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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:

Generic Medicines: Issues and Controversies

Dr. Satish Tiwari

Received for publication : 22 June 2017 Peer review : 28 June 2017 Accepted for publication : 02 July 2017

Keywords : Branded medicines, Drug combinations, Branded hospitals, Physician - pharma nexus.

The twenty first century is the era of globalization. The practice of medicine has seen many turbulent changes in this century. The practice of medicine has evolved from Art to Science and ultimately ended in Commerce. The urbanization and "Corporate culture" has added fuel to the fire. Few decades back the practice of medicine was mission, gradually it became profession and now it is practice of commission. The commission or cut- practice is gradually becoming a norm rather than an exception. This resulted in Doctor- Doctor Nexus, Doctor-pharma nexus, malpractices and commercialization of the health sector. The economic benefits of the use of generic medicines cannot be denied; and in many countries their use is essential to control healthcare spending. Given that the majority of patient-doctor encounters result in the writing of a prescription [1], the cost of the medicine prescribed is of interest both to the patient/consumer and the State. The potential cost savings associated with the use of generic medicines must be considered by the bill-payers. Generic medicines provide cost-effective alternatives to branded medicines, resulting in considerable savings to the healthcare budgets. Generic prescription drugs have been mistrusted in the past but are gaining wider acceptance. However, if consumers are poorly informed about their equivalence to branded medication, it is highly unlikely that generic medicines will be preferred over their branded equivalents [2].

Definitions:

A generic drug is defined as a medication that is produced freely after expiry of the patent protecting the branded product, necessarily being similar to the reference drug in bioequivalence in order to obtain the same therapeutic effect [3]. According to, World Health Organization (WHO), it means a pharmaceutical product which:

- Is usually intended to be interchangeable with an innovator product,
- Is manufactured without a license from the innovator company, and
- Is marketed after the expiry date of the patent or other exclusive rights [4].

Generic drugs are identical to their brand-name comparison drugs in terms of active ingredients, but their inactive ingredients can vary. Inactive ingredients do not affect the chemical activity of a drug and are added during manufacturing for stability and preservation purposes or to achieve a certain consistency, form, color, or taste.

The *reference drug* is registered with the state public health surveillance agency, and its quality must be proven scientifically when applying for registration, with its efficacy and safety being tested through clinical trials.

Branded drug is defined as medications with the same active ingredient(s), concentration, pharmaceutical form, route of administration, dosage and treatment indication, which are equivalent to the medication registered with the state agency, although allowed to differ in some characteristics, such as product size and shape, use-

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by dates, packaging, labeling, excipients and vehicles.

Drug Combinations :

The drug combinations are going to pose special problems on the issues of generic prescriptions. Is it possible to prescribe the combinations in generic? The issue becomes more obvious because there are many irrational combinations available in the market. Who is going to control all this? There is an urgent need to ban irrational combinations.

Why the Medical services are becoming Costly?

As discussed earlier, the commercialization is not the only reason for the increasing cost of medical services. The reasons are many. Some of the other important reasons include:

i) *The increasing cost of Medical Education:* In the present era, the cost of Medical education has increased tremendously. The Mushrooming of private medical institutions is one of the reasons. In these institutes the undergraduate as well as postgraduate degrees are sold at high prizes. The parents and the students have to take loans from the financial institutions and the "indebted doctors" have to repay the loans once they start the practice.

ii) *Invasion by Insurance sector:* The twenty first century is also known for invasion by Insurance sector in almost all aspects of life. Unfortunately, the health services are no exception to this. This has also resulted in increasing cost of medical establishment and services.

iii) *Five star cultures in hospital set-ups:* The revision of pay scales, insurance coverage and overall increase in earnings has resulted in increasing capability or tendency towards getting "Five star facilities or services". The patients or relatives are willing to pay any amount for getting physical amenities like TV, cable, Internet, water-cooler, air conditioners etc. in the hospitals. These are one of the important reasons for the increasing cost of medical treatments. Now-a-days we have hospitals with suits or domiciliary arrangements where the family can have most of the house-hold facilities for 5-10 days after birth of a child or surgical procedures.

iv) *The things that are cheaper may be sub-standard:* In the era of corporatization, commercialization and the increasing allowances, the cost of everything is rising. This has led to overall feeling amongst the consumer that "the more the cost- the better the quality". Hence, many people have the feeling that if they are getting something at lower cost probably the services are sub-standard.

The Branded medicines & hospitals:

In this era of globalization, we come across not only with the branded medicines but also branded hospitals (Corporate hospitals). The situation in these hospitals is not much different than the private medical colleges. These hospitals are charging exuberantly for the devices, instruments, equipment and medicines. It has been observed that some of the companies are manufacturing the same molecules at much higher costs for the corporate hospitals. Drug manufacturers are milking profits by selling the generic version of the same medicines under different trade names when there is no difference in its quality or efficacy.(Fig 1, 2) The controversy regarding the capping of prices of Stent and other devices is known to all. A stringent price cap imposed on stents has failed to break the nexus between the manufactures and the hospitals with the two colluding to push non- coronary stent and other life-saving products. Experts say that this is the usual practice with most critical care products including stents, implants, anti-cancer medicine and so on.

What are the issues?

a) Quality control measures :

The major issues preventing generic prescribing were identified to be the widespread skepticism about the reliability of bioequivalence tests and the safety of switching from branded to generic equivalents. Generic drugs are excellent low cost options provided pharmacological properties are standardized and quality control measures are followed. Unfortunately, this is not the case for many medicines (including branded) mostly due to lack of stringent measures and absence of punitive actions. Inferior regulatory and

control processes for drugs combined with price pressures increase the risk of counterfeit drug marketing.

b) The Rising cost of medicines:

Around one third of the world's population encounters difficulties in accessing medications, due to high prices, with this proportion rising to 50% in the developing countries [3]. Consequently, generic drugs are an alternative to reference drugs in many countries all over the world. The cost of generics may vary considerably across countries depending on the specific active molecule involved, such that savings may not necessarily always accrue [5]. High out of pocket prescription drug cost is associated with medication non-adherence and adverse health outcomes, and several studies have indicated cost-related prescription drug non-adherence [6]. Additionally many patients who underuse prescription drugs due to cost do not bother to communicate such information to their physician[7]. Annual prescription drug spending in the United States topped $286 billion in 2007, prompting calls for greater generic drug use to reduce costs without sacrificing quality. Generic drugs account for about two-thirds of prescriptions filled in the United States but less than 13 percent of costs. One national representative study found that switching prescriptions from brand name medications to molecularly identical generics could lead to an 11 percent reduction in overall U.S. drug costs [8].

c) Physician- Pharma Nexus:

According to Government and Medical Council of India, the doctor- pharma nexus is the cause of increasing cost of medical expenses. If we go in the details, it has been found that there are only about 250 (Two hundred fifty) basic drugs which are required for any medical treatment including emergency management. But, we have more than ten thousand pharmaceutical preparations including "irrational combinations" available in the market. These are manufactured, marketed, promoted and sold by the pharmaceuticals including multinationals with the sole aim of filling their "ever- empty wallet". Though the policy makers are now discussing of "Corporate- Social Responsibility" but in actual practice it remains a distant dream.

d) Whose Responsibility ? :

Other reasons given were that it was a doctor's responsibility, not a pharmacist's, to decide on medication and that using generics meant less money for research. In the absence of good quality generic medicines at retail pharmacy, merely getting doctors to prescribe generic medicine will end up shifting the discretion to pharmacist who are likely to dispense drugs that give them more commissions. Which company's medicines will be sold and who will decide the genuineness and efficacy? Who will be responsible for "generic prescription' and 'generic substitution'?

e) Medico-legal implications:

If the generic medicines are prescribed by doctors or dispensed by pharmaceuticals and the patient deteriorates there is every possibility of allegations or counter allegations regarding efficacy of drug. There can be allegation by the relatives that the patient deteriorated due to poor quality of the drug. In such situation, it will be very difficult to fix the liability and may result in medico-legal implications. Overall, there are so many slips between cup and lips.

Role of Pharma companies:

Whenever pharmaceutical companies introduce any new drug, the costs are enormous under the pretext that they had to invest lots of money for the research; they have the patent for manufacturing etc. Thus there is a vicious cycle of branding, patent laws, increased cost, availability etc. There is need to break this cycle if we want to promote generic drugs. The problems are more if a new research molecule or new vaccines are developed. The conflict of interests are very high and multiple. Once generics flood the markets it will be real chaotic and the chemists will then decide from which manufacturer's generic product they will serve to the patients, which ultimately will be decided by which manufacturer is giving them more discounts or in kinds. Government, Public sector etc have become synonymous with corruption these days. It is hard to believe anyone

about government's sincere intentions.

