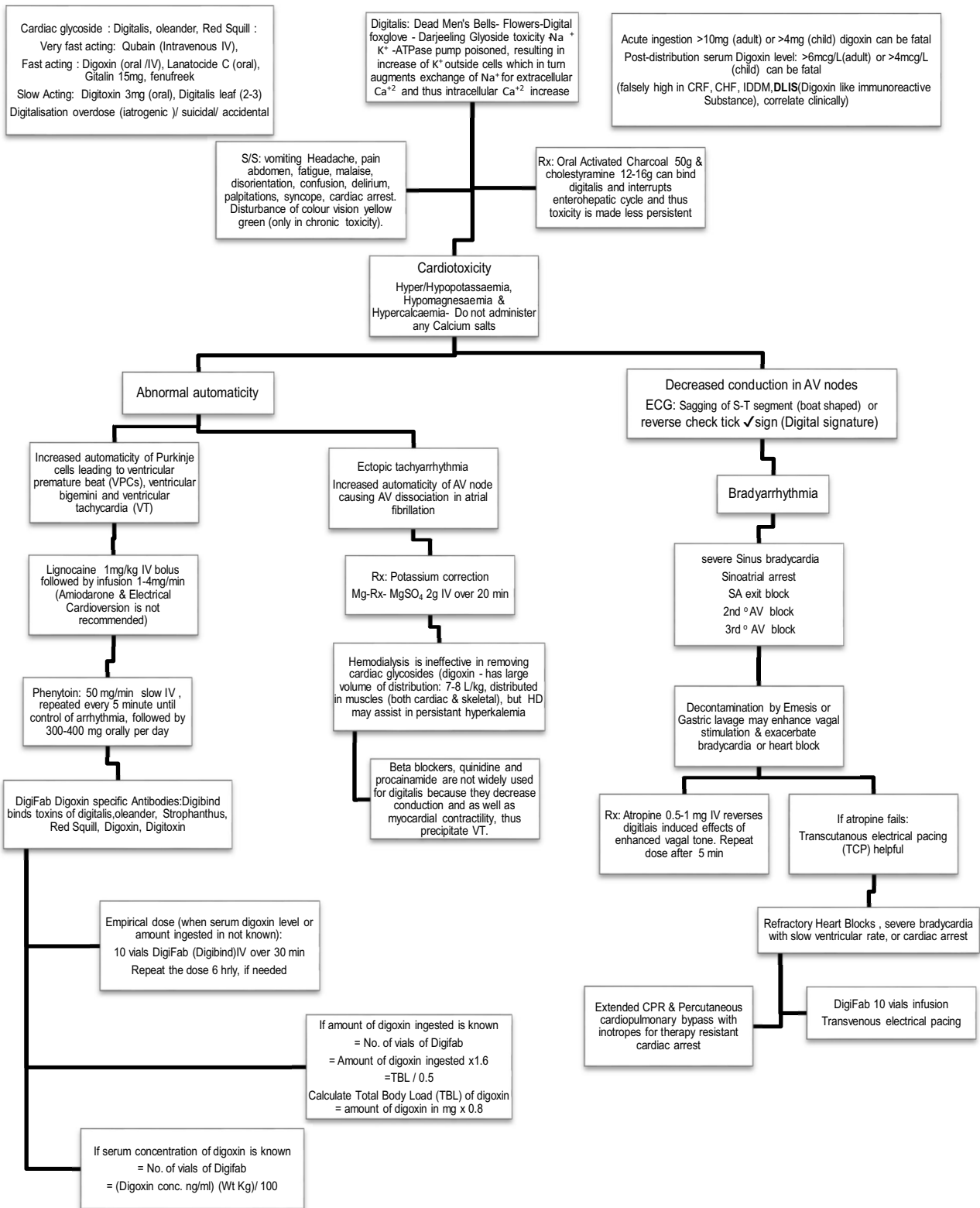


Figure 3. Cardiac glycoside toxicity: Digitalis, oleander, Strophanthus, Red Squill, fenugreek: Toxic Mind Maps by Toxic Detective of IST

- Cardiotoxic – Digitalis, Aconite, oleander, Suicide tree
- Oropharyngeal irritants- Dumcane, Philodendron
- Stomach irritants- Castor, Colocynth, Croton, Glory lily, marking nut, Mayapple, Red pepper, Rosary pea.
- Intestinal irritants- Baneberry, Pokeweed, English ivy
- Liver irritant – Neem, Ackee, Comfrey, Sassafras, Mushrooms
- Kidney irritant- oriental starfruit, Calcium oxalate producing plants
- Dermal irritants- contact dermatitis- Ivy

**Conclusion:**

The comprehensive analysis of cardiac glycosides including Digitalis, Oleander, Red Squill, Qubain, and especially Fenugreek seed derived glycosides using ISTOLS Toxidromal approach by Indian Society of Toxicology was found useful for health risk assessment of over the counter products containing toxic cardiac glycosides. This case will help in resolving confusion among the public regarding the safety of Fenugreek seeds-based healthcare herbal products. Because prevention of these toxicities are better option, than their cure. And most important, prevention of medicolegal case by proving patient's negligence beforehand, by self-medication, is better option, than fighting these allegations in the consumer courts, to prove our innocence as health care provider, filed mostly under Consumer Protection Act.

Conflict of interest: Nil

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## Perspective : Burns and Medicolegal Issues

\* Dr Anurag Verma \*\* Dr. Vivekanshu Verma

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### Keywords :

Burn injuries, Suffocation, Toxic gases, Safety precautions

Usually, burn accidents take place due to failure to prevent them[1]. Burns have tremendous medico-legal importance as they are considered to be among common causes of unnatural deaths in India.

