ASSESSMENT PROCEDURES FOR AUTISM: ETHICAL CONCERNS

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DECLARATION BY THE CANDIDATE

This thesis titled **"Assessment Procedures for Autism: Ethical Concerns"** submitted by me, for the award of the degree of **Master of Philosophy**, is an original work and has not been submitted so far in part or in full, for any other degree or diploma of any University or Institute.

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CERTIFICATE

This thesis titled **"Assessment Procedures for Autism: Ethical Concerns"** submitted by **Ms. Tresa Benjamin**, Centre for Linguistics, School of Language, Literature and Culture Studies, Jawaharlal Nehru University, New Delhi, for the award of the degree of **Master of Philosophy**, is an original work and has not been submitted so far in part or in full, for any other degree or diploma of any University or Institution.

This may be placed before the examiners for evaluation for the award of the degree of Master of Philosophy.

Prof. Vaishna Narang
(Supervisor)

Prof. Vaishna Narang
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Contents

CHAPTER 1

Introduction

Ethics, be it in research or treatment, is gaining wide importance since the recent past. Two important events like the Nuremberg Trial Code[i] and the Tuskegee Syphilis Study[ii] lead to the re-evaluation of ethical standards. Since then the understanding of ethics is undergoing a drastic change. Today there is hardly any research or treatment that is beyond the bounds of ethics.

1.1 Ethics

Ethics is defined as "the rule of conduct recognized in respect to a particular class of human action or a particular group, culture, etc. it is the branch of philosophy that deals with values relating to human conduct, with respect to the rightness and wrongness of certain actions and to the goodness and badness of the motives and ends of such actions (http://dictionary.reference.com/browse/ethics?s=t). Modern bioethics is believed to have developed from the articulation of standards to ensure that ethical conduct is being abided by in medical research. Many important ethical and legal questions can be raised when the research involves human subjects. Research ethics is concerned with the systematic analysis of such questions. Research ethics also ascertains that the participants are protected.

1.2 History of Bioethics

Bioethics, though a term fashioned as recently as 1970 by Van Renselaer Potter, a biological scientist, dates back to as ancient as medicine. Contents of The Code of Hammurabi[iii] and the Hippocratic Oath[iv] give importance to the ethical issues in clinical practice. Potter used the term to "to name his vision of a new conjunction of scientific knowledge and moral appreciation of the converging evolutionary understanding of humans in mature" (Albert R. Jonsen, pp. 3). This was a time when the creators of the atomic bomb and the biologists who were examining the human genes began to have concerns about the social significance of their fields.

Since many centuries, all the great literature cultures like Christians, Greco-Roman, Confucian, Islamic, Hindu and Buddhist associated the practice of medicine with certain moral values and qualities. Even though these associations are diverse the duties and decorum of a physician towards his patients are similar, be it anywhere in the world. Physicians who wanted to carry their work in a moral manner was dedicated, maintained confidentiality and cared for the patients without giving importance to his/her economic status. But as this became a profession economic rivalry started appearing. But this situation was changed drastically during the mid-twentieth century. Science invented more effective treatments than had ever existed till then. More people became trained physicians and physicians were not only more educated and competent. They also enjoyed more money and social prestige than the profession had ever enjoyed before. Along with this came new problems. The relationship of the physicians with the patients and other questions of morality were challenged in this new situation.

'Medical ethics' (1803) by Thomas Percival was seen as a concise and comprehensive summary of medical morality in England and America. Based on this book the American Medical Association introduced its first code of ethics for the American doctors in 1842. This had some limitations when dealing with the problems faced by modern medicine and this was noted as early as 1927. Dr. Chauncey Leake, in his edition of Percival, asserted the importance and understanding of medical morality that should be based on the theories of moral philosophy. He felt that this should be so because only with a philosophically based ethics could physicians face those problems that were creating disturbances in the personal relationship between doctors and their patients, even in the matters of trust.

Twenty five years from there, Joseph Fletcher, Professor of Moral Theology at the Episcopal Theological School, Cambridge, Massachusetts, in his book 'Morals and Medicine' did mention vaguely some denotative philosophical theories of ethics, utilitarianism. Medical morality prevailing on many traditionally controversial topics like telling the truth to patients, euthanasia, contraception and abortion were also criticizes and reformulated. His book 'Morals and Medicine' was considered to be a turning point in medical ethics.

Developments made in the field of medical technology and biological sciences made these questions even harder. One such development was of the artificial ventilators in the 1950's. This saved the patients from cardiac deaths, but left them without consciousness. An

international group of anaesthesiologists in 1957, demonstrated the ethical problems they came across in using such technologies, to a moral authority Pope Pius XII, the pope at that time. The Pope replied citing an Old Catholic teaching which propagated that no one had a moral responsibility to sustain life by using "extraordinary means". This revered philosophy by the Pope brought into light the history of Catholic moral theology which lead to a body dealing with principles and debates and arguments that surrounded medical ethics. These were applicable to the problems in modern medicine. This also induced the Catholic moral theologians to ponder about the arising moral and ethical issues in medicine.