The Government Pharmaceutical Companies:

One of the ways to reduce the cost of drugs is to have government run manufacturing and marketing units. Few decades back we had government companies like IDPL (Indian Drug and Pharmaceutical Limited), Hindustan Antibiotics Limited, Karnataka State Antibiotics Limited etc. These companies were manufacturing and marketing even the branded medicines at much cheaper rates as compared to multinationals. Why these companies were forced to close down? The government is presently investing in Bullet trains, airports, highways etc. Why we can't have the revival of these government pharmaceutical companies which can provide quality medicines at minimum costs initially at least to the government hospitals and subsequently to others. There is urgent need to explore the possibility of establishing the government pharmaceutical companies under the "Make in India" or "Skill India" start-up schemes.

Many **"Jan Aushadhi Stores"** have already been established by government, which provides medicines to the needy patients at a very affordable rate. The scheme is merely a tokenish measure and in its infancy. *"Genericart"* medicine private limited is providing branded generic medicines at 30- 70% of printed Maximum retail price (MRP) cost. There is need to promote such stores in many other parts of India. It is also important that these stores should not have the natural death due to malpractice or corruptions as happened with government companies.

Role of Physicians:

It is expected that the physicians should practice ethically uninfluenced by motive of profit. This has been mentioned even in "Hippocratic Oath". The aim of any doctor should be to serve the community and "Never do harm to anyone". But, this raises very important issue: should a physician harm himself because of corporate culture and unending corruption in establishing the health care facility? The "Indebted physicians" want to recover their investments or loans in medical education/ infrastructure. One of the modes of this recovery is from the differences in the cost of medicines, vaccines, instruments or other facilities. The benefits or advantages given by pharma or gadget/ instrument companies are one of the safest and short- cut route to achieve these. Thus unethical malpractice begins.

According to some physicians, the decision of generic medicines seems to lack a well thought-out plan, and could affect patient health. There is concern about the quality of drug, education/ qualification of chemist and off-course prescription substitution.

Role of Regulatory Authorities:

The wrong doer or unethical acts are not the gift of 21st Century; it is as old as human race. In order to regulate this there have been regulatory authorities or bodies since ancient times. The technical advances have given many newer modalities to implements various laws, Acts, rules and regulations but, unfortunately these authorities have also been infiltrated by corrupt members having their own personal interests or agenda. Recently, the health ministry had discussed the option of scrapping the MCI, which has been shrouded in controversy in recent years, altogether [9]. 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.

Drug Controller & his team has to ensure various batches of Generic drugs in lakhs, at present are having not only same quantity, quality but also bioavailability. Otherwise market at present is flooded with spurious & substandard drugs & Govt. has not enough machinery to sort it out. No punishment has been given to any Pharma Company till now[10]. DCGI should ensure that these generic versions meet prescribed quality and are manufactured under best manufacturing conditions.

Role of Judiciary:

The personal interest of members of regulatory

authority or the committees constituted by them became very obvious gradually. Personal vendetta or grudges in order to settle the scores became very obvious in their actions. The judiciary was evolved so that the personal whims or wishes can be taken care off. But, unfortunately even the judicial activism has badly failed in controlling the situation. The judiciary has its own limitations, the most obvious being the large number of pending cases and the criteria or priority for deciding the important or specific cases. The personal bias or interpretation of facts or evidences persists at different strata of judiciary resulting in reversing of judgment as we move from lower to higher court.

The Delhi High Court has set aside the Centre's decision to ban 344 fixed dose combination (FDC) medicines, including well-known brands like Corex cough syrup, Vicks Action 500 Extra and D'Cold etc. The court gave the order after hearing arguments of companies like Pfizer, Glenmark, Procter and Gamble and Cipla, the central government and some NGOs like All India Drug Action Network (AIDAN). The court had stayed the Centre's ban on 344 FDC drugs and this interim order was passed in each and every case filed before it thereafter. The Centre had argued that the FDC medicines are "new drugs" and thus, require license from Drugs Controller General of India (DCGI) for sale and manufacture. Also there were no valid licenses for making any of the banned FDCs and added it was difficult to implement any action at state level. However, it had also said that the lacks of approval for these FDCs were a secondary issue and the primary focus was that they "lacked safety and efficacy" and thus, "ban was the only answer". According to them, the banned FDCs had no "therapeutic justification". This order of Central government was set aside and the ban was lifted.

In another case, it was decided that the amendment is also violative of constitutional right of the medical practitioners as well as the pharmaceuticals companies. The present amendment is again not in public interest. The judicial notice of such type of amendment was taken long back by Hon'ble Delhi High Court in a well-known pharma company, 1983(3) PTC265 (Del). In that case the Central Government had introduced the amendment to Rule 96 and added schedule W to the Rules. It was provided that in respect of some formulations, the company has to print only the generic name on the label. It was opposed by the pharmaceuticals companies on the ground that the choice of drug will shift from the qualified doctors and specialist to a chemist shop. It was held by the court that the consumer cannot be left to at the mercy of chemist, who may give any drug as per his choice[11].

Hon'ble Delhi High Court further held that "Similarly, we cannot accept the contention that there would be no difference in formulations made by different formulators out of the same bulk drug. It was further held that obviously, there is the difference in what the petitioners call the bioavailability, i.e. therapeutic impact. Court further observed that "What has been said by first three respondents; that there is no particular difference in therapeutic impact of various formulations manufactured from the same bulk drug cannot be accepted".

Role of Government:

The Judiciary and Government have the overall power and responsibility to regulate all these unethical practices. But, government has also badly failed in its role. The judiciary, the government (elected/ nominated representatives), regulatory officials are fighting amongst themselves for superiority. In the present era, if a political party has absolute power it becomes autocratic. If there is no majority and government has to function in collaboration or cooperation with other political parties, the personal whims or agendas again erupt in a very obvious clear manners, terms and conditions. It is said that the most of the decisions are taken by sitting in air conditioned room which has no relation with the actual problems or difficulties at the grass- root level of the society or stake-holders.

Most of the politicians or officials are partners or stake-holders in the multinational companies, private medical institutions or corporate hospitals. Even in government establishments there in

conflict of interest in purchase of medicines or instruments. Many of the multinationals or corporate houses which supply the necessary requirements contribute to the party fund of the political parties. Thus the unethical acts or practices flourish under direct protection of government or regulatory authorities. According to e-medinexus, RSS affiliated body the Swadeshi Jagran Manch (SJM), wrote a letter to Prime Minister, blaming Niti Aayog and the Health Ministry for favoring pharmaceutical firms in pricing ceiling activity[12]. According to the news, 'Your departments are acting against what you have promised to the people of India.' The pharmaceutical companies are making profits in the range of 500 percent to 4000 percent and that too after imposing price controls. This is because the current formula for arriving at the ceiling price is irrational that legitimizes profiteering and is against the interests of the people. Those in the government influenced by MNCs are trying to dismantle NPPA. So powerful has the hold of the pharmaceutical companies that secretaries and joint secretaries of three ministries – Health and Family Welfare, Commerce and Industry, and Chemicals and Fertilizers– are now holding meetings with the Niti Aayog to completely dismantle the system of price control. Niti Aayog has a history of aligning with vested interest to dismantle the regime of price control.

It is expected that government should cut the prices of medicine and other pharmaceutical products or devices. There is need for stricter policy in this regards rather than a piecemeal approach. Apart from revamping the existing policy there is need to regulate drug prices keeping in mind the interest of all stake-holders. The government should phase out branded drugs in calibrated manner and ban differential pricing to promote generic prescriptions. There is need for provisions to check or restrict firms, suppliers and hospitals from inflating prices by adding margins, commissions and incentives to suppliers, doctors or chemists. Will the government also make a law for the chemists to sell only generic medicines like it's planning for the doctors?