The various issues related to burns can be -

1. Victims claiming compensation under permanent disability act, 2016 and Workmen's compensation act, 1923.
2. Accused claiming not guilty circumstantially as weapon of crime of burn is missing, misleading or misused.
3. Lawyers claiming justice under IPC.
4. Doctors claiming difficulty in providing free treatment and costly plastic surgery in post burn care and in acid attack.
5. Government claims lack of safety measures while storing inflammable and hazardous chemicals (acids) and gases causing burn accidents- LPG in domestic and industrial setup.

Section 320 of Indian Penal Code enlists various grievous body injuries. Unlike other ways of violent assault by dangerous weapons – blunt and sharp weapons – which can result in grievous hurt in one clause or two clauses only, its surprisingly unique to note that a single homicidal act of fatal burning of victim can result in grievous hurt covering all 8 clauses of 320 IPC in single act.

- 1) Emasculation by deep genital burns in males.
- 2) Permanent loss of vision- by corneal burns.
- 3) Permanent loss of hearing by burn on ear causing ruptured tympanic membrane & damage to middle ear cavity by secondary fungal infections in burn victims.
- 4) Privation of any member or Joint by joint contractures resulting from healing after burn, joint privation must involve such injury as makes them permanently stiff, so that they are

unable to perform the normal function assigned to them in human physiology.

- 5) Permanent impairing powers of any member or deprivation of a limb or joint as a result of burn of limb involves life-long crippling of it's victim with defencelessness and misery.
- 6) Permanent disfiguration of the head or face – by burn eg. facial burn in acid attack victims and kerosene burn.
- 7) Fracture or dislocation of a bone or tooth can occur with burn. Bone loss occurs quickly following a severe burn, is sustained and increases the risk of postburn fracture. Postburn bone loss should be looked for in patients with a burn injury of 40% or greater of total body surface area.
- 8) Hurt endangering life or causing severe pain or refraining from ordinary pursuits- as 2nd degree burns are very painful & require long time in healing, refraining victim from ordinary pursuits for more than 20 days. Burn injury of 40% or greater of total body surface area is dangerous to life inspite of best medical care.

This trauma has an element of suspicion of a crime added to it in many incidences.

Code of Criminal Procedures in section 39 asks every citizen to inform the police of any incidence which has harmed any human being. For the treating physician, informing the police is thus an extension of his duty as a citizen.

Except as required in section 39 (section 40 for village head, police associate or a villager) of the Criminal Procedure Code, the need of informing the police in case of a suspicious burn injury is social as well as a moral responsibility.

Following situations need to be notified to the police:-

1. All major burns when received.
2. Unexplained severity, not matching with the history or circumstances.
3. Patients received after several days of burns.

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4. Patients received without proper treatment.
5. Patients likely to succumb to the injury.
6. Patients received dead.
7. Mass casualties.

#### **Burn injuries in a married female :**

When a married female is brought with extensive burn injuries, the police tend to treat this mishap as a dowry problem unless proved otherwise with circumstantial evidences[2]. If the married life at the time of mishap is less than 10 years, then the police investigation becomes stringent and is conducted under a senior officer of the rank not less than a deputy commissioner of Police. Death in such cases would be governed by section 304 B of IPC which specifies dowry death and can lead to punishment with imprisonment for not less than 7 years to life imprisonment.

A treating physician has the responsibility of informing such accidents to legal authority. Legal understanding is not consistent and proceedings are sometimes lengthy.

Doctors engaged in management of burn patients in India need to keep themselves abreast with the legal requirements. Concept of the legal rights of burn survivor and the family are emerging now in India.

Demarcation between physical impairment status and disability to sustain are being discussed now :

Doctors can help their patients by imparting this information with pertinent details about Workmen's compensation act, Persons with disabilities act and guidelines for calculation of physical impairments.

Burn is an injury which is caused by application of heat or chemical substance to the external or internal surface of the body, which causes destruction of tissues. Fire was perhaps man's first double-edged sword, evidenced throughout history; it has served as well as destroyed mankind. Since that time the dangerous consequences of fire have been recognized and man has developed both fear and respect for it.

A significant number of deaths in India occur due to burns every year and over 10 lakh people are moderately or severely burnt every year

in this country. Burns and burn injuries are a major social, economic and public-health problem due to their mortality, morbidity and long term institution involved in the care of the burn victim, thereby emphasizing the importance of developing methods of cost effective treatment and management of such cases, which in turn require a long term multi-disciplinary approach to patient care.

This is compounded by the fact that in our country, there has been a steady increase in the incidence of female victims of burns, particularly the newly married ones, over the years, clearly indicating that such deaths cannot always be attributed to kitchen accidents and that something more sinister is at play, bride burning, for want of dowry.

Most common age group involved was 21-30 years. Married Hindu females were mostly affected. Often, the circumstances of burns are enveloped in mystery, obscurity and unreliable statements. The reason behind this action may be personal, domestic, occupational or social tragedy and more recently dowry death.

The most common time of occurrence of the burn event was between 6 – 9 PM, 23%, followed by the 9 AM –12 Noon period, 16% cases. This corresponds to the time period of preparing food in majority of the Indian households. Fatality increases as total body surface area of burn increases. Most of the burn victims succumb to infections and their complications, if they survive the initial 24 hours.

#### **Causes of death in cases of burns include :**

1. Shock which can be neurogenic due to pain, hypovolemic as a result of massive fluid loss and toxic shock due to cellular destruction and septicaemia.
2. Suffocation due to inhalation of toxic gases such as carbon monoxide and smoke leading to anoxia.
3. Accidents - sustaining severe injuries while attempting to escape from the site of fire.
4. Systemic causes - these include complications such as sepsis, electrolyte disturbances, renal failure, stress ulcers, gangrene, tetanus and septicemia.

The burn injury causes devitalization of the affected surface and produces extensive raw areas, which become moist due to the exudation of plasma, forming a medium ideal for the colonization and proliferation of various types of micro-organisms.