In 1961, the arteriovenous shunt was invented by Dr. Belding Scribner who was a professor of Medicine at University of Washington, Seattle. This was another invention which raised some unique problem. This life saving intervention was a technology to support the loss of kidney function. This device made possible continued haemodialysis for those with serious kidney dysfunction. Shortly after the invention it became apparent that the number of patients who needed this technology outnumbered the number of patients that could be accommodated for this treatment. Thislead to the formation of the "God Committee". This committee had common people as its members, who had the right to choose the patients who were to be treated and hence live. The others were rejected leaving them behind to die. A committee of this kind with members who were not doctors and who had the right to decide who should live and who should die was unprecedented in medicine. The news about this god committee was brought to light by A Life magazine article, which appeared on 21st November, 1962. This triggered off some serious public debate. This issue on life selection interested some philosophers and theologians and there began to appear some writings on this topic. A philosopher put in a suggestion saying that patients should be selected for life saving based on their social utility, assessment being made in terms of the individual's social contributions. This was refuted by a number of theologians. They argued that the judgement of social worth was against the dignity of individuals and selection by more random methods such as lotteries should be employed. The legal analysis was supportive to the theologians. This whole debate was the first of its kind in the new field of bioethics.

Another dramatic movement in the progress of medicine was in 1968 when Dr. Christian Bernard took the beating heart from one dying person and transplanted it into the chest of another who lived for several months. Heart transplantations unlike other transplantations demanded a new definition of death, as the organ should be physiologically

living and it is to be taken from a person who is already dead legally. This lead to the formulation of new definitions of death which was until then designated as the moment when breathing and circulation ceases and the most famous of these was the 'Definition of Irreversible Coma : Report of the Ad Hoc Committee at Harvard Medical School to Examine the definition of Brain Death. This was thought to be ambiguous. Thirteen years from there the newly appointed President's Commission for the Study of Ethical Problems in Medicine (1979-1982) declared a more measured definition and death was defined as 'the cessation of all brain activity, including the brain stem'. Bioethicists argued that this definition opened up new dangerous territories. They claimed that the definition did not consider those humans who lacked the possibilities of communication as alive and the definition also considered those persons who held back their biological life as dead.

The advances in the field of biomedical sciences and technologies introduced to the medical practices a wide range of moral questions. The Kennedy Institute of Ethics was founded in 1971 at Georgetown University to initiate the development of a new research field which Andre' Hellegers, the founder of the institute preferred to call "bioethics". The Encyclopaedia of Bioethics, which was planned by the Kennedy Institute in 1972, defined bioethics as "the study of the ethical dimensions of medicine and biological sciences" (Reich, 1978 pp.12-20). Another major research institute in this field was founded by Dan Callahan in 1974 called the Hastings Centre.

Dan Callahan's article "Bioethics as a Discipline" suggested that this new filed itself can "develop into a unique discipline using both the traditional methods of philosophical analysis and sensitivity to human emotion and to social and political influences with which medicine was practiced. This article manifests on what should be the role of the ethicists in the world of medicine and biology. Dan Callahan, who is a Ph.D in philosophy, felt that there was nothing in his philosophical training which prepared him to take a clear-cut ethical decision at a given hour. This situation made him say that the philosophers must know more about the world and set their standards of intellectual rigor to the nature of the problems arising in it. Callahan says "if ethics was nothing other than seeing to it that no logical fallacies were committed in the process of ethical argumentation, it would hardly be worthy of anyone's attention. It is the premises of ethical arguments, the visions behind ethical systems, the feelings which fuel ethical (or non-ethical) behaviour, which make the real difference for human life.

A few more incidents took place which attracted the attention of the world in terms of ethical concern. One such incident was that of Karen Ann Quinlan in 1975. When she was 21, Quinlan became unconscious after arriving home from a party. After she collapsed and stopped breathing twice for 15 minutes or more, the paramedics arrived and took her to a hospital, where she lapsed into a state of unconsciousness. After she was kept alive using artificial life sustaining methods for several months without improvement, her parents requested the hospital to discontinue active care and allow her to die. The hospital refused to do so, and the subsequent legal battles made newspaper headlines and triggered off significant debates. The tribunal eventually ruled in her parents' favour. Quinlan was removed from the ventilator, but her life remained. But she was in a permanent vegetative state for more than ten years. This particular case lead to a number of debates in morality, theology and bioethics. The two significant outcomes from this particular case are the formulation of ethics committee in hospitals and the development of advanced health directives. These few incidents can be considered to be those which brought about a change in the outlook towards ethical issues in medicine.

For achieving advancement in medical field, experimentation is required and for this experimentation humans are required. During the emergence of experimental medicine in the first half of the nineteenth century, Claude Bernard, the French physiologist and one of the pioneers of experimental medicine stated that “it is our duty and right to experiment on man, whenever it can save his life, cure him or gain him some personal benefit. The principle of medical and surgical morality, therefore, consists in never performing on man an experiment which might be harmful to him to any extent, even though the result might be highly advantageous to science, that is, to the health of others (Bernard ,C 191-102). But this noble statement was considered to be not real, because all experimentation included something that is unknown and also included some risks. As this century moved ahead, the contradictions in medical research with humans became more and more evident. The brutal experiments done by the Nazi physicians in concentration camps after the World War II exposed that there is no extent to which uncontrolled experimentation could go. This lead to the formation of the Nuremberg code in 1947, formed in the course of trial of those physicians.

The Nuremberg Code was considered to be the epitome of ethics concerning experimentation with humans. Nuremberg Code stated that Medical Research can be done

only after obtaining free and voluntary informed consent of the subject and also the risks and benefits must be properly balanced. It was hardly believable that such things could happen in America, but similar things did happen. Dr. Henry Breecher, a medical researcher, published an analytic expose of abuse in research with human subjects in a medical journal in 1968. Among them a study which began in 1931 by the Public Health Service and left 400 rural black men without treatment for syphilis appalled the nation (Jones J 1981). The government which funded so many biomedical researchers had to make sure that the research was abusive to its subjects and that it protected its subjects.