Role of Media and Society:

So, the ultimate responsibility of exposing this unhealthy nexus between all stake holders is now on the media and the society. Unfortunately, both of them have been left be-wildered. Even at the risk of buying substandard or downright spurious drugs hapless patient gets no economic relief in current scenario because MRP even on generic drugs is same as branded drugs. Beneficiaries right now are pharma companies who simply market the products after procuring in bulk from the manufacturers. Though they are trying to improve the situation, it seems that they are confused and misguided by all the concerned. The switch from a brand name to a generic drug may prove more of a challenge for certain patient groups than others. For example, elderly patients and poly-pharmacy users can easily become confused, especially since the new product can differ in shape, taste, and color. Additionally, cost considerations, effectiveness, and perceptions are likely to influence patients' decision to utilize generic prescription drugs[13]. Minorities and individuals with less education have been found to have more negative attitudes toward generic prescription drugs. Patients' perception of generic prescription drugs may impact how they are utilized. A number of surveys have also shown sizable proportions of "resistant customers" reporting negative views about generics, believing them to be less effective, of lower quality and unsuitable for treatment of major illnesses, as compared to their branded equivalents.

What are the options or solutions?

1) Generic substitution has been introduced in most countries in order to reduce costs and improve access to drugs.

2) Is it the prescriber or dispenser of the drug who is the final decision maker?

3) Local reputable or Government manufacturers should produce safe generic medicines.

4) Programs must be implemented in order to boost generic drug prescriptions among physicians.

5) Better communication by physicians and pharmacists to patients about equivalence of generic and brand name prescription drugs will

increase generic prescription drug use, make prescription drugs more accessible and affordable, and reduce the rising prescription drug cost.

6) More information regarding generic drugs and further research in the field of pharmacology were required to increase generic drug prescribing.

7) The Brand Substitution Policy especially by the pharmacist should be taken care.

8) Most of the medical colleges (including governments) are taking bond from the undergraduates or postgraduates for the rural services. Should we ask for oath or bond from the budding doctors that they will prescribe only generic medicines once they start practicing medicine? Should we modify the Hippocratic Oath that a doctor will prescribe only generic medicine?

9) The Medical council of India says that doctor's prescription should be in CAPITAL LETTERS as most of the prescriptions are not legible. Should we give marks for the handwriting during entrance test or counseling for admission to UG or PG courses in health sciences?

10) There is no need for enforcing doctor to write generic drugs. If the government has will to improve medical drug industry, it has to do one thing - fix rate of all drugs, they may or may not be generic. Presently many generic drugs are several times costlier than branded drugs. Most medical stores sell these drugs whenever generic drug is written. If some one wants to improve it in our country please fix the rate which is not very difficult job for Government if they want to do it honestly.

Is Law the Answer?

If we analyze the overall situation, the important issue is whether we need only generic medicines or we also need "generic doctors" (trained in ethical, congenial, malpractice free environment) or "barefoot doctors" who are willing to give their services to the needy members of the community. Is there need for "Branded Corporate Hospitals" or "Generic General Hospitals" i.e. government hospitals so as to cater to the health needs of society in the Incredible India. It is well accepted fact that if we are producing the "Branded doctors", specialists or super-specialists; we can't ask them to practice in slum or rural areas. Enacting the laws or enactments enforcing the doctors to mandatorily prescribe generic medicine may not be fruitful. The law can't be answer to all these. In fact it can be useless, counterproductive and misused as other numerous laws in our country. We need lots of introspection, political will and properly designed policies.

Conclusion:

Treatment of many patients, and in particular, of those in developing countries, is now possible because of low-cost generic drugs. In mature healthcare systems, both pharmacists and physicians support the use of generic drugs and offer them to all patients regardless of socioeconomic status. Although generic medicine use has become more widespread, there is evidence that many doctors and pharmacists hold negative views of generics and resist prescribing generic medicines. Physicians and pharmacists are aware of the potential of generic drugs in the improvement of global access to drugs. However, there are many gaps as far as knowledge, availability and substitution of generic medicines are concerned. The conflict of interest amongst various stake holders; pharmaceuticals, physicians, policy makers, authorities and Government is obvious. It is said that "the Laws are most multiplied when the state is corrupt". There are many existing laws which can tackle the menace of costly or unaffordable medical services even for the poorest of poor. There is no need for newer and newer laws. There is need for proper implementation of existing laws in spirit rather than in words. There is need to protect the innocent, while punishing the corrupt. Those who are working with guilty mind or intention need to be punished. The medical fraternity collectively wants the government to strengthen quality control mechanisms to ensure adherence to good manufacturing practices of affordable medicines to the poorest of poor.

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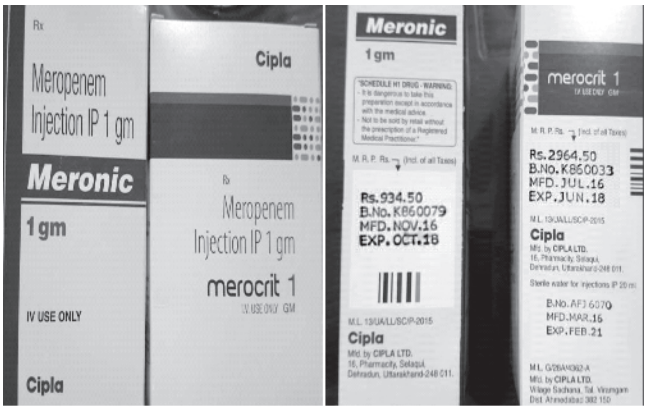

Figure 1: Different rate / cost of same dose, same drug and same company.

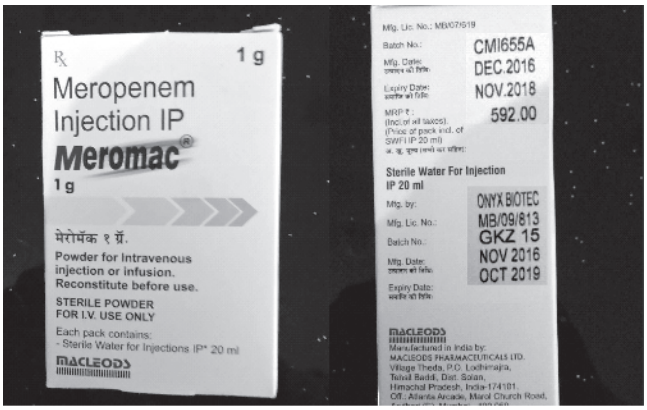

Figure 2: Different rate / cost of same dose, same drug but different company

Perspective :

Fresh Medical Graduates should not be posted to Rural Areas

Dr. Yash Paul

Received for publication : 31 Jan. 2017 Peer review : 28 Mar. 2017 Accepted for publication : 29 April 2017

Keyword : Medical Graduates, Interns, Super-specialists.

This refers to the thought provoking article by IAP President Dr. Anupam Sachdeva[1]. Dr. Sachdeva has stated: "There is another myth being propagated that the doctors are not ready to go to rural areas. It is important that we incentivize the young doctors for going to the rural area." This issue needs deliberation by the policy makers as well as by medical profession.

After passing the final M.B.B.S. examination, one has to take one year training under specialists and super-specialists as an 'intern'. But, the truth is that during this one year internship the interns are busy preparing for the pre-P.G. examination. Those who get selected become postgraduate students, rest may join the government service and aim at becoming PG student as 'in-service' candidate in due course of time.

Laboratory facilities available at rural medical centers are inadequate, rather meager or non-existing. Harsh reality is that inexperienced or less experienced doctor needs better diagnostic facilities as compared to an experienced doctor. If a fresh medical graduate is sent to the rural areas it would be great injustice to the people of that area and also may pose psychological pressure on the inexperienced doctors who may lose self esteem because of inability to handle many cases because of lack of diagnostic facilities.

The government should post every fresh graduate to a district level hospital for at-least one year where he/she can get practical experience by working under guidance of experienced seniors. After one year such doctor should be posted for 6 to 12 months at Tehsil or sub-divisional level hospital where diagnostic facilities may be slightly less thus the doctor may not only become more experienced but also would develop more confidence despite lesser facilities.

Thus every doctor should be given a chance to gain experience, skill and self confidence before being posted to rural area. People living in rural areas should not be put to hardships or harm because of the governments' policy to send inexperienced doctors where there is lack of facilities.

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Perspective :

The Ethics of Abortion in a Cultural context : A Doctor's perspective

Dr. Donna Ropmay

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Key Words: Abortion, Ethical dilemma, Law, Medical ethics, Cultural context

Abstract :

For centuries, the practice of abortion was culturally frowned upon as an act of killing a life. The decision to abort or not often presents an ethical dilemma for doctors and patients alike owing to personal convictions, religious beliefs and moral standards, even though the law in many countries allows the procedure in certain circumstances. In India, medical termination of pregnancy is legally permissible on therapeutic, eugenic, humanitarian and social grounds till the twentieth week of gestation. In the final analysis, the treating physician should be guided by sound medical ethics, prevailing laws and due consideration of the cultural context of every case under review.

