CHAPTER - 8
CONCLUSION AND SUGGESTIONS

The scholar has selected the problem human health and human rights. The concept of human rights is found as a result of protest against dictatorship and poses a struggle against the totalitarian power of the State. It denotes all the rights which are inherent in our nature and without which we cannot live as a human being. Human rights are moral principles or norms that describe certain standards of human behavior, and are regularly protected as legal rights in national and international law. They are commonly understood as inalienable fundamental rights "to which a person is inherently entitled simply because she or he is a human being," and which are "inherent in all human beings" regardless of their nation, location, language, religion, ethnic origin or any other status. They are applicable everywhere and at every time in the sense of being universal, and they are egalitarian in the sense of being the same for everyone. They require empathy and the rule of law and impose an obligation on persons to respect the human rights of others. They should not be taken away except as a result of due process based on specific circumstances, and require freedom from unlawful imprisonment, torture, and execution.

Everybody has the fundamental right to life, and that is from womb to tomb, throughout his/her life which includes healthy life and healthy life is not possible without healthy environment surrounding to his/her life. Healthy environment includes wholesome drinking water, pure, non-polluted air to breathe and a good shelter. One cannot ignore medical care and assistance. An emergency health care is a fundamental right as declared by the Supreme Court of India. [See Article 21 of the Constitution of India]

In every living creature, whether social or animal, nature has implanted enough sense of security and protection of their health. The human beings are endowed with special intelligence, so they can take better care of their health (body as well as mind). Good health is the first priority for everybody. Health means physical well being or freedom from disease. It is a state of total physical, mental and social well being. A healthy person can realise his full potential and prepare himself with better immunity, preventing him from many illness.

India still spends only around 4.2% of its national GDP towards healthcare goods and services (compared to 18% by the US). There are wide gaps between the rural and urban populations in its healthcare system which worsen the problem. A staggering 70% of the population still lives in rural areas and has no or limited access to hospitals and clinics. Consequently, the rural population mostly relies on alternative medicine and government programmes in rural health clinics. One such government programme
is the National Urban Health Mission which pays individuals for healthcare premiums, in partnership with various local private partners, which have proven ineffective to date. In contrast, the urban centers have numerous private hospitals and clinics which provide quality healthcare. These centers have better doctors, access to preventive medicine, and quality clinics which are a result of better profitability for investors compared to the not-so-profitable rural areas.

Besides the rural-urban divide, another key driver of India’s healthcare landscape is the high out-of-pocket expenditure (roughly 70%). This means that most Indian patients pay for their hospital visits and doctors’ appointments with straight up cash after care with no payment arrangements. According to the World Bank and National Commission’s report on Macroeconomics, only 5% of Indians are covered by health insurance policies. Such a low figure has resulted in a nascent health insurance market which is only available for the urban, middle and high income populations. The good news is that the penetration of the health insurance market has been increasing over the years; it has been one of the fastest-growing segments of business in India.

Coming to the regulatory side, the Indian government plays an important role in running several safety net health insurance programmes for the high-risk population and actively regulates the private insurance markets. Currently there are a handful of such programmes including the Community Health Insurance programme for the population below poverty line (like Medicaid in the US) and Life Insurance Company (LIC) policy for senior citizens (like Medicare in the US). All these plans are monitored and controlled by the government-run General Insurance Corporation, which is designed for people to pay upfront cash and then get reimbursed by filing a claim. There are additional plans offered to government employees, and a handful of private companies sell private health insurance to the public [3].

India faces a growing need to fix its basic health concerns in the areas of HIV, malaria, tuberculosis, and diarrhea. Additionally, children under five are born underweight and roughly 7% (compared to 0.8% in the US) of them die before their fifth birthday. Sadly, only a small percentage of the population has access to quality sanitation, which further exacerbates some key concerns above.

For primary healthcare, the Indian government spends only about 30% of the country’s total healthcare budget. This is just a fraction of what the US and the UK spend every year. One way to solve this problem is to address the infrastructure issue by standardizing diagnostic procedures, building rural clinics, and developing streamlined health IT systems, and improving efficiency. The need for skilled medical
graduates continues to grow, especially in rural areas which fail to attract new graduates because of financial reasons. A sizeable percentage of the graduates also go abroad to pursue higher studies and employment.

According to the Indian Brand Equity Foundation (IBEF), India is the third-largest exporter of pharmaceutical products in terms of volume. Around 80% of the market is composed of generic low-cost drugs which seem to be the major driver of this industry. The increase in the ageing population, rising incomes of the middle class, and the development of primary care facilities are expected to shape the pharmaceutical industry in future. The government has already taken some liberal measures by allowing foreign direct investment in this area which has been a key driving force behind the growth of Indian pharmacy.

The medical devices sector is the smallest piece of India’s healthcare pie. However, it is one of the fastest-growing sectors in the country like the health insurance marketplace. Till date, the industry has faced a number of regulatory challenges which has prevented its growth and development. Recently, the government has been positive on clearing regulatory hurdles related to the import-export of medical devices, and has set a few standards around clinical trials. According to *The Economic Times*, the medical devices sector is seen as the most promising area for future development by foreign and regional investors; they are highly profitable and always in demand in other countries.

During the course of study regarding human health and human rights, researcher had come across with so many issues like what are human rights? What is human health? The role of the government, society and doctors in protecting and preserving human rights through maintaining good health of human beings.

Objectives behind the study were: To identify the challenges emerged in this area and to study the causes and effects; To collect the information regarding state of health care and medical profession and to evaluate the same with reference to human rights; To study the Doctor – patient relationship; To evaluate Law, Medical Profession and human rights inter-relationship; To study the legal problems emerged in the area of Medical Profession and to find out the causes and effects; To identify the shortcomings in Laws concerning Medical Profession; To study and evaluate implementation of medical ethics; To collect the data of medical negligence and to evaluate the same; To study the principles of liability established by the laws and the courts; To study the state of right to privacy of the patients; To study the state of privileged communications between doctors and patient; and To study the decisions of the Supreme Court and High Courts and to suggest necessary amendments in laws concerning medical profession.
Hypothesis drawn were less expenditure in health care is one of the biggest impediments for maintenance of good health; Ignorance, negligence and poor state of health care invites many types of illness; Any type of illness reduces efficiency and potentiality of a person; Lack of doctors, nurses, drugs and other facilities frustrate patients and their family; Speedy morale degradation in medical profession looses trust of the patients; Strong desire for accumulation of money and wealth has made commercialization of medical profession; Pre-natal tests increase killing of female foetus, which creates imbalance in men-women ratio in society; Unemployment, poverty, starvation, helplessness compel poor persons to sale most valuable organs of their body; Inaction and omission in implementation of laws and ethics encourage illegal activities and increase crime rate in this profession also; Doctors exploit the helpless situations of patients; Morale degradation invites gender atrocity against women; Patients’ ignorance of their rights leads to violation of the same; Increasing number of cases in courts of law indicates something wrong is there.

For testing the hypothesis four questionnaires were prepared, one for lay man, second for doctors and third for the lawyers and judges and fourth for medical students as they were the stake holders for protecting and preserving human rights through maintaining good health of human beings. Response received were the source of primary data for this study. The data collected were compiled, classified, analyzed and tabulated are presented in the form of quantitative analysis in previous chapter.

Human experimentation is necessary to find out the effects of the new drugs or chemical agents on human subjects. There is a vast expansion of the drug industry and it is absolutely necessary to study their effects on the human beings. This has become the therapeutic necessity. By experimenting on human beings themselves, we get a good knowledge about their effects, side effects, required doses and the harmful reactions that can develop after their use in human bodies. The study in vitro or in animals has not shown the exact nature of the chemical effects of the drugs on human beings.