The National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research (1974-1978) was established by Congress. This commission was established to lay out the ethical principles which should be followed when doing a research. It also recommended rules and procedures to protect the well being of the human subjects. During the four year tenure of the commission it issued a statement of principle, ' The Belmont Report'. The Belmont Report brought in three principles that every researcher should follow. Those three principals were:-

- Respect for person (entails informed consent)
- Beneficence (entails the assessment of risk in relation to benefit)
- Justice (entails the just selection of subjects for research)

Many theologians and physicians were called in by the commission to help in solving the problems as it debated the ethics or research with children, with the mentally instable and with jailed persons.

Bioethics was again proved to be a discourse and discipline. The far-flung debates about abuse on subjects who were part of any experiment eventually lead to regulation and legislation. This was further developed by the analysis of concepts such as 'free and uncoerced consent' and 'research versus practice' and of the rationale behind the logic involved in arguing for the rights of research subjects in relation to the common well being of the society. The ethics of biomedical experimentation gave importance to the consent of the subject.

Selection of subjects for life and death therapies/experimentation, experiments involving human subjects, organ transplantation and its complexities all occurred during the 1960's. These topics raised concern among the professionals and the public and attracted the

attention of philosophers, theologians and legal scholars. They were also first on the agenda for the nascent bioethics. During the decade 1970-1980 a huge volume of literature on the above mentioned topics were published and several research institutes like the Hastings Centre (1969) and the Kennedy Institute at Georgetown University (1971) were established.

The period from the 1970's saw a lot of work and discussions put forward by public commissions and committees into the concepts and debates surrounding ethical concerns. Through this process the issues were clarified and the analysis and arguments concerning bioethical questions attained new and improved understanding. Scholars who initially were just the observers became attracted to these problems. Government regulations made it mandatory that all research institutions should have an Institutional Review Board (IRB) which should review and then approve all research proposals involving humans as study subjects.

Bioethics is not simply a pedantic field where arguments over methods and theories take place. It also guides policies and practices. " thus in addition to the disciplinary dimensions of method and theory, bioethics is a form of discourse, promoting public debate over substantial questions and encouraging the formation of agreement and consensus about the ways to resolve those questions" (Jonsen, 2011 pp 13). And as Callahan says "if ethics was nothing other than seeing to it that no logical fallacies were committed in the process of ethical argumentation, it would hardly be worthy of anyone's attention. It is the premises of ethical arguments, the visions behind ethical systems, the feelings which fuel ethical (or non-ethical) behaviour, which make the real difference for human life" (Callahan, 1973 pp 20).

1.2.1 Evolution of Regulation

The Nuremberg Code (1947)

During the World War II a series of medical experimentation was carried on a large number of prisoners in the concentration camps by the German Nazi regime. Those prisoners were forced into participating. There was no voluntariness on their part and no informed consent as well. Death, mental distress, disfigurement or permanent disability was the result of these experiments. The experiments could be categorized into three groups

- Medico-military research

- Miscellaneous/ Ad Hoc experiments (nothing related to human betterment)
- Racially motivated experiments

At Auschwitz and other camps, selected subjects were submitted to a lot of life threatening experiments, which were supposedly planed to help the German regime in the war front, in the development of new weapons, aid in the recuperation of the injured military personnel. Experiments were also conducted to heal homosexuality on homosexual prisoners. Many of the subjects of these experiments were murdered after the tests to study the effect after death.

After the war, these crimes were heard at what was later called the Doctor's Trial. Several of the doctors in the trial argued in their defence that there was no international regulation regarding medical practices or experiments. Repulsion at the ill-treatment committed led to the formation of the Nuremberg Code of Bioethics (Robert Proctor 2000, pp. 335-346). When the details of the Nazi concentration camps were revealed to the outside world, ethical guidelines started evolving as legal requirement. This made the people to ponder how ethical questions were actually questions of serious research. This also led to the evolution of regulations in clinical trials.

The Nuremberg Code laid down basic principles to be followed when conducting research with humans as subjects. This also formed the basis for other international guidelines on medical experiments/research/practice. A large of number of regulatory bodies from many other countries including government and government regulatory departments, health care providers began bringing out guidelines and regulations to make sure that the clinical trials were conducted following the ethical norms. The focus of the Nuremberg Code was on voluntary consent.

Despite the potential of the Nuremberg Code, ill-treatment of subjects in medical research in the 1950's and 1960's occurred. Thus in the year 1964, the World Medical Association met in Helsinki, Finland and brought out guidelines for physicians in research involving humans as subjects. This was later called as the Declaration of Helsinki.

The Declaration of Geneva (1948)

The Declaration of Geneva was made by the World Medical Association as an intended modernised revision of the Hippocratic Oath. This can be considered as a declaration of the physicians. It ties the physician with the words "the health of my patient will be my first consideration". The International Code of Medical Ethics states that "a physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient" (Hoover Herbert, 1926).