Introduction :

The medical definition of abortion is *'termination of pregnancy before the period of fetal viability'*[1]. It is derived from the Latin term ***'aboriri'*** meaning 'to get detached from its proper site'[2,3]. In some situations, it is purely spontaneous or involuntary, due to predisposing natural causes, where it is known as a miscarriage. In other settings, it could be a deliberate attempt to end an unwanted or unintended conception – induced or elective abortion. In the past, induced abortions were done by untrained and unqualified 'quacks' in conditions which were far from satisfactory, the so-called 'criminal abortions'. Today, many countries have legalized the procedure so that it can be performed by trained and qualified doctors in safe and sanitary surroundings. Through the years, abortion has been an issue encompassing not only ethical, but also legal and social dimensions worldwide. **The Medical Termination of Pregnancy Act, 1971** in India permits abortion by an experienced registered medical practitioner or a specialist in Obstetrics and Gynecology in a recognized center on therapeutic, eugenic, humanitarian and social grounds till the twentieth week of gestation. However, Section 5 of the Act allows termination at any stage if the treating physician feels that continuation of the pregnancy would be life threatening to the woman[4].

The Doctor's dilemma

From a doctor's perspective, the reasons for abortion may be justifiable and within the purview of prevailing laws, but would it be ethical to always comply with the patient's wishes? An act which is legal is not necessarily ethical. Again, ethics is defined by its social and cultural context. Further, the religious beliefs and moral values of both the physician and the patient play an important part in the decision-making process. As healthcare providers, we have to keep in mind that no two situations are alike. The general rule is to remain consistent in our approach as this would influence our actions towards patients. We have to uniformly apply our knowledge of ethical principles in a cultural and social context. In the pages that follow, three cases will be discussed for a better understanding of the dilemmas usually faced by local doctors when patients request for abortion services.

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Case 1 : 16 year old girl conceives after a relationship with her boyfriend. When confronted with the news, he dumps her. She is scared, dare not face her parents and opts for an abortion in the 11th week of gestation.

Discussion :

In this case, there are arguments for and against induced abortion. In the debate for the motion, we can argue that the continuation of pregnancy is likely to cause mental anguish to the patient and may affect her life and health. Legally performed abortions in women under age 20 are considered less dangerous (less than one death per 100,000 events) than childbirth (nine deaths per 100,000 events)[5]. Moreover, the girl has no social support either from her boyfriend who deserts her, or parents whom she has refrained from taking into her confidence out of fear and shame. While debating against the motion, we can argue that she is a minor, i.e. less than 18 years of age. Therefore, any decision that she makes or medical procedure contemplated would require parental consent for it to be legally binding. A doctor cannot go ahead before this prerequisite is fulfilled. What about the health effects? Recent scientific evidence indicates that women who have undergone abortion have a greater risk of future mental health problems[6]. The psychological scars of induced abortion remain long after the physical wound in the womb has healed.

Case 2 : A 37 year old woman, pregnant for the first time, has just received a report of her antenatal diagnostic test which shows the fetal karyotype to be positive for Trisomy 21 or Down's syndrome. Should the treating physician go along with her request for termination of pregnancy on eugenic grounds?

Discussion :

In the current situation, the physician is confronted with the dilemma of 'pro-life' or 'pro-choice'. On one hand, he/she has a moral obligation to uphold the sanctity of life from its beginning. This is one of the core values of medical ethics enshrined in the *Hippocratic Oath.* The original version of the Declaration of Geneva, adopted by the World Medical Association in 1948 says: *"I will maintain the utmost respect for human life, from the time of its conception"*[7]. On the other hand, the physician ought to respect the autonomy of the patient in deciding the fate of her own body, health and life. Of late, the latter approach is often chosen as women are becoming increasingly aware of their reproductive rights. A recent newspaper article says that a woman's body is her 'dictatorship' and not a 'democracy'[8]. However, it is not just a question of her life alone, but that of her unborn child's as well. Does the woman have absolute authority to prevent a birth in order to spare herself the mental and psychological trauma that it may cause her in future? Would it be right to end a life to prevent it from suffering? It is a fact that life for a child with Down's syndrome is not a bed of roses – rather it is a struggle against the physical and mental problems that he/she grows up with. At the same time, there are parents who have courageously faced the challenges of raising a disabled child, reaping the benefits of having fought the good fight and finishing the race with élan.

Case 3 : A happy but poor couple has four children. When the wife conceived again, the husband decided they couldn't afford another child and approached the obstetrician for medical termination of pregnancy.

Discussion :

A unique feature of Indian law allows termination of pregnancy on social grounds. This can occur when there is failure of contraceptive measures in a married woman, or when the immediate economic and social environment of the family is not conducive for bringing up a child. Hence, induced abortion is legally permissible in the above case scenario. Before proceeding further, it would be wise to talk to the wife to find out her take on the matter. While patient autonomy should be given its due place in the decision-making process of healthcare providers, a physician may sometimes feel the need to 'conscientiously object' to a choice which could hurt his/her deepest personal convictions. So, in the aforementioned situation, an alternative to abortion would be to inform and counsel the couple about the possibility

of having the baby and subsequently handing it over to an adoption agency. In case they do not want any more children in future, a permanent procedure like tubal ligation may be advised to limit family size. Locally, the Reach Shillong Ministries is doing a good job of caring for abandoned babies and street children[9]. This organization has been officially designated as the State Adoption Resource Agency (SARA). The point here is that even poor patients could be offered options other than abortion for unintended pregnancy, taking into account the social support facilities available locally. Termination is necessarily the last resort.

The Indian Scenario :

As doctors practicing in India, we are obliged to respect and obey the law of the land. **The Medical Termination of Pregnancy (MTP) Act** was passed in 1971 with a view to curbing 'unsafe' abortions by 'unskilled' hands in 'unhygienic' surroundings. As a consequence, there has been a notable drop in maternal mortality and female feticide[3]. Legislation has also resulted in greater accessibility to professional abortion services by women at large. In addition to law, we have a code of ethics provided by the Medical Council of India to keep us on the right track when confronted with difficult clinical decisions. According to Section 7.15 of the **MCI Code of Ethics Regulations, 2002,** 'A Registered Medical Practitioner shall not refuse on religious grounds alone to give assistance in or conduct of sterility, birth control, circumcision and MTP when there is a medical indication, unless the medical practitioner feels himself/herself incompetent to do so'[10].

However, in a local context, social and cultural attitudes confound the situation for doctors as the practice of induced abortion is still not widely accepted in society because it is viewed as an act of killing a baby in the womb. In Meghalaya, the church has a firm stand against the use of modern contraceptive methods and abortion, which in turn influences the reproductive decisions of converted local women. It is a belief that those who choose to abort, for reasons other than health, would invite the curse and fury of God. In this manner, abortion is deemed equivalent to murder [11]. This view may be reflected in the high total fertility rate in our state[12] .

The law has given doctors a wide safety net but this liberal approach to the issue does not mean we can endorse *'abortion on demand'*. Medical termination of pregnancy (MTP) should be an exception rather than the rule. In many cases like the ones discussed earlier, there are feasible alternatives to induced abortion. It would rather be more appropriate to counsel patients to help them have a new lease in life. For example, a mother who is carrying a baby with Down's syndrome can be assured of all the medical and psychological assistance that she needs to see her through the pregnancy and raise her child in future. A teenaged unwed mother may be given the option of handing over her baby to a reputed shelter home till she is old enough to care for her child. Adult sex education must be a part of the curriculum in schools and colleges to help adolescents cope with 'growing pains' and find purpose and direction in life. This would go a long way in preventing premarital sex and teenage pregnancy. A victim of rape who subsequently conceives is given all the compassion and support to enable her to recover from the harrowing experience. Although she has a choice of legally terminating her pregnancy, she could also be counseled to keep her baby if she has the necessary social sustenance to do so. In an incident at Bihar, a rape survivor chose to continue her pregnancy against all odds[13]. It is only cases of life-threatening maternal illness, such as decompensated heart disease or septicemia, which may justify termination of pregnancy in order to save the mother's life. In an emergency, when faced with a situation of saving either the mother's or baby's life, obstetricians generally choose the former with the notion that a woman could always conceive and bear children again. This stand appears both ethically and socially sound. However, with advances in healthcare, occasions rarely arise where the baby's life has to be sacrificed for the mother's. Lastly, elective abortion could perhaps be considered when the fetus is diagnosed with gross malformations incompatible with life outside the womb, e.g.

anencephaly[14].