Medical research is done to evolve new medicines for the existing diseases or new diseases. The new drug cannot be said to be safe for human use unless it is practiced, proved and documented to be safe, effective, and affordable by the common man. The drug may not help the patient but should not be harmful to him and should be accepted by all. Research involving new medicines or new procedures should also include the safe dosage of how much? How often? And how long? Safe mode of taking it i.e. oral or inject able - Intramuscular or Intravenous. Some drugs are effective only when given by injections and some of them cause severe pain when given intra muscular or Intravenous.

All the possible safe and less painful route of administration of the drug has to be studied. The chemicals used in medicines are already tested in animals and little knowledge is achieved about their effects, side effects etc. but it is not necessary that
we will achieve the same results when tried in human beings that is why there is a necessity of experimentation of these drugs on human beings.

**Reasons for the experimentations on human beings are done for**

(1) Therapeutic use: to improve the condition of the patient who did not respond to regular treatment and

(2) Research: to conduct the experiment to study the effects of different chemical agents on human bodies so that it can be concluded useful or useless in the treatment of the diseases.

(3) To know whether these chemical agents are safe for human consumption

(4) To study the safe dosage of how much. How often? How long? The safe mode of administration oral or inject able- intra muscular or intravenous etc

We need volunteers to try the drugs on them. They have to be informed about the aim of the research, expected effects of the drug and/or side effects of the drug. There should not be any force, fraud, misrepresentation of the facts or any pressure over the subjects to give consent for the research.

However the experimentation of the drugs on human being was misused for earning money and reckless human experimentations were conducted on fetus, minors, illiterate, insane or people in the custody of the State (as they were under custody of somebody else), resulting in to disastrous effects on them. The consent given or taken for the same may not be free from ethical questions.

The reckless human experimentation conducted on the prisoners of 2nd world war in concentration camps and on helpless civilians has thrown permanent black shade on human experimentations. Hence it was important to issue guidelines for the same.

**General Rules for Human experimentation**

1) The drug must not be harmful chemical agent

2) The drug must have been tried by other experiments in laboratory or on animals before using them for human experimentation

3) There should be scientific justification for trying them on Human beings

4) Once the side effect or harmful effect is notice the experiment should be immediately stopped
5) Experiment should be done only after taking the informed consent of the patient and/or parents and/or guardian and should be stopped as soon as the consent is withdrawn.

6) There should be no monetary gains to the patient because of the research.

7) The patient should not be suffering from any other disease so as to vitiate the results of the research e.g. he should not have a kidney disease if the drug is excreted by the kidneys.

International regulations for experimentation on human beings are mentioned in the Nuremberg Code; The Helsinki Declaration, 1984; Research with Children; Experiments on Prisoners; Sandler's Draft Code.

International Regulation for Human Experimentation: The Nuremberg Code.
[From Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10 Nuremberg, October 1946 - April 1949.]

Permissible Medical Experiments

The great weight of the evidence before us is to the effect that certain types of medical experiments on human beings, when kept within reasonably well-defined bounds, conform to the ethics of the medical profession generally. The protagonists of the practice of human experimentation justify their views on the basis that such experiments yield results for the good of society that are unprocurable by other methods or means of study. All agree, however, that certain basic* principles must be observed in order to satisfy moral, ethical and legal concepts.

The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent, should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision.

This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.
The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

The experiment should be so designed and based on the results of animal experimentation and knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.

The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

No experiment should be conducted where there is an a priori believes that death or disabling injury will occur, except, perhaps, in those experiments where the experimental physicians also serve as subjects.

The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

During the course of the experiment the human subject should be at liberty to bring the experiment to end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probably cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject. Of the ten principles which have been enumerated our judicial concern, of course, is with those requirements which are purely legal in nature? Which at least are so clearly related to matters legal that they assist us in determining criminal culpability and punishment? To go beyond that point would lead us into a field that would be beyond our sphere of competence. However, the point need not be labored. We find from the evidence that in the medical experiments which have been proved, these ten principles were much more frequently honored in their breach than in their observance. Many of the concentration camp inmates who were the victims of these atrocities were citizens of countries other than the German Reich. They were non-German nationals, including Jews and "asocial persons", both prisoners of war and civilians, who had been imprisoned and forced to submit to these tortures and barbarities without so much as a semblance of trial. In every single instance appearing
in the record, subjects were used who did not consent to the experiments; indeed, as to some of the experiments, it is not even contended by the defendants that the subjects occupied the status of volunteers.

In no case was the experimental subject at liberty of his own free choice to withdraw from any experiment. In many cases, experiments were performed by unqualified persons; were conducted at random for no adequate scientific reason,' and under revolting physical conditions. All of the experiments were conducted with unnecessary suffering and injury and but very little, if any, precautions were taken to protect or safeguard the human subjects from the possibilities of injury, disability, or death. In every one of the experiments the subjects experienced extreme pain or torture, and in most of them they suffered permanent injury, mutilation, or death, either as a direct result of the experiments or because of lack of adequate follow-up care.

Obviously all of these experiments involving brutalities, tortures, disabling injury, and death were performed in complete disregard of international conventions, the laws and customs of war, the general principles of criminal law as derived from the criminal laws of all civilized nations, and Control Council Law No. 10.

Manifestly human experiments under such conditions are contrary to "the principles of the law of nations as they result from the usages established among civilized peoples, from the laws of humanity, and from the dictates of public conscience." Whether any of the defendants in the dock are guilty of these atrocities is, of course, another question. Under the Anglo-Saxon system of jurisprudence every defendant in a criminal case is presumed to be innocent of an offense charged until the prosecution by competent, credible proof, has shown his guilt to the exclusion of every reasonable doubt. And this presumption abides with the defendant through each stage of his trial until such degree of proof has been adduced.

A "reasonable doubt" as the name implies is one conformable to reason? doubt which a reasonable man would entertain. Stated differently, it is that state of a case which, after a full and complete comparison and consideration of all the evidence would leave an unbiased, unprejudiced, reflective person, charged with the responsibility for decision, in the state of mind that he could not say that he felt an abiding conviction amounting to a moral certainty of the truth of the charge.

If any of the defendants are to be found guilty under counts two or three of the indictment it must be because the evidence has shown beyond a reasonable doubt that such defendant, without regard to nationality or the capacity in which he acted, participated as a principal in, accessory to ordered, abetted, took a consenting part in, or was connected with plans or enterprises involving the commission of at least some of the medical experiments and other atrocities which are the subject matter of these counts.
Under no other circumstances may he be convicted. Before examining the evidence to which he must look in order to determine individual culpability, a brief statement concerning some of the official agencies of the German Government and Nazi Party which will be referred to in this judgment seems desirable.

It is the mission/duty of the doctor to safeguard the health of the people in treatment of the sick persons. The Doctor must be free to use a new therapeutic measure, if, in his judgment; it offers a hope of saving life, re-stabilizing health or alleviates sufferings.

Human experimentation is necessary to find out the effects of the drugs or chemical agents on human subjects. There is a vast expansion of the drug industry and it is absolutely necessary to study their effects on the human beings. This has become the therapeutic necessity. By experiment on human beings themselves we get a good knowledge about their effects, side effects, doses and the harmful reactions that can develop after their use in human bodies. The study in vitro or in animals has not shown the exact nature of the chemical effects of the drugs on human beings.

Thus the experimentations on human beings are done for

1) Therapeutic use: to improve the condition of the patient who did not respond to regular treatment and

2) Research: to conduct the experiment to study the effects of different chemical agents on human bodies so that it can be concluded useful or useless in treatment of the diseases.