The affected individual's immune system is depressed and becomes dysfunctional, and this, compounded by the large cutaneous bacterial load, the possibility of gastrointestinal translocation, prolonged hospitalization and associated invasive diagnostic and therapeutic procedures, all contribute to sepsis.

Septicemia accounted for most of the deaths. As septicemia accounted for majority deaths, infection control programs in burn wards are necessary. *Pseudomonas aeruginosa* (31%) and *Klebsiella* (24%) were the most common micro-organisms isolated from the splenic smear in study, followed by Coagulase positive *Staph aureus* (11%) and *Proteus* (7%)[3].

Antibiotic regime effective in a particular burn unit may not be effective in another unit or the same unit after a period of time; hence, periodic microbiological studies are essential for understanding the sensitivity patterns of the prevalent strains of the micro-organisms so as to give effective antibiotic cover in cases of burn septicemia. Safety precautions and avoiding contamination will reduce the incidence of septicaemia while treating the cases of burns.

**Main objectives of post mortem examination of burnt bodies are-**

1. To determine extent and severity of burns.
2. To confirm burns as actual cause of death.

3. To positively identify the victim.
4. To determine whether carbon monoxide poisoning, alcohol or drug intoxication was present.
5. To determine whether burns were ante-mortem or post-mortem.

To determine time of death is more difficult with burns than with other corpses. Three main points to distinguish between ante-mortem and post-mortem burns are, line of redness, vesication and reparative processes such as signs of inflammation and formation of granulation tissue.

Pattern of post-mortem changes is altered in cases of burns making it difficult to determine time of death :

- Rigor mortis may not be appreciated due to stiffness of the body produced by burns.
- Post-mortem lividity or hypostasis may not be appreciated.
- Superficial injuries like abrasions and contusions may not be noticed.

If the body is exposed to heat for sufficiently long time, it assumes a characteristic 'pugilistic attitude' with lower limbs flexed at hip and knee while upper limbs are flexed at elbow and wrist.

Accidental burns accounted for 55.6% cases. As accidental deaths were most common, mass education, elimination of poverty and adopting safe cooking habits will reduce the incidence of fatal thermal burn cases.

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## Short Communication:

# Medical records – Medico Legal issues

Dr. Shivakumar F. Kumbar

Received for publication : 5 April 2020 Peer review : 10 April 2020 Accepted for publication : 14 April 2020

### Keywords:

Case records, Case laws, MCI guidelines, Private hospitals

### Introduction:

India is slowly becoming a litigant society. It is high time that the medical professional should take a serious look at the facts of the physical and legal details of medical records.

### Evidentiary value:

All written material is documentary evidence in the eyes of courts of law. Medical records are documentary evidences, which are of immense help not only in medico legal cases but also in defending the doctor in cases of negligence suits or allegations against him/her. Punjab High Court has reminded the doctors that they should not scrawl on documents for self-assumption and has even asked to ensure that the element of legibility is injected into their handwriting. Doctor's illegible handwriting causes 7000 deaths in US every year.

### Types of Medical Records:

Broadly, medical records are of two types, viz. (i) personal and (ii) impersonal used for research or statistics. They can also be further divided as: (i) paper records (hard copies) and (ii) computerized records.

### Obligation of hospitals to provide copy of case record to patient:

It is obligatory for doctors, hospitals to provide the copy of the case record or medical record to the patient or his legal representatives.

### Case Laws:

#### (a) Kanhaiyalal R Trivedi v/s Dr. Satynarayan Vishwakarama (Gujarat)

The Hon'ble High Court of Gujrat has held that the hospital and doctor were held guilty of deficiency in service as case records were not produced before the court to refute the allegation of a lack of standard care.

#### (b) Raghunath Raheja v/s Maharashtra Medical Council – Bombay H/C

The petitioner demanded his wife's indoor case records, which were denied to him. He filed a writ petition in the High Court of Bombay along with his complaints against the Maharashtra Medical Council. The court directed the Maharashtra Medical Council to issue a circular to all hospitals and doctors calling upon them to furnish the copies of the case papers and all relevant documents to the patient or the near relative on demand, subject to payment of usual charges.

#### (c) P.P. Ismail v/s K.K. Radha – NCDR

The Hon'ble National Commission for Consumer Dispute Redressal Forum has held the hospital vicariously liable for the negligent action of the doctor on the basis of the bill showing the professional fees of the doctor and the discharge certificate under the letterhead of the hospital signed by the doctor.

#### (d) S.A. Quereshi v/s Padode Memorial Hospital and Research Centre – Bhopal

It was held that the plea of destroying the case sheet as per the general practice of the hospitals appeared to the court as an attempt to suppress certain facts that are likely to be revealed from the case sheet. The opposite party was found negligent as he should have retained the case records until the disposal of the complaint.

**(e) Dr. Shyam Kumar v/s Rameshbhai, Harmanbhai Kachiya**

The Hon'ble National Commission of Consumer Dispute Redressal Forum has held that not producing medical records to the patient prevents the complainant from seeking an expert opinion and it is the duty of the person in possession of the medical records to produce it in the court and adverse inference could be drawn for not producing the records.

**(f) Rajappa v/s Sree Chitra Tirunal Institute for Medical Science – Kerala**

The petitioner is entitled to photocopies of the entire case sheet and the respondents cannot decline to give the same by stating that the details are available in Appendix 3 furnished, which they are willing to furnish." The Kerala High Court has further explained:

"It is also to be noticed that Regulations do not provide any immunity for any medical record to be retained by any medical practitioner of the hospital from being given to the patient. On the other hand it is expressly provided that a patient should be given medical records in Appendix 3 with supporting documents.

**(g) Ruby Hall clinic**

A Bombay High Court ruled against Ruby hall clinic and said that patient has a right over his record with the hospital and hospital should provide copy of it within a reasonable time (MMC says 3days ) and hospital is entitled to charge a reasonable amount for the same.