Conclusion :

Abortion is an issue with wide-ranging medical, legal, social and moral implications. An ethical decision for the physician is based on the principles of medical ethics to be interpreted in a cultural and social context. Although conflicts can arise in a particular situation, it would be best for us to adopt a balanced approach where the patients' needs are met without compromising our personal values and deepest convictions. We have to keep in mind that every case is unique and decided on a case by case basis. The fact, however, remains that human life is precious and must be given a chance to bloom where it is (im)planted.

Acknowledgement:

I'd like to express my sincere thanks to all the Obstetricians and Gynecologists of Shillong who provided valuable inputs which helped me compose the article.

Disclaimer:

The views expressed in this article are the author's own and do not reflect the official position of the institution.

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Review Article :

Medicolegal Case and Postmortem – When and why ?

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Keywords: Medicolegal Case, Injury, Ambulance, Good Samaritan Law, Postmortem.

Every patient, if dies unnatural death, needs Postmortem examination, to establish the cause of death; whether it was natural or unnatural. Whenever patient is injured physically or chemically, with suspicion of intention of harm by the accused, it becomes a medicolegal case. When a patient is injured outside the hospital and patient is brought for treatment then the doctor has to inform the police and prepare MLC report. And when the patient injured inside the hospital either due to slipping on wet floor in the bathroom or due to lack of proper medical care, then it becomes a medicolegal issue of medical negligence. This adverse event should be reported to administration, to rectify the injury, to prevent future events and to the legal department, so that proper documentation is maintained for future court litigation.

MEDICO- LEGAL CASE (MLC) can be expressed as any case of injury, disease or infirmity or death in which law enforcing agencies have to enquire in to the matter and fix the responsibility of a person or a group of persons responsible for causing the said injury, disease or infirmity or death and penalize as per the existing law of land[1].

It includes [2].

(a) Assault and battery, including domestic violence and child abuse

(b) Accidents like Road Traffic Accidents (RTA), industrial accidents etc.

(c) Cases of trauma with suspicion of foul play

(d) Electrical injuries and Burns

(e) Fatal Poisoning, Alcohol Intoxication

(f) Undiagnosed coma

(g) Chemical injuries and acid attacks

(h) Burns and Scalds in young married females

(j) Sexual Offences – natural (rape) or unnatural (sodomy)

(k) Criminal abortions

(l) Attempted suicide with slit wrist, hanging from roof, poisoning

(m) Cases of asphyxia as a result of hanging, strangulation, drowning, suffocation etc.

(n) Custodial deaths in arrested

(o) Death on OT table in the operation theatre

(p) Unnatural deaths

(q) Death due to snake bite, scorpion sting or Bee sting.

(r) Fire Arm injuries

(s) Fatal Drug overdose and Drug abuse

(t) Dead brought to the Hospital

(u) Deaths occurring within 24 hours of hospitalization without establishment of a diagnosis

(v) Battered baby syndrome

(x) Human Bites and Animal Bites

Why animal bite can be MLC?

Snake bite can kill the victim within 24 hours, and many cases of foul play have been reported in which snakes were put in pot intentionally by rivals to kill others for property. It becomes non-bailable offence under 328 IPC (grievous hurt by poison). If a farmer dies due to snake bite while working in fields, then 50,000 Rs compensation is given by Forest department under Wildlife protection act. Same is applicable in death by bites by wild cats

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like Lion, Tiger, Leopard and Fox. So hurt by all wild animals is MLC for claiming compensation. Dog bite can be MLC, if bitten by pet dog because it is suspected foul play. Police complaints were made that two neighbours during mutual quarrel ordered the tamed pet dog to bite the other neighbour to settle scores. Since dogbite can lead to rabies, a life threatening infection, so it can be non-bailable offence under 328 IPC (grievous hurt by endangering life) and 270 IPC (Malignant act likely to spread infectious disease dangerous to life) with imprisonment of 2 yrs.

Is Human bite an MLC?

Human bite is an MLC, because it is intentional harm done, Famous Boxer Mike Tyson teared the ear of his rival player by biting and resulted in permanent disfiguration of face. All bites which are Grievous in nature and endangering life of victim. Law takes Human bite by cutting canine teeth as sharp weapon, and becomes non-bailable offence under 324 IPC (grievous hurt by sharp weapon). Human Bites are very common to find on body of victims of sexual assault, domestic abuse, which can be used to identify the accused by pattern of teeth in forensic odontology[3].

Is teeth bite mark – blunt trauma or sharp weapon trauma?

Since, teeth bites are caused by front teeth-canines and incisors- both having sharp ends – causing injury, so teeth bite causing loss of vital tissue- eg., ear cut in Boxer Mike Tyson's case becomes grievous hurt by sharp weapon.

What if Assault on victim with Coexisting Disease, leads to death of victim? [4]

During a quarrel, death occurs from High BP-rupture of the Brain aneurysm, cerebral hemorrhage, aortic dissection or acute Myocardial infarction or status asthmaticus or rupture of enlarged spleen in malaria, or any other natural disease. The assailant will not be responsible for the death of the victim, but can be charged with grievous hurt.

Should Doctor report an MLC at house call for Ambulance transfer?

Many times, Ambulance is called by the police or attendants of the injured patients at scene of crime to shift a Medicolegal Case in Ambulance to nearby Hospital. Sometimes, we receive a vague urgent phone call in midnight for ambulance by nearby resident neighbours of victim, that a sick dying patient needs to be shifted urgent medical attention, and when we reach to pickup patient, we come to know that it's a gunshot, strangulation or rape. We can't just leave a rape victim and run away, as its offence in recent Anti Rape laws of India (376 IPC Criminal Law (Amendment) Act, 2013), and we can't refuse medical treatment to sexual assault victim, acid attack victim (326A IPC Criminal Law (Amendment) Act, 2013). Then it becomes legal duty of every medical personnel to report medicolegal case and preserve the evidence of crime, otherwise he can be punished for not reporting crime and not giving first aid medical treatment, since we are on record by phone calls and CCTV camera installed in most of residential buildings.

Later we are summoned to court for medical evidence, in which we become the first independent witness of scene of crime.

What are latest "Good Samaritan" guidelines for saving life of roadside victims?

In Indian gazette notification 2015, Ministry of Road Transport and Highways (MoRTH) notified the "Good Samaritan" guidelines. As per the guidelines, the disclosure of personal information by a Good Samaritan who brings an injured person to the hospital was made voluntary. They also provided that a Good Samaritan would not be liable for any civil or criminal liability. So we as ambulance person will not be unnecessarily harassed in courts, if we are doing our duty in good faith, to save the life of victim [5].

When is Postmortem indicated for patients?

- When death is unnatural- trauma, injury, poisoning, accident, burn
- When death is unexpected and sudden and suspected foul play
- When death is due to negligence – Roadside accident, Industrial accident, therapeutic misadventure in Hospital
- When death occurs in restricted area- Operation Theater, Police station lockup, Prison.
- Maternal Death during sterilization, abortion, delivery, Caesarian section[6].

When is Postmortem done without any antemortem MLC?	
304- A of IPC Alleged Medical Negligence ● Death of young female during delivery ● Death during surgery	304- B of IPC Alleged Dowry deaths ● Whenever young female dies within 7yrs. of marriage by poisoning, assault, hanging, drowning, burn, electrocution, fall from roof or any injury and there is previous complaint of cruelty by in-laws and husband for dowry - 498-A of IPC

Why Postmortem is required by Law?

(a) To find out the cause of death- natural or unnatural. Natural cause of death is not punishable for accused, but unnatural cause proves the guilt of accused. If it is intentional – to kill- its homicide- its punishable for imprisonment of accused. If it's just accidental without any motive to harm- its negligent act due to lack of care – penalty to victim [7].

(b) To find out the time passed since death to corroborate the day of crime.

(c) To identify the deceased, in cases where it is unknown unclaimed (Mr. Nitish Katara murder case – blunt injury head by hammer – RTA – Burn- can't identify)

(d) To find out the injuries on body before death / after death.

(e) To collect relevant information to assist the investigating officers to arrive at a conclusion whether death is accidental, suicidal or homicidal.

(f) In case of infants whether it is live born / still born / dead born and if live born the period of survival and the cause of death.

(g) To collect evidence- pieces of vital organs and samples of blood and body fluids and foreign bodies- gunshot bullets- to establish the weapon of crime.

(h) To opine as to whether medical attendance following injury or poisoning was given or not (Kennedy phenomenon) – Smt. Indira Gandhi's murder - suturing and repair of wounds vanished the track of wound.