3) To know whether these chemical agents are safe for human consumption.

However the experimentation of the drugs on human being was misused for earning money and reckless human experimentations were conducted on fetus, minors, illiterate, insane or people in the custody of the State resulting in to disastrous effects on them. The consent given or taken for the same may not be free from ethical questions.

The reckless human experimentation conducted on the prisoners of 2nd world war in concentration camps and on helpless civilians have thrown permanent black shade on human experimentations. Hence it was important to issue guidelines for the same.

Helsinki Declaration is one such guidelines adopted by the 18th World Medical assembly in England in June 1964. It drew up a code of conduct for doctors intending to conduct any experimental scheme of research or treatment upon live patients.

**Article 1.9 of the Helsinki Declaration states that**, In any research on human beings Each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail.
They should be informed that they are at liberty to abstain from participation in the study and are free to withdraw consent to participation at any time.

The Physician should then obtain the freely given informed consent preferably in writing.

**Important Provision of the Helsinki Declaration can be summarized as follows:**

1) Bio medical research involving Human subjects must confined to generally accepted scientific principle and should be based on adequately performed laboratory and animal experimentations

2) Design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol

3) Bio-medical research involving human subjects should be conducted by scientifically qualified person and under supervision of clinically competent Medical person.

4) Bio-medical research involving human subjects cannot legitimately carried out unless the importance of objective achieved is more or in proportion to the inherent risk to the subject.

5) Every Bio-medical research involving human subjects should be preceded by the careful assessment of the pre detectable risk in comparison with forcible benefit of the subject.

6) Right of safeguard of the integrity of the human research subject should always be respected.

7) Every precaution must be taken to respect the privacy of the research human subject

8) Physician should abstain from engaging himself in research project involving human subject unless they are satisfied that the hazards involved are pre detectable & Curable.

9) Physician is obliged to preserve accuracy in Publication of the results of the research

10) While obtaining informed consent from the research human being, the physician should be particularly cautious that it should be free consent not under any duress & the human subject is not under any undue influence and/or has dependent relationship with him
11) In case of legal incompetence of the human subject informed consent is to be taken from parents and/or legal guardian in accordance with the statutory provisions of law. If there is any suspicion than through due process of law.

12) Research Protocol should always contain a statement of involved ethical consideration and should indicate that the principles enunciated in the research are complied with.

13) Special precaution must be taken by the doctor in performing clinical research in which personality of the patient is likely to be altered by the drugs.

14) The research team should discontinue the research if they think that continuation of the research is harmful to the patient.

**Issues regarding the research on the children are also burning one:**

It has been recognized in law and medical ethics that children can not authorize medical treatment for themselves, except in special circumstances. Authorization must be sought from the parent.

Historically, the source of this respect for parental authority was due to the view that children were the property of their parents, and thus parents had the right to determine how their "property" was to be treated.

Today, we still speak of parental rights, although the justification for these rights no longer rests on an analysis of children as property. Instead, respect for the rights of parents is viewed as a mechanism for valuing and fostering the institution of the family and the freedom of adults to perpetuate family traditions and commitments.

Another important line of justification for respecting the authority of parents is due to the view that the interests of the child are generally best served by decisional authority of the parent. The parent is thought not only to be in the best position to determine what is in the interests of the child but is also thought to be generally motivated to act in the child's best interests.

When research involving children offers a prospect of medical benefit to the child, Parents are generally thought to have the authority to determine whether their children should be made subjects of such research, and no child can be used ethically and/ or legally in research without the parent's permission. Where the research does not offer any prospect of benefit to the child, the legitimacy of the parent as authorizer is questionable

The law recognizes several exceptions, designed primarily to protect the child from what society at large considers being unacceptable or unjustifiable harm or risk of harm.
1) Laws against the physical abuse of children are perhaps the most obvious example of such limitations on parental authority. In the context of research, the question arises of whether a parent has the authority to permit a child to be put at risk of harm in an experiment from which the child could not possibly benefit medically. In this case, the child is to be used as a means to the ends of others. Children are not in a position to determine for themselves whether they wish to agree to such a use and thus cannot themselves render the use morally acceptable. Should parents have such authority? Should anyone?

2) This question was resolved as a matter of public policy in the 1970s through the work of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and the subsequent. In 1983 - recommendations of the National Commission were adopted as federal regulations governing research involving children.

3) These regulations state that children can participate in federally funded research that poses greater than minimal risks to the subject if a local review committee (an institutional review board, or IRB) finds that the potential risk is "justified by the anticipated benefit to the subjects";

4) The word consent is purposely avoided in these regulations to distinguish parental permission and minor assent from the autonomous, legally valid consent of a competent adult.

5) Federal regulations do allow non therapeutic research on children if an institutional review board or IRB determines that the research presents "no greater than minimal risk" to the children, who would serve as subjects,

6) As with therapeutic pediatric research, parents or guardians must grant "permission" and children who are deemed capable must offer "assent."

7) The regulations also allow for non therapeutic research with children that does present more than minimal risk, again with parental permission and assent of the child (as appropriate), but only if the risk represents a minor increase over minimal risk, the procedures involved are commensurate with the general life experiences of subjects, and the research is likely to yield knowledge of "vital importance" about the subjects' disorder or condition.

8) Research with children that is not otherwise approvable may be permitted, only under special, and presumably rare, circumstances. In addition to local institutional review board or IRB review, such research must withstand the special scrutiny of the secretary of the agency sponsoring the research, who is to be advised by a special IRB. The secretary must also allow the opportunity for "public review and comment" on a proposed non therapeutic research project that is not otherwise approvable.
9) The regulations thus draw a sharp distinction between therapeutic and non-therapeutic research. Non-therapeutic research, while severely restricted, is not banned. The decision to permit parents to authorize the use of their children in non-therapeutic research reflects both the recognition that some important advances in pediatrics could come only from research with children that was of no benefit to them and the recognition that we all—as parents, as potential future parents, and as members of society—share in the interest of advancing the health of the young. At the same time, however, parental authority to permit such use of a child is generally restricted to research judged to pose little risk; as important as it is to promote the welfare of children (as a class), this interest justifies only minor infringements of the principle not to use people as mere means to the ends of others.

There was significant research interest in infants and children as early as the eighteenth century, as scientists began to experiment with vaccines and immunization. Children were particularly valuable subjects for this type of research because in general, they were less likely than adults to have been exposed to the disease being studied.

A child's response to immunizations was also of great interest because most immunizations are performed during childhood.

During the nineteenth century, the Industrial Revolution greatly increased the number of child laborers, and the public began to acknowledge the need for laws to protect children from abuse.

Physicians started to specialize in pediatrics, studying specifically the health problems and diseases that afflicted children. Simultaneously, as social reformers were creating a wide range of institutions for children, such as orphanages, schools, foundling homes, and hospitals, scientists recognized the value of research conducted in these types of institutions.

In the late nineteenth and early twentieth century's, Alfred F. Hess, the medical director of the Hebrew Infant Asylum in New York City, conducted pertussis vaccine trials and undertook extensive studies of the anatomy and physiology of digestion in infants at the asylum. According to Advisory Committee member and historian Susan Lederer, Hess sought to take advantage of the conditions in the asylum as they approximated those "conditions which are insisted on in considering the course of experimental infection among laboratory animals, but which can rarely be controlled in a study of infestation in man." Although many shared Hess's laudable goal of improving the health of asylum children, many people drew the line at the pediatrician's investigations of scurvy and rickets. In order to study the disease, Hess and his colleagues withheld orange juice from infants at the asylum until they developed lesions characteristic of scurvy. Responding to the public discussion of the
ethics of using children in such non-therapeutic experiments, the editors of one American medical journal insisted that such investigations gave the children an opportunity to repay their debt to society, even as they conceded that experimentation on human beings should be limited to "children as may be utilized with parental consent."