The Declaration of Helsinki (1964)

The Nuremberg Code had some drawbacks in those aspects concerning the legally incompetent subjects such as the mentally ill and temporarily incapacitated children and these drawbacks were addressed in the Declaration of Helsinki. The concept of therapeutic versus non-therapeutic research was also introduced in this declaration. The following premise was the foundation of the Declaration of Helsinki: "it is the mission of the physician to safeguard the health of the people" (Levin RJ, 1999). The Declaration originally formed in 1964 June, in Helsinki, Finland, has since undergone six revisions in 1975, 1983, 1989, 1996, 2000 and the most recent in 2008 at the General Assembly.

Among the many changes which were incorporated into the document was a greater stress on the requirement to benefit those communities that participate in the research. Attention was also called upon to the ethical concerns of those on whom the experiments are conducted and yet, would not gain any benefit from the research. Article 19 put forward the idea of social justice, and covers the range from the individual to the community as a whole by stating that 'research is only justified if there is a reasonable likelihood that the population in which the research is carried out stand to benefit from the results of the research' (Carlson 2004)

This Declaration forms the founding basis for other subsequent documents as this takes an important place in the history of research ethics. This importance is gained by the Declaration because it can be considered as the pioneer effort of the medical community to control research by itself.

International Covenant on Civil and Political Rights (1966)

The Universal Declaration of Human Rights of 1948 [v] was systematized into two covenants which the United Nations General Assembly adopted on 16th December of 1966. This covenant can be considered as a benchmark in the attempts of the global community to promote and ensure human rights. This covenant upholds the right to life[vi] and specifies that no human being should be subjected to torture, forced labour, captivity and or should be kept in arbitrary hold. It also states that no human being should be prevented from freedom of movement, freedom of expression and freedom of association (Sarah Joseph, 2005). The Covenant stated that 'No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his consent to medical or scientific treatment' (ICMR Code, 2006)

The Belmont Report (1978)

In spite of the attempts to assure the safety of the subjects in a study, several unethical practices were still practiced [the mentally ill children at Willowbrook Home were given hepatitis with the aim to analyze the natural advancement of the disease. (Bulger, 2002). This led to the establishment of the National Research Act of 1974 by the 93rd United States Congress[vii]. The Congress also set up the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research. The Belmont Report was formulated by this National Commission. The Belmont Report laid down a set of principles and guidelines. Any research involving human participants were to comply by these principles and guidelines. The Belmont Report also formulated three basic principles, which all researchers were to be following. The three principles are:-

- Respect for persons (treating people with respect and courtesy and giving importance to informed consent)
- Beneficence (the benefits of the research project must be maximised and the risk to the participating subjects must be minimised)
- Justice (equal and just distribution of the costs and benefits among the research subjects) (Janet F. Zimmerman, 1997)

These principles still remain important in all the research involving human subjects.

Universal Declaration on Bioethics and Human Rights (2005)

The Universal Declaration on Bioethics and Human Rights was brought out by the UNESCO in October 2005. The document begins with the aims, objectives and the evolution of the guidelines. The document is witting of the unparalleled capability of the human beings to ponder about their own being and about their environment. This document also talks about the rapid advancement in the field of science and technology, which in turn affects the human life and understanding. The document is addressed to the States and it addresses the ethical issues related to medicine, life sciences and associated technologies as applied to human beings, taking into account their social, legal and environmental dimensions (Universal Declaration on Bioethics and Human Rights Document, 2005)

For the first time, the international community to respect and apply the fundamental principles of bioethics was set forth within a single text. The document holds that it is essential for the international community to set up universal guidelines and principles that will render a basis for humanity's response to the always increasing quandaries and arguments that the fields of science and technology poses for the human kind and the environment.

The aims of the document can be mentioned briefly as:

- To promote respect for human dignity and protect human rights, by ensuring respect for the life of human beings
- To safeguard and promote the interest of the present and future generations
- To underline the importance of biodiversity and its conservation as a common concern of human kind.
- To foster multidisciplinary and pluralistic dialogue about bioethical issues between all stake holders and within society as a whole. (Universal Declaration on Bioethics and Human Rights, October 2005)

As per the document, moral sensitivity and ethical reflections is required to be an integral part of the processes involving scientific and technological developments and

bioethics should have a pivotal role in the options that is made available for problems arising from these models of developments.

1.3 International Ethical Guidelines

Advancements in the medical field depend on research which involves experimentation on human subjects. A basic distinction is to be made between medical research which results in a diagnosis or therapy for a patient and medical research which is absolutely scientific without any direct diagnosis or therapy to the person involved in the research. The purpose of biomedical research which involves human beings as subjects should be to improve the understanding and standards of diagnosis and therapy. A number of international organizations have come forward with the ethical guidelines for research involving human subjects. Some of them include the Belmont Report, the CIOMS guidelines, the UNESCO document and the WHO document.

The council for International Organization of Medical Sciences (CIOMS)

In 1949 the Council for International Organization of Medical Sciences (CIOMS) was formed conjointly by the World Health Organization (WHO) and the United Nations Scientific and Cultural Organization (UNESCO). The main aims of this organization were to help and encourage international activities in the field of biomedical research. The CIOMS has done works in the fields of bioethics, international health policy, development of drugs, etc. During the late 1970's CIOMS attempted research in the field of bioethics in association with WHO and this resulted in the formation of the 'Proposed Ethical Guidelines' in 1982. Later, in 1993 the 'International Ethical Guidelines for Biomedical Research Involving Human Subjects, again with the association of the WHO was published. This was later updated in 2002. This updated document consists of twenty-one guidelines. "The Guidelines relate mainly to ethical justification and scientific validity of research; ethical review; informed consent; vulnerability of individuals, groups, communities and populations; women as research subjects; equity regarding burdens and benefits; choice of control in clinical trials; confidentiality; compensation for injury; strengthening of national or local capacity for

ethical review; and obligations of sponsors to provide health-care services"(http://www.cioms.ch/frame_guidelines_nov_2002.htm).