(i) To ascertain the period of survival following receipt of injury or poisoning

(j) To find out the time passed since death since last meal.

(k) Whether the position of the dead body was changed or dragged after death.

(l) To opine as to the place and circumstances of death – basing on detection of modified forms of putrefaction

(m) In presence of multiple injuries – what was the number of assailants (Ms. Nirbhaya case of Delhi- multiple injuries all over the body in short time –witnessed by co-victim- proved involvement of all the accused).

(n) To connect the accused with the offence (Ms. Priyadarshini Mattu case- Helmet used to kill the victim- blood stain on helmet of accused and blunt trauma impact noticed on the victim's body – established the link)

(o) To collect samples for chemical analysis, histological exam (polonium or alprax poisoning)

(p) To opine as to whether medical attendance following injury or poisoning was given or not (Kennedy phenomenon- suturing done to stop bleeding)

Why MLC and Postmortem necessary in Death on Table in OT? [8]

- OT is closed space with restricted entry to outsiders
- No relative is allowed inside OT with the patient
- Allegations of organ removal or unnecessary surgery by relative.
- Blame game starts in court in between surgeon and anesthetist.

What Postmortem can establish in Death on Table in OT? [9]

- Was the death due to effect of anesthetic or due to bleeding during surgical procedure or due to the natural disease for which operation was being carried out?
- Would the patient have died at the time he had died, if he has gone through anesthesia or operation in well-equipped hospital with well qualified doctors (like AIIMS)?
- Was the surgery necessary to save the life of patient?
- Was the death due to some unsuspected natural disease directly unrelated to the disease for which surgery was performed?
- Was CPR and advanced cardiac life support given to save the life of patient, after the fatal negligent wrong act during anesthesia / surgery?

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Letter to Editor :

Why should recipient of a bounced cheque be punished?

Dr. Yash Paul

Do we punish a patient or his/her attendant if a doctor or nurse gives wrong medicine? Answer is No. In case a cheque bounces due to any reason, recipient of bounced cheque is charged money in lieu of service charges for bounced cheque, which is not charged for a regular cheque.

On 17th January 2012, I had sent a petition to The Council of States (Rajya Sabha) where I had raised two points :

1. No penalty should be imposed on the recipient of the bounced cheque.
2. Additional penalty should be imposed upon the person who had issue such cheque and created problems and inconveniences for the recipient of the bounced cheque. This amount should be paid to the recipient of the cheque.

I received a response from Ministry of Finance Ref. No. F. No. 6/3/2012-BO-III dated 24th July 2012, which stated: Damodaran Committee in its report has observed "...while there is a broad based consensus on the need for reasonable penalty on the drawee, payable to both the presenting and the issuing banks, the presenting party should be exempt from penalties". The recommendation is under examination with Reserve Bank of India.

On 11th May 2016 I had sent reminder to the Ministry of Finance and Reserve Bank of India. Reserve Bank of India in its response dated 19th July 2016 Ref. No. DPSS CO (CHD) No. 232-103-06-03/2015-16 stated: "With regard to your suggestion that additional penalty may be collected from the drawer of a bounced cheque and paid to the beneficiary, we advise that this cannot be considered as a solution to the problem of cheque bouncing due to insufficient funds and such a proposal is not under examination by RBI." Surprisingly RBI is silent on the issue that presenting party should be exempt from penalty, though it has been 'under examination with RBI for more than four years now.'

This shows that we have lot of sympathy for wrong doer ..... 'becharaa' (poor fellow).

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Medico Legal News

Dr. Santosh Pande

Not all anomalies can be detected by ultrasound- NCDRC while dismissing Rs 17 lakh complaint

"Not all anomalies can be detected by ultrasound study." A case claiming Rs. 17 lakhs compensation was dismissed by the National Consumer Disputes Redressal Commission, that was seen alleging failure on part of Doctors to diagnose fetal anomalies.

Case details - S.Saravanan V/s M/S RASI Clinic & 3 ORS, Tamilnadu . Judgement Dated : 20 Mar 2017.

Facts in short-

1. The complainant along with his wife approached the Respondent on 20.09-2007 and the doctor confirmed the 2nd pregnancy. It was contended by the couple that due to extraction of 4 teeth 2 days back, the wife consumed heavy doses of pain killer medicine and requested to advise for termination of pregnancy if the fetus would face any problem due to these medicine! But this possibility was ruled out by doctors.

2. Then the patient was referred for regular scanning with the Respondent No. 2 and all the 3 ultrasound scans were normal and heart activity was recorded.

3. On 16.06.2008 a female baby was born under C-Section. But as the baby had breathing problems, she was referred to another Hospital. The baby was diagnosed as 15 days old neonate with Down's phenotype and Tetralogy of Fallot with severely hypoplastic MPA & PA confluence.

4. Thus a case of Medical Negligence was filed against all the doctors for Rs. 17 Lakhs alleging that the doctors did not give the correct advice at the first instance about the adverse effects of the pain killer medicines and that the doctors failed to diagnose fetal anomalies. Both the lower forums dismissed the Complaint.

5. The Indian Medical Council (MCI) was impleaded as the party, but since no relief was claimed against it, it's name was deleted.

6. The Doctors refuted all the allegations made against them. It was contended that the lady did not come for the follow-up in time. While the Ultrasound on the 12-13 week recommended a repeat ultrasound at 18-20 weeks, but the patient did not come for the same.

The complainant in response to this then told the court that while the report stated repeat ultrasound at 18-20 weeks, the gynecologist herself did not advice the same to the patient and hence there was negligence.

Held : 1. The Commission observed from the evidence that the complainant never uttered a single word in the complaint that the doctor was deficient in not advising scan/ultrasound between 18-20 weeks of pregnancy and this was the total new case made up.

2. Relieving the doctors from the charges of negligence it was observed that there is no proof much less of an expert witness that complications developed due to the effect of medicines taken for dental treatment and secondly, there was no occasion to advise any higher level scan as all the scans were found normal as per the report of sonography expert and the lady failed to come for the second ultrasound/scan during the duration of 18-20 weeks of pregnancy.

3. The Commission pointed out the footnote at the end of the report which started as , "Not all anomalies can be detected by ultrasound study…". Moreover the court observed that since here was no

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occasion for the Gynecologist /clinic to advice any higher level scan/ ultrasound. Thus, there has been no negligence on the part of Gynecologist /clinic because first of all, there is no proof that complications developed due to the effects of medicines taken for dental treatment and secondly, there was no occasion to advice any higher level scan as all the scans were found normal as per the report of the sonography expert, OP-2.

This is very important judgment for both, Gynecologist and Sonologist. Anomaly scan is very important aspect in pregnancy and no doctor would purposely give wrong report.

But the question remains, that if the anomaly would have been detected, the patient would have exercised her right of MTP. But what if it would have been detected after 20 weeks? Only ray of hope is Supreme Court. But recently we have seen the contradictory judgments of Apex Court on this topic. One which allowed the MTP even after 20 weeks and the recent one disallowed in the case of Down syndrome! This judgment again emphasizes the need to amend the MTP act [1].

Medical Negligence: Human Rights Commission fines Govt, Recommends suspension of Doctor

Mumbai: In a Medical negligence case pending before the Maharashtra State Human Rights Commission, the commission is reported to have pronounced its judgment after two years, holding the Doctor guilty of negligence. The commission, in its judgment, has ordered the state government to pay a compensation of Rs. 5 lakhs to the patient, while also directing the Maharashtra Medical Council (MMC) to suspend or cancel the licence of the surgeon Dr. Mannan Singh.

Indian Express reports about the case of a 32 year old farmer Mr. Dengade who had come to the Yashvant Rao Chavan Hospital, Pune with complaints of Varicose Veins. In Sept. 2015 he was operated for the disease. During the surgery, it was alleged that the operating surgeon (the registrar at the Surgery Department) damaged the femoral artery in the right leg that carries blood supply to lower limb. The artery damage led to excessive bleeding forcing Dengade to undergo amputation.

" I was given two days to decide about amputation. The doctors said I can lose my life because my leg had turned black and infection could spread," Dengde told Indian Express. An expert committee consisting of 5 doctors from Sasoon Hospital was constituted to investigate the case which observed, "Considering the injury to femoral artery and vein, operating surgeon Dr. Mannam Singh is responsible for the complications. Improper treatment technique seems to be the cause of the injury." "Injury caused during surgery indicated gross negligence."