Hess's work was not the only case in which experiments involving children attracted negative public opinion. In 1896, for example, American antivivisectionists attacked a Boston pediatrician, Arthur Wentworth, who performed lumbar punctures on infants and children in order to establish the safety and utility of the procedure. The antivivisectionists were particularly alarmed because this procedure, which caused pain and discomfort, did not confer any benefits to the subjects. John B. Roberts, a physician from Philadelphia, labeled Wentworth's procedures "human vivisection," saying that "using the children in the hospital without explaining his plan to their mothers or gaining their permission intensified public fear of hospitals."

The twentieth century brought new drugs and advanced technologies, which allowed for increased research on children. The conduct of this experimentation, however, was largely left to the individual investigator. When his experimental gelatin injections provoked "alarming symptoms of prostration and collapse in three normal children (including a 'feeble-minded' four-year-old girl), the physician Isaac Abt stopped his pediatric experiments and began experimenting on rabbits."

Legislation was proposed throughout the country to protect children and pregnant women from experimenting physicians. Two proposals were introduced in the U.S. Senate in 1900 and 1902; proposals "to prohibit such terrible experiments on children, insane persons and pregnant women and to ensure 'that no experiment should be performed on any other human being without his intelligent written consent' were introduced in the Illinois legislature" in 1905 and 1907; in 1914 and 1923, the New York legislature considered bills, that prohibited experimentation with children. These bills did not become law, it is clear that some unease concerning non-therapeutic research on children existed among the public and elected officials.

Reaction to the polio vaccine trials conducted during the 1930s further demonstrated the growing discomfort over pediatric experimentation as thousands of American children were involved in what some considered at the time to be premature human trials of the polio vaccine. Although it appears that parental consent was obtained for a number of these studies, the controversy over these trials stalled polio vaccine research for almost two decades and generally made investigators ambivalent about the use of human subjects.

**Case Study Analysis reveals that although there are no legal cases that bear directly on non-therapeutic research with children during this period, an appellate court ruling**
in 1941, *Bonner v. Moran*, involving the performance of a non therapeutic medical procedure on a child without parental consent, suggests how such a case might have been decided. John Bonner, a fifteen-year-old African-American boy from Washington, D.C., had undergone an experimental skin graft for the benefit of Clara Howard, a cousin suffering from severe burns. When he discovered that John Bonner had the same blood type as the burn victim, Howard's plastic surgeon, Robert Moran, persuaded Bonner to allow him to fashion "a tube of flesh" by cutting from the boy's "arm pit to his waist line." This procedure, however, was conducted without the consent of a parent, as "his mother, with whom he lived, was ill at the time and knew nothing about the arrangement. “Moran then attached the free end of Bonner's flesh tube to Clara Howard, hoping that the flesh-and-blood link would bring benefit to the burned girl. Due to poor circulation in the tube, the procedure did not help the burn patient and put the healthy boy, who was required to stay in the hospital for two months, at significant risk (and left him with permanent scars). Bonner's mother brought suit against Moran for assault and battery.

The appellate court based its ruling against Moran on what it perceived as a disturbing combination of a lack of direct benefit for John Bonner and a lack of permission from the boy's mother:

Here we have a case of a surgical operation not for the benefit of the person operated on but for another. We are constrained, therefore, to feel that the consent of the parent was necessary.

The court did not refer to the episode as an instance of experimentation, but the parallels between this novel procedure performed for the benefit of another and a non therapeutic medical experiment are quite powerful.

There were no written rules of professional ethics for the conduct of research on children prior to 1964. Taken literally, the Nuremberg Code, which requires that all subjects of research "have legal capacity to give consent," precludes all research with children. There is no reason to believe, that the judges at Nuremberg meant to impose such a prohibition, and the Nuremberg Code did not result in a ban on research with children.

Pediatric research flourished after World War II, as did biomedical research in general. What is less clear is how this research was conducted, and on whom. One source of evidence about legal thinking on pediatric research, if not actual practice, is the writings of Irving Ladimer, a lawyer who, in 1958, concluded his doctoral dissertation, "Legal and Ethical Implications of Medical Research on Human Beings," with an appendix devoted to the issues surrounding "Experimentation on Persons Not Competent to Provide Personal Consent," whom he defined broadly as minors and mental incompetents. Ladimer argued that it was "permissible to employ minors and incompetents as subjects of medical investigations, where there is informed consent
by a parent or guardian (including the state) for procedures which also significantly benefit or may be expected to benefit the individual. He expressed particular concern about the use of institutionalized children—even with proxy permission—in research, that did not hold the possibility of personal benefit: "Permission given by parents or the state to utilize institutionalized children, without any suggestion of benefit to the children, may well be beyond the ambit of parental or guardianship rights."

The World Medical Association ratified a code of ethics for human experimentation at a meeting in Helsinki. Unlike the Nuremberg Code, this statement, known as the Declaration of Helsinki, recognizes that research may be conducted on people with "legal incapacity to consent."

1) The Declaration distinguishes between two kinds of research: "Clinical Research Combined with Professional Care" and "Non-therapeutic Clinical Research."

2) It permits the use of people with legal incapacity to consent as subjects in both kinds of research, provided that the consent of the subject's legal guardian is procured.

3) Subjects of the first kind of research are referred to as patients; disclosure to and consent from patient-subjects are required by the Declaration, "consistent with patient psychology."

4) The Declaration does not specify whether considerations of "patient psychology" also could justify not obtaining the consent of the guardian where the subject does not have the legal capacity to consent.

5) The subjects of "non-therapeutic clinical research" are not referred to as patients, but as human beings, who must be "fully informed" and whose "free consent" must be obtained.

6) The Declaration also requires that non therapeutic research be discontinued if in the judgment of the investigators to proceed would "be harmful to the individual." Thus, although the Declaration permits parents to authorize the use of their children as subjects in non-therapeutic research, such research is not intended to be "harmful" to the subjects.

The language and reasoning of the Declaration was unclear and confusing with regard to clinical research, both therapeutic and non therapeutic, on legally incapacitated individuals. It was revised in 1975, at a time when the ethics of research with human subjects was receiving considerable public attention in the United States both in the 1960s and early 1970s, public controversies erupted about several cases of research involving human subjects, controversies that led to the establishment of the National Commission and publication of the federal regulations. One of the most well known of these cases involved research on institutionalized children. During the 1950s and 1960s, Dr. Saul Krugman of New York University conducted studies of hepatitis at
the Willow brook State School, an institution for the severely mentally retarded. To study the natural history, effects, and progression of the disease, Krugman and his staff systematically infected newly arrived children with strains of the virus. Although the investigators did obtain the permission of the parents to involve their children in the research, critics of the Willow brook experiments maintained that the parents were manipulated into consenting because, at least in the later years of the research, the institution was overcrowded and the long waits for admittance were allegedly shorter for children who were entering the research, unit. Henry Beecher, a Harvard anesthesiologist whose impact on the history of research ethics condemned Krugman and his staff for not properly informing the parents about the risks involved in the experiment. Beecher also challenged the legal status of parental consent when no therapeutic benefit for the child was anticipated. A New York state senator, Seymour R. Thaler, criticized the Willow brook research on the pages of the *New York Times* in 1967, only to Gomes to its defense later in 1971. Also in the early 1970s Willow brook became the subject of a heated debate in the medical literature. Dr. Krugman was one of the participants at the LMRI "Social Responsibility in Pediatric Research" conference where he expressed pride that he routinely obtained permission from the parents of the children in his studies. In that group in 1961, Krugman was thus among those pediatric investigators most sympathetic to the position that children could not be used as mere means to the ends of the researcher without the authorization of the parent.