**Private Hospitals must provide Medical records under RTI :**

**a) Fortis Hospital -**

The son claimed for the hospitals records but the hospital denied his request Right to information (RTI) on the plea that the requested information was "private, confidential and privileged". Rejecting the claim by the Fortis Hospital, Central Information Commission (CIC) has held that malpractice by private hospitals "amounting to medical terrorism". The CIC has

ended this remarkable judgment by calling that the government, MCI and other regularly authorities have to see that "license to practice medicine will not become license to kill and extort and come to the rescue of the helpless patients".

**b) Nisha Priya Bhatia v/s Institute of Human Behavior and Allied Sciences.**

"The patient has a right to his/her medical record and Respondent Hospital Authorities have a duty to provide the same under Right to Information Act, 2005, Consumer Protection Act, 1986, The Medical Council Act as per world medical ethics. The Commission recommended the Public Authority to develop a timeframe mechanism of disclosure of medical records to patients or their relatives with safeguards for privacy and confidentiality of the patient"

**c) Shri Prabhat Kumar v/s Directorate of Health Services**

"The Commission recommends the Government of India, States and Union Territories, besides the respondent authority in this case, to take necessary steps to enforce the right to information, i.e., forcing the private hospitals to give medical records of the patients on day to day basis, because this daily disclosure will prevent undesirable practices of altering records after damage caused to patient.

**Other Important cases:**

**1) Prendergast v/s Sam and Dee Limited.**

It was apparently the first case in which a patient, who had suffered injury after being given the wrong medication, successfully sued not only the pharmacist who dispensed the wrong medication but also the doctor whose illegibly written prescription had misled the pharmacist. In all previous cases of this nature, only the pharmacist has been held liable. Subject to any reversal by the Court of Appeal or the House of Lords, this High Court decision represents a landmark in the law of medical negligence.

**2) Dr. Kunal Saha v/s Dr. Sukumar Mukherjee and others.**

Deficiency in service was upheld in view of erratic medication and poor records at the AMRI hospital.

**3) The Medical Supdt. St. Gregorious Mission Hospital, Kerala**

Alcoholic psychosis and for de-addiction of drugs who committed suicide himself by hanging in an empty hospital ward.

**Preservation of the Medical Records:**

There are no specific, definite guidelines in India regarding how long to retain medical records. The hospitals follow their own pattern retaining the records for varied periods of time.

- 1) As per Limitation Act 1963 and section 24A of CPA 1986 – Records should be maintained for two years for OPD and three years for IPD. However CPA allows for condoning the delay appropriate cases.
- 2) As per MCI guidelines – Record should be preserved for three years in IPD cases from the commencement of the treatment and MLC cases should be maintained until the final disposal of case even though only a complaint or notice is received.
- 3) As per the PC & PNDDT Act documents should be maintained for a period of two years or until the disposal of the proceedings. The PNDDT

Rules, 1996 requires that when the records are maintained on a computer, a printed copy of the record should be preserved after authentication by the person responsible for such record.

- 4) As per the clinical establishment (Registration & Regulation) Rules, 2010, “Copies of all records and statistics shall be kept with the clinical establishment concerned for at least 3 or 5 years or in the accordance with any other relevant Act in force at the time”.
- 5) As per the DGHS (Directorate General of Health Services) – A minimum recommended period of retention of OPD is for 5 years and IPD is for 10 years and MLC's 10 years which are applicable to Central Government hospitals only and not to the private establishments as per hospital manual.
- 6) As per Income Tax Rules 1962 – Doctors in private practice are required to preserve the daily case register as per Form 3C for a period of six years from the end of the relevant assessment year. That would ordinarily mean for seven years from the close of the accounting year.

**Conclusions:**

Thus, it is important to maintain the case papers in proper formats. The records shall be handed over to the patients or relatives if demanded as per the provisions of various Acts or legislations in force at that time; not providing the documents may amount to negligence.



## Medicolegal News:

Compiled by : Dr. Santosh Pande

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### **SC Awards Rs 76 Lakhs Compensation to a blind child from a hospital guilty of not doing ROPEye Test in Premature birth**

**New Delhi:** SC awarded Rs 76 lakhs compensation to parents of a blind child increasing compensation from Rs 64 lakhs fined by National Consumer Disputes Redressal Commission (NCDRC) order noting Hospital vicariously liable for the acts of negligence committed by the doctors engaged or empanelled to provide medical care, the Supreme Court has directed the hospital to pay compensation to the family of a prematurely born baby whose mandatory check-up of Retinopathy of Prematurity was missed after birth or in neonatal or infancy period as a result, the preterm baby suffered from total blindness.

The order came following a civil appeal filed by the hospital and the doctors, aggrieved by the verdict passed by the commission in a medical negligence case that doctors and hospital guilty of medical negligence since they failed to carry out the mandatory check-up of Retinopathy of Prematurity (“ROP”) on a pre-term baby, which led to his total blindness.

The case concerned a baby born pre-term at 32 weeks' gestation, with a weight of 1.49 kg at the time of birth and was under ante-natal care of a gynecologist. The gynecologist referred the case for intensive care to hospital. At the time of admission, the general condition of the baby was poor, and was diagnosed as “32 weeks preterm AGA with HMD”. The baby was treated in the Neo-natal ICU of the Pediatrics Unit and was put on ventilatory support, and Surfactant injections were administered gradually. The patient stayed in the hospital for almost 4 weeks and was discharged on 29.04.2005, which was 27 days

after birth. Post-discharge, the baby was brought for a follow-up check-up on 04.05.2005 to the Pediatrics Unit of the General OPD of the hospital, when the baby was 4 weeks and 4 days old. The baby was examined by two Consultant Pediatricians. On 13.07.2005, the baby was brought for a 2nd follow-up visit when he was over 3 months old. The pediatrician advised BERA scan/test to be conducted. Notably, there was no advice or recommendation for ROP check-up till then.