Observing from the expert committee's report, the human rights commission held the doctor guilty of negligence, directing the MMC to take action against him. Further observing that the patient was a sugarcane farmer, who has not been able to work since amputation, and his wife earning Rs, 150 per day, the Pimpri-Chinchwad Municipal Corporation has been directed by MSHRC to pay compensation of Rs. 5 lakhs to Dengde [2].

After 20 years, SC absolves doctor of medical negligence charge.

The Supreme Court has absolved a doctor from Maharashtra of the charge of medical negligence after 20 years of an incident in which a road accident victim succumbed to injuries at a hospital. The Apex court relied on its earlier verdict to say that in cases where negligence is alleged against professionals like doctors the court should be careful before instituting criminal proceedings.The court said it has been held that "it is not possible for any doctor to assure or guarantee that the result of treatment would invariably be positive and the only assurance which a professional can give is that he is professionally competent , has requisite skill and has undertaken the task entrusted to him with reasonable care."

Referring to earlier judgment, a bench of Justices M B Lokur and Deepak Gupta set aside the order of Nagpur bench of Bombay High Court by which criminal proceedings have initiated against the doctor who was a surgeon on call at a hospital where the victim was admitted.

"Applying a law laid down in a case, we are of the view that this is not the case where the appellant should face trial especially when 20 years have already elapsed," it said. The doctor on August 29, 1997, when called to the Irwin Hospital , Amravati to attend a victim, examined him and made a note that a physician be called after finding the patient suffering from abdominal pain.

The main allegation against the surgeon was that she did not wait for physician to arrive especially when the patient was suffering from Hemophilia, a condition that affects the blood's ability to clot. As a result the victim died the very next day and the physician she had called never turned up. A complaint was subsequently lodged in the police station, wherein it was alleged by the brother of the deceased that the patient died as a result of negligence of the three doctors of hospital.

In a separate departmental inquiry, three doctors were held negligent in performing their duties and one was debarred annual increment as penalty, the surgeon was permanently prohibited from entering Irwin Hospital, Amravati, and third doctor was transferred. The surgeon then filed a plea for quashing of charge against her, but her petition was rejected by the High Court on the ground that the question whether inaction in her part in leaving the deceased at about 11 PM and not waiting for physician to turn up, amounted to rash negligent act on her behalf, would be decided during trial.

The Apex court, while allowing the appeal, said the only allegation the appellant (Surgeon) is that she left the patient but being a surgeon on call, she came to the hospital when she was called and examined the patient. " As per her judgment, she could find no evidence of bleeding or injury and, therefore, she noted that a physician be called. Therefore, she left the hospital at about 11 PM. True it is that she did not wait for physician to come, but it can be assumed that she would have expected that the physician would come soon," the bench said. "This may be an error in judgment but is definitely not a rash and negligent act contemplated under section 304-A of IPC. It is nobody's case that she was called again by the nursing staff on duty. If the condition of patient had worsened between 11 PM and 5 PM, the next morning, the nursing staff could have again called for the appellant, but they did not do so," it said. The bench said, "In the fact and circumstances of this case, it cannot be said that the appellant is guilty of criminal negligence. At best it is an error of judgment" [3].

Hospital Absolved, but Doctor fined Rs 41 lakh in medical negligence case

Mumbai: Calling it not a case of accident but blameworthy rashness, the Maharashtra State Consumer Dispute Redressal Commission was seen ordering a doctor to pay a compensation of Rs. 41 lakh in a case of medical negligence that led to the death of a female patient 15 years ago.

The commission observed that Dr. Ashit Hegde, intensivist attached to PD Hinduja Hospital lacked skill and due care while treating her for collection of fluid around her lungs that resulted in a rupture of her spleen leading to her death.

The case was that of a 35 year old female, who had come to casualty to the hospital, with complaints of breathlessness and chest pain. She had earliar been advised hospitalization on account of suspected hepatitis. At the casualty Dr. Hegde diagnosed her with Pleural Effusion and began treatment with procedure of tapping to take out excess fluid.

The family of the patient alleged that the doctor was negligent during treatment and punctured her spleen while doing tapping for Plural Effusion, leading to internal bleeding and her eventual death. The counsel for the patient argued that negligence was evident, as while tapping her with a needle twice to clear the effusion, Dr. Hegade had failed to take help of an ultrasound. "There was profuse internal bleeding ," he said. A scan showed that the needle had punctured the spleen.

The doctor denied any negligence and argued that the patient suffered from alcoholic hepatitis and early cirrhosis of liver. The commission said , "It is true that the patient would not have survived for many years with such ailments… but Dr. Hegde is personally blameworthy for the punctured spleen

which hastened the death. "

The doctor had "Casually " performed what he said was a "minor procedure" on the woman on July 23, 2002, in the hospital's casualty section, after diagnosing "pleural effusion," the commission observed.

"The subsequent decision to remove the affected spleen, in a major operation , was the obvious cause of death in post-mortem findings and established the doctor's negligence," said the commission while slapping a compensation of Rs. 41 Lakhs on the doctor.

What is also interesting to note in this case is that based on the argument put forward by all the parties, the commission concluded that the hospital was not at fault and absolved it. "Hinduja Hospital has no role in the deficiencies in service rendered to the patient," held Justice A P Bhangale, the commission president, and judicial member D R Shirasao.

"This was not a case of accident but blameworthy rashness…on the part of Dr. Hegde," said the judgment. Hospitals generally have a vicarious liability in cases of medical negligence.

While the family had demanded a compensation of Rs. 87 lakh, the commission observed the demand to be exorbitant and reduced the amount to Rs. 41 lakhs. "Compensation cannot be a lottery or a jackpot for a patient who was suffering from jaundice, hepatitis for which she was under Dr. Hegde's treatment. " [4]

References:

1. http://medicaldialogues.in/not-all-anomalies-can-be-detected-by-ultrasound-ncdrc-while-dismissing-rs-17-lakh-complaint/ Accessed on 11/04/2017
2. http://medicaldialogues.in/medical-negligence-human-rights-commission-fines-govt-recommends-suspension-of-doctor/ Accessed on 15/04/2017
3. http://medicaldialogues.in/after-20-years-sc-absolves-doctor-of-medical-negliegence-charge/ Accessed on 17/04/2017
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Indian Medico- Legal Ethics Association

Professional Assistance / Welfare Scheme

1) The scheme shall be known as PAS "Professional Assistance Scheme".
2) ONLY the life member of IMLEA shall be the beneficiary of this scheme on yearly basis. The member can renew to remain continuous beneficiary of this scheme by paying renewal fees every year. The scheme shall assist the member ONLY as far as the medical negligence is concerned.
3) This scheme shall be assisting the members by:
   i) Medico-legal guidance in hours of crisis. A committee of subject experts shall be formed which will guide the members in the hours of crisis.
   ii) Expert opinion if there are cases in court of law.
   iii) Guidance of legal experts. A team of Legal and 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 and extent of practice, number of beds in case of indoor facilities and depending upon the other liabilities.
5) The financial contribution towards the scheme shall be as follows:
6) The hospital can become the member of this scheme only if all the members associated with the hospital have their personal professional indemnity under the scheme.
7) A trust / committee / company/ society shall look after the management of the collected fund. The scheme shall initially be run in collaboration with the New India Assurance or National Insurance Company.
8) The Financial assistance will be like Medical Indemnity welfare scheme, where indemnity part

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

	Qualification / Specialty	Ten Lakhs	Twenty Lakhs	Forty Lakhs	Fifty Lakhs	One Crore
1	Physician / doctors with Bachelor degree and/or OPD Practice	450	900	1800	2200	4000
2	Physician / doctors with PG degree &/ or Indoor Practice	950	1900	3700	4500	8500
3	Physician / doctors with Practice of Surgery	1900	3800	7300	8500	16000
4	Plastic Surgeons, Anesthetist etc	2800	5600	10000	12000	22000
5	● 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 single case; amount shall be calculated on individual to individual basis for extra 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 additional charges can be included for other benefits like OPD/ indoor attendance, instruments, fire, personnel injuries etc					

Hospital Establishment :

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

Medical colleges/ Corporate hospitals after discussing with hospital administration.

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

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

shall be covered by government / IRDA approved companies or any other private company.

9) The amount shall be deposited in the Central Indemnity Reserve Fund (CIRF) of the association. The association shall be responsible only for the financial assistance. Any compensation/ cost/ damages awarded by judicial trial shall be looked after by government / IRDA approved insurance companies or any other similar private company.

10) Experts will be involved so that we have better vision and outcome of the scheme.