**Issues regarding experiments on Prisoners have also remained in lime light till today.** During wars, many young men are drafted, and then put in harm's way. Society tolerated this dangerous involuntary servitude, because it was necessary for the greater good and a better future.

This same argument was used to justify medical experiments on criminals in prison ([Rothman 317 N.E.J.M. 1195(1987)] during World War II. Because when a person is in prison does not relieve him of an opportunity to serve his country and human progress, by participating in medical research. "Every man must do his part."

If there currently is no draft and no military conflict to endanger normal people, we can still use this argument, because disease always threatens society. Nonconsensual medical experiments are wrong. The fact that young men are killed in wars to which they did not consent is a separate injustice, which is technically irrelevant to discussing medical experiments.

It is permissible to conduct medical experiments on prisoners, if they volunteer and provide informed consent. Prisoners who are sane still have some rights of self-determination and autonomy; it is wrong to say or to declare that no prisoner can consent to research. Prisoners have harmed society and participating in medical experiments is one of the ways that they can volunteer to help society. The prisoners should not receive a reduction in their sentence as the result of participation in
medical experiments, since their participation is not part of their punishment, but an independent act. Further, the possibility of reduction of sentences would inject an element of coercion into the prisoner's decision. However, it is acceptable to pay the prisoners, money for their participation. There are ethical concerns about allowing medical experiments on prisoners, who volunteer:

It is strange that liberals who object to allowing prisoners to voluntarily participate in medical research don't blink an eye at allowing seriously ill patients to participate in research. There can be no doubt that someone who is seriously ill is frightened, perhaps fearful of his/her life. By characterizing the experiment as a "new treatment", the experimenters can exploit the natural desire of the patient to receive the newest [and presumably the best] treatment possible. Participating in an experiment is also a way to get admitted to a superior hospital or to be treated by outstanding physicians (e.g., professor of medicine). Ingelfinger, 287 NEJM 466 (1972).

**Issues regarding practice of another branch of medicine and prescribing drugs is valid and legal or not, viz.,** Whether the homoeopathic, unani and ayurveda doctors may be allowed to prescribe allopathic drugs to their patients or not?

In a move that has been strongly resisted by doctors, the Maharashtra Cabinet on Thursday allowed homoeopathic doctors in the State to prescribe allopathic drugs after completing a one-year course at the Maharashtra University of Health Sciences.

The decision came after major disagreements in the Cabinet itself.

The government’s reasoning is that few doctors are willing to work in rural areas, and this will help to boost medical care in villages. The decision covers only those who have passed the Bachelor in Homoeopathic Medicine. There are roughly 62,000 homoeopaths in the State.

The Indian Medical Association said it would challenge the decision in court. “Why should rural areas suffer at the hands of unqualified practitioners? This decision has been taken because homoeopathic colleges are lying vacant and many are controlled by politicians,” IMA secretary Jayesh Lele said.

“This is a dangerous decision. It is not so simple to learn about allopathic drugs. They can cure but they also have side-effects and can kill. No other State has allowed this,” said Kishor Taori, chairman of the Maharashtra Medical Council.

The decision saw a major discord among Ministers. It was proposed by Medical Education Minister Vijaykumar Gavit of the Nationalist Congress Party and supported by Jaidutt Kshirsagar and Rajesh Tope, also of the same party. However, Public Health Minister Suresh Shetty and Water Conservation Minister Nitin Raut, both of the Congress, strongly opposed it.
Over a month after its controversial decision to allow homeopathic doctors to prescribe allopathy drugs, the state Cabinet has decided to allow unani and ayurveda practitioners to legally prescribe allopathic drugs and perform minor surgeries. There are more than 70,000 graduate and post-graduate ayurveda and unani practitioners in the state.

The proposal was put forward by the medical education department, even as the law and judiciary department questioned its validity. The medical education department argued that ayurveda and unani doctors were already prescribing allopathy drugs and the proposed move will allow them to do so legally. Additionally, the cabinet also decided to allow post-graduate ayurveda and unani doctors to perform minor surgeries such as cataract, hydrocele, appendix, vasectomy, hysterectomy etc. legally.

A senior official said that following two government notifications in 1992 and 1999, ayurveda and unani practitioners were already prescribing allopathic drugs, albeit with difficulties. “They were facing difficulties in prescribing allopathic drugs as the notifications were not incorporated in the Maharashtra Medical Practitioners Act, 1961. The Act will now be amended to this effect,” said the official.

The department has argued that the move will improve the reach of medical service in rural areas, where 1,983 of the 8,847 posts of doctors under the public health department are vacant at present.

While 25 per cent of posts of medical officers in the public health department are reserved for ayurveda doctors, unani doctors have been making a demand for 10 per cent reservation. “Both Bachelors of Ayurvedic Medicine and Surgery and Bachelor of Unani Medicine and Surgery courses have subjects that cover modern practice of medicine and surgery. Moreover, M.S/M.D (ayurveda) and MS/MD (Unani) will be allowed to perform those surgeries that they have studied,” the official said.

Medical associations have criticised the move. Dr Jayesh Lele, secretary of Indian Medical Association (IMA), Maharashtra chapter, said, “We will challenge the state government’s decision in court. This is a mere election stunt. The government needs to keep the medical field in mind. This will hamper practice of medicine.”

Dr Kishor Taori, president of Maharashtra Medical council (MMC), said, “As per the Medical Council of India norms, a doctor practicing a particular branch of medicine cannot practise any other branch. We will not register doctors who wish to prescribe both allopathic and ayurvedic/unani medicines.”
Case Study Analysis

Cases relating to human organs transplantation

Dr. Shyam Sundar Prasad Vs. State of Bihar (now Jharkhand). Judgment

The appellant Dr. Shyam Sundar Prasad was put on trial along with other accused to face charges under Sections 307, 326, 328 and 420 of the Indian Penal Code, Section 34 of the Indian Penal Code read with Sections 109, 201 and 343 of the Indian Penal Code on the allegation that accused persons in conspiracy with each other fraudulently and in deceitful manner removed the kidney of Nasir Ali. The trial court while referring the case of the other accused persons to the court at Bombay where the case instituted under Sections 18, 19 and 20 of the Transplantation of the Human Organs Act is pending, convicted the appellant under Sections 109 and 201 of the Indian Penal Code and sentenced him to undergo rigorous imprisonment for five years and further for one year for the offence under Section 109 and 201 of the Indian Penal Code respectively.