Thereafter, in November 2005, abnormal visual responses were observed in the baby. The patient's mother (complainant) sought for the medical records of the baby to have his follow up treatment done. However, the medical records were not made available by the hospital.

The patient was taken to another eye clinic in Delhi where an ultrasound (B. Scan) was conducted. This was followed by another ultrasound at eye hospital, Delhi for further examination where diagnosis revealed that the baby had ROP Stage 5 in both eyes, which is a case of total retinal detachment. The condition of ROP Stage 5 was confirmed at Centre for Ophthalmic Sciences at AIIMS, New Delhi.

This led the complainant to the gynecologist to seek for an explanation as to how the medical condition of the baby had remained undiagnosed.

Thereafter, a legal notice was issued to the hospital to provide the entire in-patient medical records of the baby in compliance with Regulation 1.3.2 of the Indian Medical Council (Professional Conduct, Etiquette's and Ethics) Regulations, 2002 (“IMC Regulations”). However, the hospital failed to furnish the records.

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Taking a step forward, the complainant moved the Delhi Medical Council (DMC) to obtain the medical records. DMC issued a warning to the hospital for the delay in supplying the medical records. Eventually, more than two years after discharge, the hospital provided the medical records along with the case summary. The medical record mentioned that ROP check-up was conducted on 26.04.2005. However, the patient's family contended, that no ROP examination was conducted.

The complainant approached the NCDRC, alleging medical negligence and deficiency in service on the part of the hospital and the doctors and asking compensation for the permanent physical disability, mental agony, and social stigma, deprivation of normal human life, companionship, torture and harassment etc.

The commission directed the Medical Board, AIIMS to give an expert opinion in the matter. The report submitted by the Medical Board of AIIMS stated; "As per standard guidelines (National Neonatology Forum), the new born babies who are born at 32 weeks' gestation or less, should have their eyes examined at 3-4 weeks of age and more frequent check-ups to be done thereafter. The doctor examined the baby at 24 days of age in accordance with established protocol. If ROP screening does not reveal any ROP, then repeat examination should be performed after 2 weeks. The Report goes on to say that after discharge, the baby was brought twice to the General OPD of the hospital. There is no record to show that the baby was brought after 2 weeks of discharge to the Pediatrics OPD clinic when subsequent progression could have been assessed and treated on time."

The National Commission finally was of the considered view that neither the ROP screening was performed, nor was any advice for follow up of ROP given and directed the appellants to pay Rs 64 lakh as compensation. The commission noted; "ROP screening is a team-

work of the Pediatrician, Ophthalmologist and the NICU nurse. There is no medical documentation of the ROP screening procedural details. The O.P. should have performed the retinal examination with binocular indirect ophthalmoscope on dilation of the pupil with scleral depression to ascertain avascular zone at the periphery of the retina. The National Commission found that nothing was forthcoming from Page 102 of the medical records. It appears to be a bare visual examination done by O.P. in haste to cover up the case."

Aggrieved by the orders, the hospital and the medical practitioners approached the apex court, besides the complainant also appealed for enhancing the amount of compensation awarded. The court heard all the parties, wherein the appellant contended that "The critical condition of the baby and possible neuro-development, visual and hearing sequel was informed to the parents. The baby was given utmost care and attention by the doctors of the hospital."

However, the patient's family contended that the doctors of the hospital did not at any stage conduct the ROP examination of the baby, who was a premature baby, nor was the family ever informed about the high risk of ROP in a premature baby, and the necessity for regular check-ups. Further, the hospital had deliberately withheld the medical records for over two years after discharge, the complainant alleged, adding that even the discharge slip did not disclose any instructions advising that the infant be brought for ROP examination.

"If the standard protocol had been carried out by the Doctors, the ROP would have been detected at an early stage, and could have been cured, since it is medically known to be reversible at the early stages," quotes the contention.

Referring to the Bolam Test and other judgments on medical negligence, the Court observed that the reasonable standard of care for a premature baby mandates screening and checking up for ROP. The court noted; "A medical

professional should be alert to the hazards and risks in any professional task he undertakes to the extent that other ordinarily competent members of the profession would be alert. He must bring to any professional task he undertakes reasonable skill that other ordinarily competent members of his profession would bring.”

The apex court, finally upheld the commission's decision and revised the quantum of compensation to Rs 76,00,000 and issued directives on the utilization of the amount awarded. The court held; “It is well established that a hospital is vicariously liable for the acts of negligence committed by the doctors engaged or empanelled to provide medical care. It is a common experience that when a patient goes to a hospital, he/she goes there on account of the reputation of the hospital, and with the hope that due and proper care will be taken by the hospital authorities. If the hospital fails to discharge their duties through their doctors, being employed on job basis or employed on a contract basis, it is the hospital which has to justify the acts of commission or omission on behalf of their doctors.”

**Ref.:** *SC Awards Rs 76 Lakhs Compensation To A Blind Child From A Hospital Guilty Of Not Doing ROP Eye Test In Premature Birth. Accessed on 21/12/19*

### **Five doctors practicing without valid degrees, arrested in Mumbai**

**Mumbai:** On Friday, Mumbai Police crime branch conducted raids at five places across the western suburbs and arrested five people for allegedly practicing medicine and running dispensaries without valid degrees. The police said that all the accused were operating the clinics without proper medical knowledge.

Akbar Pathan, deputy commissioner of police (crime branch) said that before conducting the raids, they had sent informers as patients to these clinics to verify if the information received

about doctors operating without valid degrees is true. After getting a confirmation from them, they conducted raids and arrested the five accused.