11) The payment to the experts, Legal and med-legal experts shall be done as per the pre-decided remuneration. Payment issues discussed, agreed and processes shall be laid down by the members of these scheme.

12) If legal notice / case is received by member he should forward the necessary documents to the concerned person.

13) Reply to the notice/case should be made only after discussing with the expert committee.

14) A discontinued member if he wants to join the scheme again will be treated as a new member.

15) Most of the negligence litigations related to medical practice EXCEPT the criminal negligence cases shall be covered under this scheme. The scheme will also NOT COVER the damages arising out of fire, malicious intension, natural calamity or similar incidences.

16) All the doctors working in the hospital (Junior, Senior, Temporary, Permanent etc) shall be the members of the IMLEA, if the hospital wants to avail the benefits of this scheme.

17) The scheme can cover untrained hospital staff by paying extra amount as per the decision of expert committee.

18) A district/ State/ Regional level committee can be established for the scheme.

19) There will be involvement of electronic group of IMLEA for electronic data protection.

20) Flow Chart shall be established on what happens when a member approaches with a complaint made against him or her [Doctors in Distress (DnD) processes].

21) Telephone Help Line: setting up and manning will be done.

22) Planning will be done to start the Certificate / Diploma / Fellowship Course on med-leg issues to create a pool of experts.

23) Efforts will be made to spread preventive medico-legal aspects with respect to record keeping, consent and patient communication and this shall be integral and continuous process undertaken for beneficiary of scheme by suitable medium.

Contribution in JIMLEA

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

The Members of Professional Assistance Scheme

S.No.	Name	Place	Speciality
1	Dr. Dinesh B Thakare	Amravati	Pathologist
2	Dr. Satish K Tiwari	Amravati	Pediatrician
3	Dr. Rajendra W. Baitule	Amravati	Orthopedic
4	Dr. Usha S Tiwari	Amravati	Hospi/ N Home
5	Dr. Yogesh R Zanwar	Amravati	Dermatologist
6	Dr. Ramawatar R. Soni	Amravati	Pathologist
7	Dr. Rajendra R. Borkar	Wardha	Pediatrician
8	Dr. Alka V. Kuthe	Amravati	Ob.&Gyn.
9	Dr. Vijay M Kuthe	Amravati	Orthopedic
10	Dr. Neelima M Ardak	Amravati	Ob.&Gyn.
11	Dr. Vinita B Yadav	Gurgaon	Ob.&Gyn.
12	Dr. Balraj Yadav	Gurgaon	Pediatrician
13	Dr. Dinakara P	Bengaluru	Pediatrician
14	Dr. Shriniket Tidke	Amravati	Pediatrician
15	Dr. Shraddha Tidke	Amravati	Gen Practitioner
16	Dr. Gajanan Patil	Morshi	Pediatrician
17	Dr. Madhuri Patil	Morshi	Obs & Gyn
18	Dr. Ashish Varma	Wardha	Pediatrician
19	Dr. Anuj Varma	Wardha	Physician
20	Dr. Neha Varma	Wardha	Ob & Gyn
21	Dr. Ramesh Varma	Wardha	Gen Practitioner
22	Dr. Kiran Borkar	Wardha	Ob & Gyn
23	Dr. Prabhat Goel	Gurgaon	Physician
24	Dr. Sunil Mahajan	Wardha	Pathologist
25	Dr. Ashish Jain	Gurgaon	Pediatrician
26	Dr. Neetu Jain	Gurgaon	Pulmonologist
27	Dr. Bhupesh Bhond	Amravati	Pediatrician
28	Dr. R K Maheshwari	Barmer	Pediatrician
29	Dr. Jayant Shah	Nandurbar	Pediatrician
30	Dr. Kesavulu	Hindupur AP	Pediatrician
31	Dr. Ashim Kr Ghosh	Burdwan WB	Pediatrician
32	Dr. Archana Tiwari	Gwalior	Ob & Gyn
33	Dr. Mukul Tiwari	Gwalior	Pediatrician
34	Dr. Chandravanti Hariyani	Nagpur	Pediatrician
35	Dr. V P Goswami	Indore	Pediatrician
36	Dr. Sudhir Mishra	Jamshedpur	Pediatrician
37	Dr. Lalchand Charan	Udaipur	Pediatrician
38	Dr. Sunil Sakarkar	Amravati	Dermatologist
39	Dr. Mrutunjay Dash	Bhubaneshwar	Pediatrician
40	Dr. J Bikrant K Prusty	Bhubaneshwar	Pediatrician
41	Dr. Ashish Satav	Dharni	Physician
42	Dr. Kavita Satav	Dharni	Opthalmologist
43	Dr. D P Gosavi	Amravati	Pediatrician
44	Dr. Narendra Gandhi	Rajnandgaon	Pediatrician
45	Dr. Apurva Kale	Amravati	Pediatrician
46	Dr. Prashant Gahukar	Amravati	Pathologist
47	Dr. Asit Guin	Jabalpur	Physician
48	Dr. Sanjeev Borade	Amravati	Ob & Gyn
49	Dr. Usha Gajbhiye	Amravati	Pediatric Surgeon
50	Dr. Kush Jhunjhunwala	Nagpur	Pediatrician
51	Dr. Satish Agrawal	Amravati	Pediatrician
52	Dr. Ravi Motwani	Gadchiroli	Pediatrician
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56	Dr. Anuradha Kakani	Amravati	Ob & Gyn
57	Dr. Sikandar Adwani	Amravati	Neurophysician
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59	Dr. Pawan Agrawal	Amravati	Cardiologist
60	Dr. Madhuri Agrawal	Amravati	Pediatrician
61	Dr. Rupesh Kulwal	Pune	Pediatrician
62	Dr. Jyoti Agrawal	Amravati	Pediatrician
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94	Dr. Aniruddh Bhamburkar	Akola	Physician
95	Dr. Nilesh Dayama	Akola	Pediatrician
96	Dr. Paridhi Dayama	Akola	Pediatrician
97	Dr. Nabendu Chaudhary	Burdwan	Pediatrician
98	Dr. Kripasindhu Chattarjee	Burdwan	Pediatrician
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Life Membership fee (individual Rs.3500/-, couple Rs.6000/-) by CBS (At Par, Multicity Cheque) or DD, in the name of Indian Medico-legal & Ethics Association (IMLEA) payable at Amravati. Send to Dr.Satish Tiwari, Yashodanagar No.2, Amravati-444606, Maharashtra.

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National Conference of Indian Medico Legal & Ethics Association

28th & 29th October, 2017

Dear Academicians,

Greetings from IAP and IMA Odisha State Branch. You must be aware of different incidence of physical abuse on Doctors, Paramedical Staff, destruction of various medical infrastructure and the different complicated rules made by different state government all over India which has resulted this profession making more difficult and stressful. Therefore we are pleased to announce 3rd National Medicolegal Conference at Bhubaneswar, the Capital city of Odisha, the land of Lord Jagannath also famous for its cultural heritage and historical background. Bhubaneswar is the fastest growing city, ranked as No.1 smart city of India. In this conference we will have many lectures, group discussions and open house discussion about day to day medical problem. We invite delegates from the field of pediatrics, medicine, O & G, anaesthesiology, intensivists, doctors from corporate hospitals. The speakers are not only from medical field but also from judiciary, senior police officials and senior advocates.

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Dr. Asutosh Mahapatra
(Organizing Secretary)

SUGGESTED TOPICS FOR MEDICOLEGAL CONFERENCE

- Introduction
- Are we legally safe?
- Is this Negligence?
- How should I defend my own case?
- Facing the media
- Preventable Medical Error
- Legal hurdles in Medical practice
- Police & Doctors: Friends or Foes
- Ethical dilemmas for Physician
- Black sheep in medical practice
- Issues in Quality care
- Caring at the age of viability
- Withdrawal of Life support : DNR guidelines
- Save the girls: Preconception to post menopause
- Legal Issues in Immunization
- Difficult situations in day to day practice- How to handle?
- Legal Issues in Critical care
- Legal Issues in Adolescence
- Legal Issues in Neonatal care
- Exaggerated health claims/ Junk food/Health Drinks
- Am I responsible for my staff's Acts?
- Important / Landmark Judgments
- Case based discussions
- The way we talk : Communicating with patients/relatives
- Documentation /Record maintenance
- Is my consent form proper & valid?
- Clinical Establishment Bill
- Nursing Home Acts
- Calculation of compensation
- MCI guidelines /Regulations
- Who is going to regulate?
- Moot Courts
- Group activities & role plays