The case of the prosecution is that one Nasir Ali lodged a complaint case before the court of Judicial Magistrate, Bhilwandi under Sections 420, 406/34 of the Indian Penal Code and Sections 18.19 and 20 of the Transplantation of the Human Organs Act, 1994 against Shyam Kumar Sharma et all, a nurse, named as Mery, Dr. Tabrez and also 2-3 Doctors (not named) of Harkisandas Narrotumdas Hospital and Research Center, Bombay alleging therein that accused persons fraudulently and in deceitful manner got his kidney removed, The investigations from Harkisandas Narrotumdas Hospital and Research Center, as to whether one person named as Nasir Ali has been operated open in the Hospital as a kidney donor was replied in negative by the Hospital. However, it was informed that one Nasir Ali has been tested for HLA typing on 13.3.1997. Thereafter in order to get the matter regarding removal of kidney verified Nasir Ali was referred to J.J. Hospital, Bombay and on being examined it was reported by the said Hospital as "left kidney not visualized". It has been alleged that some times in May, 1997 he came across with one Deepak at Bombay to whom he expressed his desire to go to Saudi Arab, he introduced him to Shyam Kumar Sharma who asked for Rs. 40,000/- for the work to be done. The informant paid him Rs. 40,000/- and then brought him to Harkisandas Narrotumdas Hospital and Research Center where stool and urine were given for test. Then he introduced him to Dr. Tabrez and a nurse Mery, who brought him to Ranchi and took him to a Nursing home where blood sample was taken on the plea that if everything is found normal in the test, then only he could be sent to Saudi Arab. He was kept in one room of the Nursing home where in the night Dr. Tabrez, nurse Mery, who had come from Bombay as well as Dr. Prasad and his staff came and informed that blood report is not normal and hence he cannot be sent to Saudi Arab, then Dr. Tabrez told him that things can be set at right if blood transfusion is done and for that he will have to

1 MANU/JH/0679/2006.
undergo a small operation, to which he agreed and then one injection was
administered and thereafter he became senseless and after a week he found him in a
bed of Hospital named as Harkisandas Narrotumdas Hospital and Research Center,
Bombay, where he was kept for about 7-8 months. The nurse Mery disclosed him that
after removing his kidney it has been sold to some foreign national but neither they
are paying money to her nor they are ready to share the money and in this way he has
been duped by the accused persons. After knowing all these things, he fled from
Hospital and reported the matter to the police station and thereafter he on the advice
of his well wishers lodged the case in the court.

He was further brought to Rachi and taken to Prasad Nursing Home. The authorities
of the Hospital denied that any kidney was taken out at Prasad
Nursing home, and did make enquiry from the appellant but he flatly denied that any
kidney of the informant has been taken out. There was no record showing removal of
the kidney in the Nursing Home. But certain documents the affidavits, of different
donors indicating therein that donors voluntarily agreed to donate kidney to different
recipients and gave consent to be operated upon at the Prasad Nursing Home- were
seized.. On investigations it was found that several instruments installed were meant
for transplantation of the kidney. Some of the witnesses deposed that only that
dialysis was being done in the Prasad Nursing Home. Some said that Doctors from
outside used to be called for kidney transplantation., One Nurse administered
injection to him, as a result of which he became unconscious and when he woke up,
he found that he has been operated upon at Bombay.

On the basis of evidence; as indicated above the trial court did hold that Nasir Ali got
his kidney removed on his own volition and sold it to someone for its transplantation
in another human beings and that kidney of Nasir Ali was removed under the
supervision of the appellant in the Nursing Home belonging to the appellant. Having
holding so, the trial court, however, did refer the case of other accused namely,
Shyam Kumar Sharma at all to the court at Bombay where the case instituted under
Sections 18, 19 and 20 of the Transplantation of the Human Organs Act, 1994, was
pending. However, the trial court did find the appellant guilty under Section 109 of
the Indian Penal Code for abating the commission of the offence under Sections 18,
19 and 20 of the Transplantation of the Human Organs Act and also under Section
201 for causing the evidence of commission of the offence under Sections 18, 19, and
20 of the Transplantation of the Human Organs Act disappeared. Accordingly, the
appellant was convicted and sentenced as aforesaid Being aggrieved with that order of
conviction and sentence, the appellant has preferred this appeal. His Lordship held
that and on perusal on the records, I do find that the informant Nasir Ali when he was
brought to the Nursing Home of the appellant at Ranchi, the accused persons, who
had brought him from Bombay got his blood test done at Prasad Nursing Home and
then Dr. Tabrez told him that report is not normal and in order to get the things right
he has to undergo small operation to which he agreed and then injection was given
and he became unconscious and when he regained consciousness, he found in a bed of a Hospital at Bombay, he found that he has been operated upon and all these things were done at Bombay. Thus, it is evident that there has been absolutely nothing in the evidence to show that he was ever operated upon at Prasad Nursing Home. Similarly, it is shown that kidney transplantation was being carried out at Prasad Nursing Home for which Doctor used to come from different places such as Ahmedabad, Bombay, Lucknow, Delhi, Kolkata etc. However Nasir Ali, did identify the Prasad Nursing Home. I do find that there has been no evidence to the effect that Nasir Ali was operated upon at Ranchi in Prasad Nursing Home

In the circumstances, the order of conviction and sentence passed by the court below is hereby set aside.

Kuldeep Singh Vs. State of Tamil Nadu.

The petitioner No. 1 was undergoing treatment at Devaki Hospital at Chennai for renal disorder. The hospital in question is duly approved by the authorities under, the Transplantation of Human Organs Act, 1994 (in short the 'Act') read with Transplantation of Human Organs Rules, 1995 (in short the 'Rules') and is permitted to undertake Kidney transplantation. Doctors treating petitioner No. 1 were of the view that both the kidneys of petitioner No. 1 have failed to function. Petitioner No. 2 wanted to donate one kidney to petitioner No. 1 to save his life. The gesture was actuated by love and affection and there is no other consideration involved.

An application was made under the Act before respondent No. 2- the Director of Medical Education, Govt, of Tamil Nadu, Chennai for issuance of 'No Objection Certificate' (in short the 'NOC'). The respondent No. 2 by letter dated 10.3.2005 indicated to the petitioners that the NOC is to be issued by the Authorisation Committee of the Punjab State (respondent No. 3) as the Authorization Committee of the State of Tamil Nadu cannot issue such a certificate. It was indicated that since both the petitioners belong to the State of Punjab , only the Authorisation Committee of the said State had competence to issue the NOC. When request was made to respondent No. 3 through respondent No. 4 i.e. the Director, Research and Medical Education, Punjab, it was indicated to the petitioners by said respondents that it is only the Authorisation Committee of the State of Tamil Nadu which can issue the certificate, as the transplantation was intended to be done in the said State.

The petitioners have made a grievance that because of the ticklish issue as to which State has the competence to issue the NOC; the life of petitioner No. 1 is in peril.

We had issued notice to both the State Governments who are represented by their learned counsel. The State of Tamil Nadu re-iterated its stand that only the Authorisation-Committee of the State of Punjab was competent to issue the NOC.

2MANU/SC/0238/2005)
Right to Medical Treatment

1) Pt. Parmanad Katara Vs. Union of India

This case refers to the (Art.21) for right to health, Art.32, Art.41 and 42 right to get the treatment in sickness and disablement.

In this case, Pt. Parmanad Katara was a small human right activist fighting for good cause of general public interest. He filed a writ petition on the basis of a report in Hindustan times in which it was alleged that a man traveling by Scooter and was knocked down by a speeding car. He had an head injury and was bleeding profusely. He was picked by a person on the road and he took him to the nearest hospital. The doctor refused to attend to him and give treatment. He could not get the treatment due to lack of operative facilities for a Head injury and non availability of a Neuro Surgeon. He was advised to take him to a different hospital located about 20 km away authorized to treat Medico-Legal cases. At last he died on the way.

The Supreme Court has held that there cannot be two opinions that preservation of Human life is of paramount importance. Every Medical Practitioner whether practicing or attached to government or private Hospital has a profound obligation to extend his services, with due expertise for protecting life. No law or statute can intervene to avoid or delay the discharge of this paramount obligation cast upon the members of the Medical profession. Many a times the member of the Medical Profession avoids his duty to help a dying person because it might turn out to be a medico-legal case. No doubt a Physician is free to choose his patient whom he wants to serve. However, he should respond to any request for his assistance in an emergency.