The guidelines prescribed by the 'International Ethical Guidelines for Biomedical Research Involving Human Subjects' are on the following aspects:

- Ethical justification and scientific validity of biomedical research involving human beings
- Ethical review committees
- Ethical review of externally sponsored research
- Individual informed consent
- Obtaining informed consent: Essential information for prospective research subjects
- Obtaining informed consent: Obligations of sponsors and investigators
- Inducement to participate
- Benefits and risks of study participation
- Special limitations on risk when research involves individuals who are not capable of giving informed consent
- Research in populations and communities with limited resources
- Choice of control in clinical trials
- Equitable distribution of burdens and benefits in the selection of groups of subjects in research
- Research involving vulnerable persons
- Research involving children
- Research involving individuals who by reason of mental or behavioural disorders are not capable of giving adequately informed consent
- Women as research subjects

- Pregnant women as research participants
- Safeguarding confidentiality
- Right of injured subjects to treatment and compensation
- Strengthening capacity for ethical and scientific review and biomedical research
- Ethical obligation of external sponsors to provide health-care services

(http://www.cioms.ch/frame_guidelines_nov_2002.htm)

The guidelines owe their historical basis in the Declaration of Helsinki. These guidelines are contrived to be useful to countries in prescribing the national policies in ethics of biomedical research involving human beings as subjects, the application of these ethical standards in local situations and establishing and improving ethical review procedures. (http://www.cioms.ch/frame_guidelines_nov_2002.htm).

The Belmont Report (1978)

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- Justice (equal and just distribution of the costs and benefits among the research subjects) (Janet F. Zimmerman, 1997)

These principles still remain important in all the research involving human subjects. Guidelines and regulations on the ethical issues in clinical trials in the United States owe its emergence to the Belmont Report. Apart from the United States, many other countries have also accepted these guidelines.

Universal Declaration on Bioethics and Human Rights (2005) – UNESCO Document

The Universal Declaration on Bioethics and Human Rights was brought out by the UNESCO in October 2005. The document begins with the aims, objectives and the evolution of the guidelines. The document is witting of the unparalleled capability of the human beings to ponder about their own being and about their environment. This document also talks about the rapid advancement in the field of science and technology, which in turn affects the human life and understanding. The document is addressed to the States and it addresses the ethical issues related to medicine, life sciences and associated technologies as applied to human beings, taking into account their social, legal and environmental dimensions (Universal Declaration on Bioethics and Human Rights Document, 2005)

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- To foster multidisciplinary and pluralistic dialogue about bioethical issues between all stake holders and within society as a whole. (Universal Declaration on Bioethics and Human Rights, October 2005)

As per the document, moral sensitivity and ethical reflections is required to be an integral part of the processes involving scientific and technological developments and bioethics should have a pivotal role in the options that is made available for problems arising from these models of developments. The UNESCO proclaims this document to uphold the following concerns:

- Progress in science and technology will contribute to justice, interest of humanity and equity
- Paying attention to the women's position will help in understanding social realities and will help in achieving equity
- Strengthening global association in the field of bioethics
- The needs of developing countries, vulnerable and indigenous population should be taken into consideration
- All human beings should gain from the same ethical measurements in the field of medical and life science research.

1.4 Clinical Trial Practices in India

International clinic research is evading India. Despite this fact, it is definitely not the west that is acquainting India with these clinical researches. Two ancient scripts, Charaka Samhita[ix] and Sushruta Samhita[x] portraits India's proficiency in the field of medical research since the ancient past. However, there have been drastic changes in the field of clinical research since that time. In the present day situation, clinical trials should be conducted only by following a set of regulated guidelines brought out by some international/national organizations. A large number of laws regarding clinical research exist in India as well. Some of them are mentioned below.

Ethical Guidelines for Biomedical Research on Human Participants (Indian Council of Medical Research (ICMR))

The Indian Council of Medical research brought out the 'Policy Statement on Ethical Considerations involved in Research on Human Subjects' in 1980 and this was at a later revised in 2000 as the 'Ethical guidelines for Biomedical Research on Human Subjects' (Ethical Guidelines for Biomedical Research on Human Participants, 2006). The challenge that was faced in India was the application of international ethical principles to biomedical research in the context of the multicultural Indian society with a large number of health care systems, each with its own standard. These changes are taken care of by the ICMR guidelines. The ethical issues that can arise in particular situations, keeping up with the national policies and the demand of the Indian culture are also addressed by these guidelines.

The 'Ethical Guidelines for Research on Human Participants' also known as the ICMR code consists of the following statements:

- Statement of General Principles on Research using Human Participants in Biomedical Research
- Statement of Specific Principles on Research using Human Participants in specific areas of Biomedical Research

The Statement of general principles includes the following:

- Principle of essentiality
- Principles of voluntariness, informed consent and community agreement
- Principles of non-exploitation
- Principles of privacy and confidentiality
- Principles of precaution and risk minimization
- Principles of professional competence
- Principles of accountability and transparency
- Principles of the maximisation of the public interest and of distributive justice

- Principles of totality of responsibility
- Principles of public domain
- Principles of compliance
- Principles of institutional arrangements

Other topics that are covered by the ICMR Code include:

- Ethical review procedures
- General ethical issues
- Statement of specific principles for clinical evaluation of drugs, devices, vaccines, diagnostics, herbal remedies
- Statement of specific principles for epidemiological studies
- Statement of specific principles for human genetics and genomics research
- Statement of specific principles for research in transplantation
- Statement of specific principles for assisted reproductive technologies.