Two of the accused — Ramkumar Mishra, 52; and Swapankumar Mandal, 49 — operated their clinics in Vile Parle (West), while the third accused, 32-year-old Hanif Agharia, ran a clinic at Patel compound in Versova. The Oshiwara police has registered a case against him. Two other accused — Tukaram Bhiva Thorat, 52; and Aziz Shaikh, 42 — were lifted from their clinics in Malwani area of Malad (West). Thorat used to run the 'Sheetal Clinic' and Shaikh had named his dispensary as 'Mother and Childcare Clinic'.

The five have been arrested under sections 419 (Punishment for cheating by personation) and 420 (cheating and dishonestly inducing the delivery of property) of the Indian Penal Code, and applicable sections of the Maharashtra Medical Practitioners Act.

In the last three months, 14 fake doctors are been arrested from across the city for practicing without valid licenses.

**Ref.** <https://medicaldialogues.in/hospital-wins-rs-1-crore-defamation-lawsuit-against-patient-who-left-without-paying-bill/> Accessed on 13/01/2020

### **Doctor booked for negligence after four months of minor's death**

**Mumbai:** The police have filed a case of causing death due to medical negligence against the doctor after 4 months of the death of a 16-year-old girl who was admitted to a nursing home at Vasai for suspected dengue.

The action had come after doctors at Palghar district health department concluded that it was a case of medical negligence.

Kajal Choudhary, a class 10 student, was admitted on September 16 with complaint of severe headache. The next day, she complained of uneasiness. The family alleged that the treating doctor kept them in the dark about Kajal's condition

and did not allow them to shift her to another hospital. And by afternoon, they were informed of Kajal's death.

The body was taken for autopsy to the J J hospital but the report is still pending. The family filed a medical negligence case against the doctor at Manickpur police station and alleged that the doctor administered wrong medicine that caused her death.

Manickpur police inspector Rajendra Kamble said that Kajal's medical reports are sent to the panel of doctors of the district health department. The expert panel stated that the doctor should have sought opinion of "MD doctor". The police said that the doctor has been booked for causing death due to negligence.

**Ref:**<http://u.emedinews.org/gtrack?clientid=13324&ul=%0DAFVdVQVOAUwHF0RDRFhbVxEDCwUAcFNUBVkJGwVdWE1K&ml=A1FRU0wCTARVXQ8HSw==&sl=dB8mH2VhTGMuMUtDGVVbUwULCwQSQxpWFlcZBQ==&pp=0> & Accessed on 27/01/2020

### **Rs 50-lakh fine for ads endorsing fair skin with 5 year jail, proposes government**

Advertisements which promote fairness creams, health drinks that claim improvement in height of children and products which promote anti-ageing remedies would be banned soon and would also invite a jail term extending up to five years.

The ministry of health and family welfare has finalized Drugs and Magic Remedies (Objectionable Advertisements) (Amendment) Bill, 2020, that increases the number of diseases and disorders covered under the Act.

The legislation has banned advertisements of products and magic remedies that have claimed to cure diseases and disorders like AIDS, diabetes, deafness and low vision. The list has been increased from 54 to 78.

The draft amendment has banned advertisements of products that promote fairness creams, improve sexual performance and cure

premature ageing and greying of hair, increase in height of children or adults, enhancing the brain capacity and memory, improvement in strength of teeth and vision and change of fetal gender by drugs.

Under Section 7 of the Act, the first verdict is punishable with imprisonment of up to six months or fine or both and a following verdict can also result in imprisonment of up to a year or fine, or both.

The amendment also proposes to escalate the penalties. For the first conviction, the proposed punishment is imprisonment of up to two years and fine up to Rs 10 lakh. For following conviction, the imprisonment can extend to five years with a fine of up to Rs 50 lakh.

**Ref.:** <http://u.emedinews.org/gtrack?clientid=13324&ul=%0DAFVdVQVOAUwHF0RDRFhbVxEDCwUAcFNUBVkJGwVdWE1K&ml=A1FTVEwCTARUVA4OSw==&sl=dB8mH2VhTGMuMUtDGVVbUwULCwQSQxpWFlcZBQ==&pp=0> Accessed on 07/02/2020

### **Medical geneticist can do ultrasound Petitioner : Sonological Society of India**

#### **Order**

1. The petitioner claims that it is a society established to promote awareness in the field of diagnostic ultrasound and to educate and spread awareness amongst general public against female foeticide.
2. The learned counsel appearing for the petitioner submits that members of the petitioner are all qualified medical doctors.
3. The petitioner is, essentially, aggrieved by the communication dated 05.10.2018 sent by the respondent, whereby the petitioner's demand for issuance of a notification permitting MBBS doctors to practice ultrasound under the provisions of Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 (hereafter referred to as 'PC&PNDT Act') was rejected. It is the petitioner's case that MBBS doctors who are

qualified as medical geneticists, as defined under Section 2(g) of the PC&PNDT Act, are also entitled to establish ultrasound clinics.

4. The petitioner relies on the provisions of Rule 3(3)(1) of the Preconception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996 (hereafter referred to as 'PC&PNDT Rules').
5. At the outset, it would be relevant to refer to Section 2(g) of the PC&PNDT Act and Rule 3(3)(1) of the PC&PNDT Rules. Section 2(g) of the PC&PNDT is set out below:-

“2(g) “medical geneticist” includes a person who possesses a degree or diploma in genetic science in the fields of sex selection and pre-natal diagnostic techniques or has experience of not less than two years in any of these fields after obtaining (i) any one of the medical qualifications recognised under the Indian Medical Council Act, 1956 (102 of 1956); or (ii) a post-graduate degree in biological sciences”
6. Rule 3(3)(1) of the PC&PNDT Rules is set out below: “(3) (1) Any person having adequate space and being or employing (c) A medical geneticist.”
7. Indisputably, all persons who hold medical qualifications recognised under the Indian Medical Council Act, 1956 and who have the necessary experience of not less than two years in the specified field, would qualify as medical geneticists within the meaning of Section 2(g) of the PC&PNDT Act.
8. In terms of Rule 3(3)(1)© of the PC&PNDT Rules, any person who employs a medical geneticist can set up a genetic clinic/ultrasound clinic/imaging centre.
9. The petitioner's demand from the respondent that the latter issue a notification to allow all

MBBS doctors to practice ultrasound under the PC&PNDT Act and PC&PNDT Rules has not been acceded to by the respondent.