The Supreme Court has further held that, whenever a member of the medical Profession is approached and if he finds, that whatever assistance he could give is not sufficient to save the life of the patient, & some better assistance is necessary, it is the duty of the medical man so approached, to provide primary medical aid to the patient and then refer the patient to the hospital, where the expertise facilities required for the treatment are available. The practice of the doctors and certain Government institutions to refuse even the primary medical aid to the patient and referring them to other hospitals simply because medico legal cases is deprecated ,and no medical man shall commit an act of negligence that may deprive the patient from necessary care

2) Paschim Bengal Khod Majdoor Samiti and others Vs. Government of west Bengal

This case refers to the (Art.21) for right to health and Art.41 and 42 making it, the duty of the state to provide the treatment in sickness and disablement.

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3 AIR 1989SC2039
4 1996 (4) SCC 37.
One member of the Paschim Bengal Khod Majdoor Samiti fell from the train and got Head injury, for which he needed a Neuro Surgeon, to operate on him. He moved from 7-8 Hospitals and was turned down for lack of operative facilities for a Head injury and non availability of a Neuro Surgeon. At last, he was admitted and operated at some hospital after wastage of few hours. He was alright, but he sued the Government for not providing adequate facilities for Neuro Surgery in the State Hospital.

The supreme court has held that, it is the responsibility of the State to provide for the facilities of treatment in the state run hospitals and held this inability to provide Neuro Surgery in the State Hospital, as violation of Article 41,42 to be read with art.21 and penalized the Bengal Government with a fine of Rs. 25000.00 and. It was held that Life without health is no life at all.

**Suggestions as to the Duties and responsibilities of the Doctors in general:**

1. **Character of Physician**

   (Doctor with qualification of MBBS or MBBS with post graduate degree/ diploma or with equivalent qualification on any medical discipline):

   A physician shall uphold the dignity and honour of his profession.

   The prime object of the medical profession is to render service to humanity; reward or financial gain is a subordinate consideration. Who-so-ever chooses his profession, assumes the obligation to conduct him in accordance with its ideals. A physician should be an upright man, instructed in the art of healings. He shall keep himself pure in character and be diligent in caring for the sick; he should be modest, sober, patient prompt in discharging his duty without anxiety; conducting himself with propriety in his profession and in all the action of his life.

   No person other than a doctor having qualification recognized by Medical Council of India and registered with Medical Council of India/State Medical Council(s) is allowed to practice modern system of Medicine or Surgery. A person obtaining qualification in any other system of Medicine is not allowed to practice Modern system of Medicine in any form.

2. **Maintaining good medical practice:**

   The Principal objective of the medical profession is to render service to humanity with full respect for the dignity of profession and man. Physicians should merit the confidence of patient entrusted to their care, rendering to each a full measure of service and devotion. Physician should try continuously to improve medical
knowledge and skills and should make available to their patients and colleagues the benefits of their professional attainments. The physician should practice methods of healing founded on scientific basis and should not associate professionally with anyone who violates this principal. The honoured ideals of the medical profession imply that the responsibilities of the physician extend not only to individuals also to society.

**Membership in Medical Society:** For the advancement of the profession, a physician should affiliate with association and societies of allopathic medical professions and involves actively in the functioning such bodies.

A Physician should participate in professional meetings as part of Continuing Medical Education programmes, for at least 30 hours every five years. Organized by reputed professional academic bodies or any other authorized organizations. The compliance of this requirement shall be informed regularly to Medical Council of India or the State Medical Council as the case may be.

3. **Maintenance of medical records:**

Every physician shall maintain the medical records pertaining to his/ her indoor patients for a period of 3 years from the date of commencement of the treatment in a standard Performa laid down by the Medical Council of India and attached as Appendix 3.

If any request is made for medical records either by the patients/ authorized attendant or legal authorities involved, the same may be duly acknowledged and documents shall be issued within the period of 72 hours.

A registered medical practitioner shall maintain a Register of Medical Certificates giving full details of certificates issued. When issuing a medical certificate he/she shall always enter the identification marks of the patient and keep a copy of the certificate. He or She shall not omit to record the signature and/or thumb mark, address and at least one identification mark of the patient on the medical certificates or report. The medical certificate shall be prepared as in Appendix 2.

Efforts shall be made to computerize medical records for quick retrieval.

4 **Display of registration numbers:**

Every physician shall display the registration number accorded to him by the State Medical Council / Medical Council of India in his clinic and in all his prescriptions, certificates, money receipts given to his patients.
Physician shall display as suffix to their names only recognized medical degrees or such certificates/diplomas and memberships/ honors which confer professional knowledge or recognizes any exemplary qualification achievements.

5. Use of Generic names of drugs:

Every physician should, as far as possible, prescribe drugs with generic names and he/she shall ensure that there is a rational prescription and use of drugs.

6. Highest Quality Assurance in patient care:

Every physician should aid in safeguarding the profession against admission to it of those who are deficient in moral character or education. Physician shall not employ in connection with his professional practice any attendant to who is neither registered nor enlisted under the Medical acts in force and shall not permit such persons to attend, treat or perform operations upon patients wherever professional discretion or skill is required.

7. Exposure of Unethical Conduct:

A Physician should expose, without fear or favour, incompetent or corrupt, dishonest or unethical conduct on the part of members of the profession.

8. Payment of Professional Services:

The physician engaged in practice of medicine shall give priority to the interest of patients. The personal financial interests of a doctor should not conflict with the medical interests of the patients. A physician should announce his fees before rendering service and not after the operation or treatment is under way. Remuneration received for such services should be in the form and amount specifically announced to the patient at the time the service is rendered. It is unethical to enter into a contract of "no care no payments". Physician rendering service on behalf of the State shall refrain from anticipating any consideration.

9. Evasion of Legal Restriction:

The Physician shall observe the laws of the country in regulating the practice of medicine and shall not assist others to evade such laws. He should be cooperative in observance and enforcement of sanitary laws and State Acts like Drugs and Cosmetic Act, 1940; Pharmacy Act, 1948; Narcotic Drugs and Psychotropic Substances Act, 1985; Medical Termination of Pregnancy Act, 1971; Transplantation of Human Organ Act, 1994; Drugs and Magic Remedies (Objectionable Advertisement) Act, 1995; and Bio-Medical Waste (Management and Handling) Rules, 1998; and such other Acts,
Rules, Regulations made by the Central / State Governments or local Administrative Bodies or any other relevant Act relating to the protection and promotion of public health.

Suggestions as to the duties of physicians to other patients

Obligation to the sick:

Though a physician is not bound to treat each and every person asking his services, he should not only be ever ready to respond to the calls of the sick and the injured, but should be mindful of the high character of his mission and the responsibility he discharges in the course of his professional duties. In his treatment he should never forget that the health and the lives of those entrusted to his care depend on his skill and attention. A physician should Endeavour to add to comfort of the sick by making his visits at the hour indicated to the patient. A physician advising a patient to seek service of another physician is acceptable; however, in case of emergency a physician must treat the patient. No physician shall arbitrarily refuse treatment to a patient. However for good reason, when a patient suffering from an ailment which is not within the range of experience of the treating physician, the physician may refuse treatment and refer the patient to another physician.

Medical practitioner having any incapacity detrimental to the patient or which can affect his performance vis-a-vis the patient is not permitted to practice his profession.

Patience, Delicacy and Secrecy:

Patience and delicacy should characterize the physician. Confidences concerning individual or domestic life entrusted by patients to a physician and defects in the disposition or character of patients observed during medical attendance should never be revealed unless their revelation is required by the laws of the State. Sometimes, however, a physician must determine whether his duty to society requires him to employ knowledge, obtained through confidence as a physician, to protect a healthy person against a communicable disease to which he is about to be exposed. In such instance, the physician should act as he would wish another to act toward one of his known family in like circumstances.