In the Indian context, a researcher will have to give due consideration for autonomy versus harmony of the environment of the research participant. This will be helpful in ensuring the guarding of the human rights of the vulnerable and indigenous population.

Drugs and Cosmetic Act – 1940

In 1973, in Central Legislative Assembly, a bill was introduced. It was introduced to give effect to the testimonials to control the import of drugs into British India given by the Drugs Enquiry Committee. This bill was in turn cited to the Select Committee and the Committee conveyed the impression that what more was worthy was a more comprehensive measure for the control on the manufacture, distribution and import of drugs. A suggestion was made to the Provincial Governments by the Central Government to necessitate the Provincial Legislature to pass resolutions authorizing the Central Legislature to pass the act for controlling things relating to drugs control to fall within the Provincial Sphere. The

resolution was passed from the Provincial Legislature for the Provincial Government and was sent to the Central Government to regulate the production, distribution, sale and import of drugs and cosmetics. Therewith the Drugs and Cosmetics Bill was introduced in the Central Legislative Assembly and passed. It got the accede of the Governor General on 10th April, 1940 and thence the Drugs and Cosmetic Act of 1940. (http://www.medindia.net/indian_health_act/drugs-and-cosmetics-act-1940-the-central-drugs-laboratory.htm)

Medical Council of India Act – 1956

In February 1934, under the Parliament Act – the Indian Medical Council Act, 1933- a statutory body, the Medical Council of India, was established. The Indian Medical Council Act of 1956 abrogated the Indian Medical Council Act of 1933. Further amendments were made to this act in 1958 through an ordinance proclaimed by the President of India. Through this ordinance some new sections namely section 10A, 10B and 10C were introduced in the Indian Medical Council Act of 1956. These new sections were added mainly to control the mushroom growth of medical colleges, starting of new courses and increase in the number of seats in courses without any prior reception from the Ministry of Health Family Welfare, Government of India. This statement was notified in the Gazette of India part 11 by the government of India on 3rd April 1993. Another amendment was published in the Gazette of India on 28th June 2003 by the Central Government to improve the Screening Test Regulations, 2002 stating that an examinee will have to pass all the three papers in the same attempt, without any restriction on the number of attempts to appear in the test. On 1st March 2004, another amendment was notified by the Government of India in the Gazette of India, concerning the improvements on the Regulations on Graduate Medical Education, 1997 stating that "there shall be no admission of students in respect of any academic session beyond 30th September under any circumstance. The universities shall not register any student admitted beyond the said date. The Medical Council of India may direct, that any student identified as having obtained admission after the last date of closure of admission be discharged from the course of study, or any medical qualification granted to such a student shall not be a recognized qualification for the purpose of the Indian Medical Council Act, 1956. The institutions which grant admission to any student after the last date specified from the same shall also be liable to face such action as may be prescribed by the Medical Council

of India including surrender of seats equivalent to the extent of such admission made from its sanctioned intake capacity for the succeeding academic year." (http://www.mciindia.org/ActsandAmendments/TheMedicalCouncilAct1956.aspx)

The Indian Medicine Central Council Act - 1970

The Central Council of Indian Medicine was constituted in 1984 and reconstituted in 1995. It is a statutory body. The main aims of the Indian Medicine Central Council can be stated as follow:

1. To prescribe minimum standards of education in Indian System of Medicine viz Ayurved, Siddha and Unani Tibb.

2. The recognition and withdrawal of recognition of medical qualification in Indian Medicine if standards are not met (http://www.medindia.net/indian_health_act/the-central-drugs-laboratory.htm)

Regulatory changes in India regarding clinical trials:

In the year 2005, schedule Y of the Drugs and Cosmetics Act was amended. Earlier, the requirement was that all foreign drugs be retested at one stage below the highest stage of testing abroad. Concomitant phase 2 and phase 3 trials is allowed by the schedule Y. India can also become a part of global trials. But still phase 1 should be repeated for safety.

The advantages of performing clinical trials in India include;

- Large numbers of people with a range of illnesses,
- Relatively low costs, availability of trained human power and infrastructure,
- Hhigh enrolment rates (higher than in the West),
- Good patient compliance/ retention, and

- An "increasingly accommodating regulatory environment"

India is a place which offers people with the right diseases. They're also treatment naïve- they would not have been able to afford treatment – and this makes them ideal for the testing of new drugs. This scenario paved way for India becoming a global hub for clinical trials. The loopholes in the legal system of our country pave way for the multinational companies to outsource clinical trials to India. This opinion is drawn on the basis of concerns about timelines for regulatory approvals, deficiencies in the functioning of the ethics committees, and an unethical approach to the recruitment of illiterate and vulnerable Indian people to clinical trials. In order to control the above situation and make the clinical trials transparent the ICMR is maintaining a clinical trial registry in India (http://www.medindia.net/indian_health_act/drugs-and-cosmetics-act-1940-the-central-drugs-laboratory.htm)

1.5 Spheres of Bioethics

Bioethics, though a term fashioned as recently as 1970 by Van Renselaer Potter, a biological scientist, dates back to as ancient as medicine. Contents of The Code of Hammurabi and the Hippocratic Oath give importance to the ethical issues in clinical practice. Potter used the term to "to name his vision of a new conjunction of scientific knowledge and moral appreciation of the converging evolutionary understanding of humans in mature" (Albert R. Jonsen, pp. 3). The initial focus of bioethics was on those ethical issues which concerned the clinical care. In addition to this, bioethics focuses on moral, legal, political and social issues relating to medicine, life sciences technologies and biomedical researches.