10. Mr Mahajan, learned counsel appearing for the respondent, states that in so far as the prayer demanding the issuance of a notification is concerned, there is no provision for doing so and therefore, the decision to reject the same cannot be faulted. In so far as the reasons for not acceding to the demand are concerned, clearly the same would have to be tested in individual cases, keeping in view their medical qualifications and experience.
11. In view of the above, the present petition is disposed of by leaving the issue – whether a medical geneticist can operate ultrasound clinics – open to be considered in an appropriate case. The members of petitioner are not precluded from applying for registration with the concerned State Government. The issue whether they are otherwise entitled to practice diagnostic ultrasound will be considered in the given facts of individual cases. It is also clarified that the reasons given by the respondent in the impugned demand would not come in the way of the concerned individuals in making their applications to the concerned authorities, which shall consider the same in accordance with law.
12. The petition is disposed of with the aforesaid observations. The pending application is also disposed of.

**Ref. :** <http://u.emedinews.org/gtrack?clientid=13324&ul=%0DAFVdVQVOAUwHF0RDRFhbVxEDCwUAcFNUBVkJGwVdWE1K&ml=A1FSU0wCTARUVwMGSw==&sl=dB8mH2VhTGMuMUtDGVVbUwULCwQSQxpWF1cZBQ==&pp=0&Accessed on 10/02/2020>





## Indian Medico- Legal Ethics Association Professional Assistance / Welfare Scheme

- 1) The scheme shall be known as PAS “Professional Assistance Scheme”.
- 2) **ONLY the life member of IMLEA, IAP& PAI** 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) The financial contribution towards the scheme shall be as follows:

<b>Admission Fee(One Time, non-refundable)</b>	
Physician with Bachelor degree	Rs. 1000
Physician with Post graduate diploma	Rs. 2000
Physician with Post graduate degree	Rs. 3000
Super specialist	Rs. 4000
Surgeons, Anesthetist etc	Rs. 5000
Surgeons with Super specialist qualification	Rs. 6000

S. no	Qualification/ Specialty	Ten Lakhs	Twenty Lakhs	Forty Lakhs	Fifty Lakhs	One Crore
1	Physician / doctors with Bachelor degree and/or OPD Practice	<b>450</b> <b>(625)</b>	<b>900</b> <b>(1250)</b>	<b>1800</b> <b>(2500)</b>	<b>2200</b> <b>(3125)</b>	<b>4000</b> <b>(6250)</b>
2	Physician / doctors with PG degree &/ or Indoor Practice	<b>950</b> <b>(1250)</b>	<b>1900</b> <b>(2500)</b>	<b>3700</b> <b>(5000)</b>	<b>4500</b> <b>(6250)</b>	<b>8500</b> <b>(12500)</b>
3	Physician / doctors with Practice of Surgery	<b>1900</b> <b>(2500)</b>	<b>3800</b> <b>(5000)</b>	<b>7300</b> <b>(10000)</b>	<b>8500</b> <b>(12500)</b>	<b>16000</b> <b>(25000)</b>
4	Plastic Surgeons, Anesthetist etc	<b>2800</b> <b>(3750)</b>	<b>5600</b> <b>(7500)</b>	<b>10000</b> <b>(15000)</b>	<b>12000</b> <b>(18625)</b>	<b>22000</b> <b>(37250)</b>

- Figure in brackets indicates amount if you directly do through Insurance Company**
- The amount includes the charges of New India Assurance company charges as well as the charges of Human Medico-Legal Consultants Company.
  - This scheme is for **AOY** (Any one year Limit); amount shall be calculated on individual to individual basis for extra **AOA** (Any one Accident limit) assistance.
  - **5% concession on payment for three years & 10% concession for payment for five years** on individual to individual basis.
  - Physician / doctors visiting other hospitals shall have to pay 5% extra
  - The additional charges 15 % for those working with radioactive treatment.
  - The a dditional charges can be included for other benefits like OPD/ indoor attendance, instruments, fire, personnel injuries etc

**PAS for Hospital Establishments:**

<b>Annual Fee for Hospitals Establishment</b>
Rs/- 300 per lakh + 1 rupee/OPD Patient (total OPD in one calendar year) + 5 rupee per IPD patient (total admissions in one calendar year) + GST 18 %+ 7.5 % of basic premium for Unqualified Staff.
<b>The exact calculations will depend upon number of OPD &amp; Indoor patients as per the actual number given by the hospital.</b> Medical colleges/ Corporate hospitals after discussing with hospital administration.
This scheme is for <b>AOY</b> (Any one year Limit); amount shall be calculated on individual to individual basis for extra <b>AOA</b> (Any one Accident limit) assistance.
5% concession on payment for three years & 10% concession for payment for five years on individual to individual basis.