Prognosis:

The physician should neither exaggerate nor minimize the gravity of a patient's condition. He should ensure himself that the patient, his relatives or his responsible
friends have such knowledge of the patient's condition as will serve the best interests of the patient and the family.

The Patient must not be neglected:

A physician is free to choose whom he will serve. He should, however, respond to any request for his assistance in an emergency. Once having undertaken a case, the physician should not neglect the patient, nor should he withdraw from the case without giving adequate notice to the patient and his family. Provisionally or fully registered medical practitioner shall not willfully commit an act of negligence that may deprive his patient or patients from necessary medical care.

Engagement for an Obstetric case:

When a physician who has been engaged to attend an obstetric case is absent and another is sent for and delivery accomplished, the acting physician is entitled to his professional fees, but should secure that patient's consent to resign on the arrival of the physician engaged.

Health service business issues

Health services business is flourishing due to the implications of globalization in health services, effect of liberalization of healthcare service business on the availability, quality and cost of such services in developing countries, policies and strategies adopted by different countries for export of health services and their experiences regarding the same policies and measures to ensure that healthcare service business is not at the expense of national priorities and against the interests of the poor, with increasing commercialization of health services, maintenance of public-private balance in their delivery, role of the international community and multilateral organizations including the WHO and the WTO, developing countries spend less than 5% of their GDP on health care, do not have adequate funding, adequate allocation, use of resources, have unevenly mixed-up priorities, shortage of physical and human resources in health sector e.g. India has population: bed ratio of one per 1,000, health sector gets 3% of total budgeted expenditure, insufficient investment in preventive and curative care and basic health services for the poor, demand for health services far exceeds the supply capacity of the existing medical delivery system in most developing countries, over investment in production of medical graduates and specialists relative to absorption capacity, less focus on training of nurses, GP, technicians.

At least these should be observed:
Allocating more resources to training of specialists when there is a dearth of technicians and nurses is an inefficient use of resources, leads to an outflow of specialists and highly trained health professionals results in loss of subsidized training and investment provided by the government and a shortage of both GP and specialists in the country;

Increase budgeted expenditure on health care to improve the availability and quality of human and physical resources. Priority to increase the number of hospitals, dispensaries, beds, and the supply of doctors, nurses, and technicians;

Reducing the high cost of land in urban areas and providing land at subsidized rates in urban areas for setting up medical establishments and facilities, providing financial assistance such as soft loans for hospital construction and equipment, sharing of specialized and high cost facilities by institutions to rationalize costs and revamping management procedures to increase the efficiency and reduce the cost of health care;

Revenue generated from trade in health services can be used towards development of the domestic health care sector and taxes collected from foreign owned commercial hospitals can be invested in the public health system;

Enforce uniform standards of training and practice within the country to standardize and register private hospitals, clinics, nursing homes, and other medical centers to ensure the quality of health services available to the public;

Countries should assess their needs in specific segments of the health profession and accordingly invest in training and facilities;

Large investment in public sector in health care is wasted because of improper planning, financing and organization of the health care delivery system

Only 20% of routine morbidity and less than half of the hospitalizations are treated through public institutions / providers; rest is taken care of by private sector

60% to 85% of all non-hospital care is by GP (including outright quacks and cross-practitioners.

**The new initiatives from the govt. were**

The Government of India has allocated Rs 3,000 crore in the 12th Five-Year Plan (2012–17) for development of the medical device sector. 

in 11th plan budget allocation to health sector is just $20 billion(0.9% of the GDP).But for 12th plan, govt. triples the allocation and raised it to $55billions (2.5%of GDP).

Medical devices were brought under the ambit of the Drugs and Cosmetics (Amendment) Bill, 2013.
100 per cent FDI is permitted for health and medical services under the automatic route.

The Department of Health Research has decided to set up a Medical Technology Assessment Board to evaluate all kinds of Medical Technologies.

Reduced excise and customs duty (reduced to 5% from 25%).

Import duty on medical equipment reduced to 7.5%.

Exemption from service tax.

The benefit of section 10(23G) of the IT act has been extended to financial institutions those providing long term capital to hospitals above 100 beds.

The benefit of section 80 -IB extended to rural hospitals above 100 beds. Such hospitals are entitled to 100% deduction on profits for 5 years.

Established NHM (RHM+UHM). RSBY expanded to more sections of downtrodden.

National mission for geriatric care is established.

In FY2014-allocated $85 crore for improving medical education & research.

**Importance of health statistics and Millennium Development Goals (MDGs)**

The need for statistical health information has been on the rise, in recent times. The world community has turned its attention to meeting the targets set by the Millennium Development Goals (MDGs). In terms of health care, more resources are going towards the prevention and treatment of high burden diseases such as HIV/AIDS, tuberculosis and malaria. The World Health Organization (WHO) has also duly emphasized that investment in Health Management Information Systems (HMIS) could reap multiple benefits such as:

- Helping decision makers to detect and control emerging and endemic health problems, monitor progress towards health goals, and promote equity;

- Empowering individuals and communities with timely and understandable health-related information, and drive improvements in quality of services;

- Strengthening the evidence base for effective health policies, permitting evaluation of scale-up efforts, and enabling innovation through research and;

- Improving governance, mobilizing new resources and ensuring accountability in the way they are used
In this regard, decision makers need to be well equipped to measure whether policies and programmes are directed at the right beneficiaries, are meeting set targets and whether appropriate monitoring and evaluation tools are in place. Donors are also increasingly placing more emphasis on performance, linking the release of funds to performance based measures.

Further the post-2015 development agenda emphasizes on poverty eradication especially in the developing countries, which was identified at Rio+20 as the greatest global challenge. Despite impressive gains in poverty eradication, this remains the central challenge facing us today. People in developing countries continue to be the most poor and deprived and despite impressive growth rates, there remains a yawning gap between the developing and developed countries on practically all indicators per capita income, energy consumption, resource consumption, human development index. (National Consultation Report, Post-2105 Development Framework: India, 2013)

Given that there is growing inequality and regional poverty in India, the post-2015, a futuristic agenda with a more inclusive bottom-up process needs to be brought out for addressing the emerging areas of concern, including inequality, demographics, climate change and space for new development partnerships. Human development and poverty eradication, along with issues of equality, must be the focus of a future framework.

Limitations of data especially in developing countries are a real concern, as available data is not reliable. Post-2015 presents an opportunity to think beyond what data is available so that countries can invest in capacity building to get it. (CIGI, TISS, KDI, Post 2015 Development Goals, Targets and Indicators: Indian Perspectives, Mumbai, India / Meeting Report, August, 2012) Rio+20 recognized the importance of universal health coverage. Unlike the MDGs which focused on communicable diseases, the post-2015 development agenda should start focusing on non-communicable diseases such as diabetes, heart diseases and also the neglected tropical diseases. For inclusive development, creation of basic infrastructure in developing countries is identified as major bottleneck. Lack of effective infra also hampers progress on other indicators such as health and education facilities. There needs to be enough policy space for developing countries to focus on this important aspect of development.

The research is an endless process. However, it is to be completed within the time limit, resources available and intelligence of the scholar. It is hereby confessed that whatever the best is attempted. The reader of this study may feel that so many issues regarding human health and human rights are left untouched. But that was the limitations on the part of the scholar. It is affirmed that the research in this area is still possible, specifically issues on experimentation of drugs on human being, allowing treating the patients with unfamiliar stream of treatment, decline of moral values in
medical profession, commercialization of medical profession, etc. The scholar wish and prays to almighty God for restoration of the best practices of doctors and preservation and protection of human rights.

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