Three different broad spheres of bioethics are realized. They are:

- Academic bioethics – this sphere of bioethics focuses primarily "on how the theoretical and practical aspects of medicine affect considerations such as special obligations or responsibilities of clinicians, what is valuable, good, right and so in the biomedical context and how one might go about providing systematic accounts of such considerations" (A.M Viens and Peter A Singer, 1)

- Public policy and law bioethics – this sphere focuses on how "legal and extra-legal institutions can and should be involved in the regulation of clinical and research practices" (A.M Viens and Peter A Singer, 1)
- Clinical ethics – the focus of clinical ethics "is directly related to how the incorporation of bioethics into clinical practice can help to improve patient care" (A.M Viens and Peter A Singer, 1)

These three spheres of bioethics are interconnected and works across multiple spheres are done by scholars and clinicians. Apart from these divisions, a number of different bioethical methodologies have been advanced for the incorporation of bioethics into clinical practice. They are divided into four broad divisions. They are:

- Practical or applied ethics – the ethical issues that can come up in practice through the application of aspects of particular ethical theories or specific notions/concepts to concrete clinical or research cases is addressed by this approach. Here the focus is on providing theoretical framework concerning what conditions can make an action good or a policy right, rather than focusing on providing a decision procedure for how can the ethical issues be solved (A.M Viens and Peter A Singer, 3)
- Principlism – the aim of this approach is to provide ethical guidance in clinical practice through a specified number of moral principles. The most famous versions of bioethical principlism is given by Beauchamp and Childress (2001), the principles being that of autonomy, beneficence, non-malfeasance and justice. But principlism is being criticized for being too blunt and insensitive as it tries to apply a few ethical principles to all the problems in all the circumstances (A.M Viens and Peter A Singer, 3)
- Casuistry – ethical problems are addressed in this approach through specific issues and paradigm cases that have arisen in clinical education or practice. This methodology offers a bottom-up approach where case based reasoning is used to identify the morally relevant features of a situation and it is related to the specific situation of a former case and its solution. Clinicians find this approach appealing to deal with ethical problems. The main criticism against this approach was that it does not provide a clear method for working through ethical issues (A.M Viens and Peter A Singer, 4)

- Combination of techniques – this approach is used to identify and solve ethical conflicts, disagreements and other related problems. The ethical issues that arise in clinical practice are treated as those similar to inter-personal issues. A major criticism against this approach is that it fails to address the source of moral conflict (A.M Viens and Peter A Singer, 4)

When human beings are the subjects in an experiment, a lot of ethical issues arise and these will mainly concern informed consent, confidentiality and some duties of physician towards a patient. The main aspects of ethics are the following:

- Consent
- Confidentiality
- Disclosure

1.6 Key Concepts of Ethics

1.6.1 Informed Consent

Consent is defined as the "autonomous authorization of a medical intervention...by individual patients" (Beauchamp and Faden, 2004). In the present day scenario, informed consent is an important step in any research or medical practice. During the procedure of obtaining informed consent, the participant or the patient agrees to become a part of the research or clinical procedure after being fully aware about the way the procedure is carried out, its benefits and advantages and risks (Bulger, 2002). In an ideal situation, after understanding about the research project or clinical practice completely, the participant or the patient gives a full and conscious agreement to the researcher or the clinician to be a part of the procedure. The process of obtaining the informed consent has a lot of ethical concerns surrounding it. The importance of informed consent can be completely understood only if the history that lead to the inclusion of informed consent in research projects is known and this has been discussed earlier in this chapter.

Informed consent was framed to ensure that a research participant or a patient is completely aware of the advantages, benefits and risks that is involved in the procedure and

the patient or participant is fully aware of the procedure and how it is carried out. But when it comes to real life situations, it may not be as practical and easy as it seems to be. There is a high chance for misunderstandings as there may be concealed communication barriers between the researcher/clinician and participant/patient. This may not give the participant/patient the privilege to make a decision and give informed consent after being fully aware of the procedure. The barriers between the researcher and the participant can also be because of cultural differences and sometimes because of the differences in the religious practices. The participant's blind belief in science can lead to false expectation and this may also cause a problem. Both the researcher/clinician and the participant/patient must be aware of these barriers. If a participant/patient misunderstands the procedure involved in the experiment/clinical practice, he/she may be unknowingly participating in a procedure which he/she may not approve of. If at a later stage the participant/patient becomes aware of this situation, their physical or psychological well being might be greatly affected. This is one of the reasons for why the researcher/clinician should be ethically obliged to clear all the misunderstandings and make the participant/patient fully aware of the actual procedure involved.

Consent can be given either explicitly or implicitly. Explicit consent can be in either in written or in words. Implied consent happens when a patient/participant expresses his willingness to take part in the procedure by way or his/her behaviour.

The concept of consent is important as it is based on the principles of patient autonomy (patient's/participant's right to make a fully informed and free decision about his/her healthcare) and respect for persons (avoid conducting unwanted procedures). Obtaining informed consent may be exempted in tow cases. They are:

- Situations where when the truth is told to the patient, it might lead to more harm
- Situations where the patient by himself/herself gives the decision making power to the clinician or another third party.