- 6) The hospital can become the member of this scheme only if all the members associated with the hospital have their personal professional indemnity under the scheme.
- 2) A trust / committee / company/ society shall look after the management of the collected fund. The scheme shall initially be run in collaboration with the New India Assurance or National Insurance Company.
- 3) 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.
- 4) **The amount shall be deposited in the Central Indemnity Reserve Fund (CIRF) of the association. The association shall be responsible only for the financial assistance.** Any compensation/cost/damages awarded by judicial trial shall be looked after by government / IRDA approved insurance companies or any other similar private company.
- 5) Experts will be involved so that we have better vision & outcome of the scheme.
- 6) 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.
- 7) If legal notice / case are received by member he should forward the necessary documents to the concerned person.
- 8) Reply to the notice/case should be made only after discussing with the expert committee.
- 9) A discontinued member if he wants to join the scheme again will be treated as a new member.
- 10) **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.**
- 11) 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.
- 12) The scheme can cover untrained hospital staff by paying extra amount as per the decision of expert committee.
- 13) A district/ State/ Regional level committee can be established for the scheme.
- 14) There will be involvement of electronic group of IMLEA for electronic data protection.
- 15) 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].
- 16) **Telephone Help Line:** setting up and manning will be done.
- 17) Planning will be done to start the **Certificate / Diploma / Fellowship Course on med-leg issues** to create a pool of experts.
- 18) 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.



**The Members of Professional Assistance Scheme**

S.N	Name	Place	Speciality				
1	Dr. Dinesh B Thakare	Amravati	Pathologist	67	Dr. Manjit Singh	Patiala	Pediatrician
2	Dr. Neelima M Ardak	Amravati	Ob.&Gyn.	68	Dr. Mrinmoy Sinha	Nadia (W.B)	Pediatrician
3	Dr. Rajendra W. Baitule	Amravati	Orthopedic	69	Dr. Ravi Shankar Akhare	Chandrapur	Pediatrician
4	Dr. Yogesh R Zanwar	Amravati	Dermatologist	70	Dr. Lalit Meshram	Chandrapur	Pediatrician
5	Dr. Ramawatar R. Soni	Amravati	Pathologist	71	Dr. Vivek Shivhare	Nagpur	Pediatrician
6	Dr. Rajendra R. Borkar	Wardha	Pediatrician	72	Dr. Ravishankara M	Banglore	Pediatrician
7	Dr. Satish K Tiwari	Amravati	Pediatrician	73	Dr. Bhooshan Holey	Nagpur	Pediatrician
8	Dr. Usha S Tiwari	Amravati	Hospi/ N Home	74	Dr. Amol Rajguru	Akot	Ob & Gyn
9	Dr. Vinita B Yadav	Gurgaon	Ob.&Gyn.	75	Dr. Rujuda Rajguru	Akot	Ob & Gyn
10	Dr. Balraj Yadav	Gurgaon	Pediatrician	76	Dr. Sireesh V	Banglore	Pediatrician
11	Dr. Dinakara P	Bengaluru	Pediatrician	77	Dr. Ashish Batham	Indore	Pediatrician
12	Dr. Shriniket Tidke	Amravati	Pediatrician	78	Dr. Abinash Singh	Kushinagar	Pediatrician
13	Dr. Gajanan Patil	Morshi	Pediatrician	79	Dr. Brajesh Gupta	Deoghar	Pediatrician
14	Dr. Madhuri Patil	Morshi	Obs & Gyn	80	Dr. Ramesh Kumar	Deoghar	Pediatrician
15	Dr. Vijay M Kuthe	Amravati	Orthopedic	81	Dr. V P Goswami	Indore	Pediatrician
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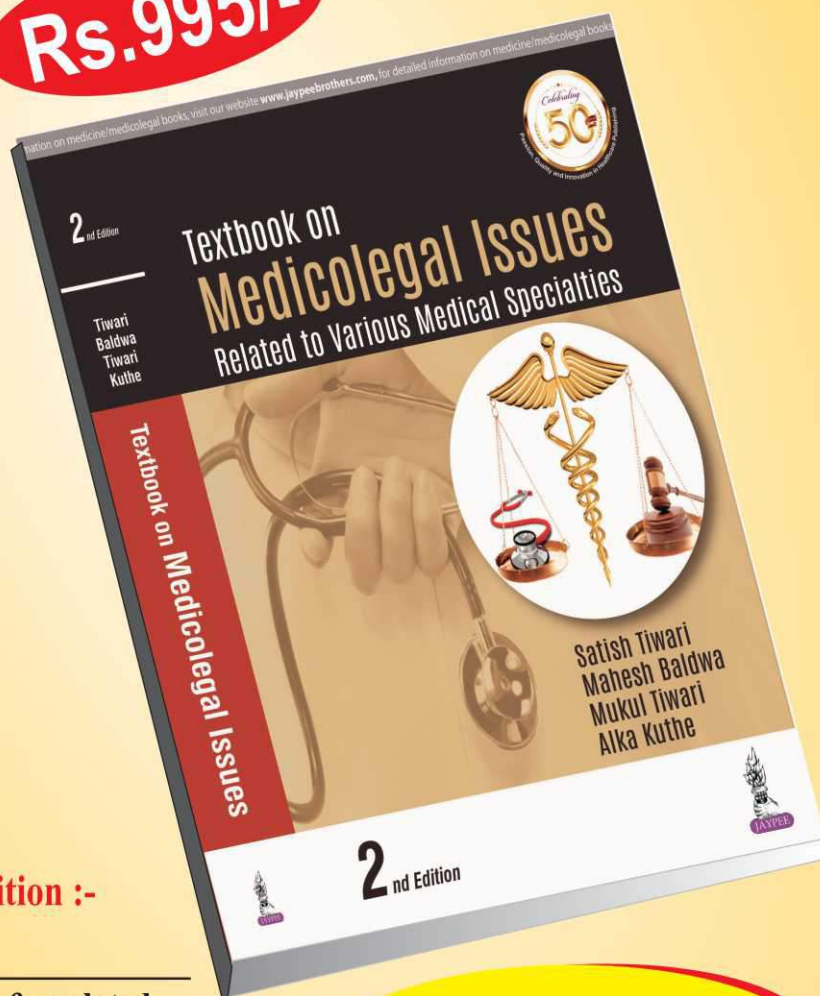
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