Legal aspect

In many jurisdictions, getting informed consent from the patient is required by the law. The 'Convention on Human Rights and Biomedicine' states that:

> *"An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks. The person concerned may freely withdraw consent at any time"* (Singer A Peter and Viens A M, 13)

An exception to the necessity of consent is in an emergency situation and this is recognized by all the jurisdictions. This type of emergency can arise when immediate treatment is required to save the life or to sustain the health of a person. This kind of an emergency is given an exception because a delay in treatment may lead to the death of the patient. But a clinician is always advised to get the consent from a person who can act as a substitute decision maker of the patient.

Policy

Almost all the international as well as the national organizations require that informed consent should be obtained from the participant/patient. The World Medical Association's (2005) 'Declaration on the Rights of the Patient' states:

> "*The patient has the right to self-determination, to make free decisions regarding himself/herself. The physician will inform the patient of the consequences of his/her decisions. A mentally competent adult patient has the right to give or withhold consent to any diagnostic procedure or therapy. The patient has the right to the information necessary to make his/her decision. The patient should understand clearly what is the purpose of any test or treatment, what the results would imply, and what would be the implications of withholding consent."* (Singer A Peter and Viens A M, 13)

How should consent be approached in practice?

The participant's/patient's freedom to give or refuse consent is being widely accepted since the recent past. It is an obligation on the researcher's or clinician's part to help the participant/ patient to practice this right. When a participant/patient is required to give informed consent, it is implied that the participant/patient will be well aware of the available options given by the researcher/clinician. The process by which informed consent is obtained will also help the participant/patient to be a part in the problem solving process and they will also to actively participate in the decision making process and there by authorize it. Consent has three basic components. They are:

- Capacity
- Disclosure
- Voluntariness

1.6.1. A. Capacity

Capacity can be defined a 'set of "functional abilities" that a person needs to possess in order to make a specific decision' (Singer A Peter and Viens A M, 17). The ability to understand relevant information which is necessary to make a decision and the ability to understand the possible risks and benefits are included in this ability. Sometimes, a patient who is ill or under heavy medications may not be able to take the right decision or may not be able to choose from available options the option best suited for them. It may be noted that this capacity is relevant only to make decisions regarding the specific medical option available for them and not to make all decisions regarding healthcare. If a participant/patient has to make an autonomous decision or has to give informed consent for any research/medical practice that particular individual must possess decision making capacity. The concept of autonomy of the patient attains any value only when the concerned person is able to make relevant decisions. If this capacity to make a decision is lacking in a person, they may take decisions which may not act in their best interest and thus may lead to harm. Is this case, the person concerned should be protected from any such harm. If the participant/patient possesses decision-making capacity, then the choice the participant/patient selects must be respected by the researcher/clinician. If the participant/patient does not possess this capacity, then alternate

arrangements must be made, so that someone else can make the decision on behalf of the patient (http://ucsf.edu/lm/ethics/Content%20Pages/fast_fact_competence.htm)

The basic elements of capacity are the following:

1) Understanding: - understanding can be considered to be the most basic element of capacity. If a participant/patient has to consent to a given option or to refuse it, the subject got to have some basic understanding of the facts involved in that decision.
2) Appreciation :- once the basic facts are properly understood by the concerned person, the person should also have an appreciation of the nature and importance of the decision they made
3) Reasoning: - if a participant/patient does not possess the ability to reason the information given to them, it may be impossible to appreciate the issues that may arise in the decision they are going to make.
4) Choice: - in certain situations it may be noted that the concerned person possess the required understanding, appreciation and reasoning, but they may not be able to express or communicate what their decision is. They may not be able to make a choice. If a person is not able to communicate their choice, it may not be possible to know their intended decision.
5) Values:- in this context, values may be understood as 'good'. The concerned person should know what is good for them. In such a situation only the patient will be able to balance between the risks and benefits of the procedure.

(Singer A Peter and Viens A M, 19)

Legal Aspect

Decision-making capacity is an essential element of valid consent. Most jurisdictions view capacity from the initial point that all adults possess the capacity to make decision. The legal position gets complicated when it comes to children. In such a case when a child is involved, the approach may depend upon the jurisdiction. The law states that the threshold for

finding of capacity may vary. As put forward by a senior English Judge, ”the more serious the decision, the greater the capacity required” ((Singer A Peter and Viens A M, 18).

Policy

Capacity is one of the basic concepts of a valid consent. This gives the concept of capacity due consideration in policies regarding medical practices or experiments. The hospitals and other research institutions will have a policy of their own which will be in accordance with the national policy. Capacity and lack of capacity should be discussed in the documents of policy.

How should Capacity be approached in Practice?

In a normal clinical condition, capacity may not be considered as an important factor. But when consent is required from a person who may be impaired or when a patient refuses a treatment which the physician thinks is important and best suited for the patient, then capacity gets its due importance.

1.6.1. B Disclosure

Disclosure can be defined as the process during which the researcher/clinician provides the complete information about the research/treatment to the participant/patient. Disclosure forms an important element of informed consent. The patient has a right to the full information available about the proposed research/treatment and then to make a decision. It is the duty of the researcher/physician to let the participant/patient know about the research/clinical procedure and thereby help the participant/patient to decide the best suited option for them. The participant/patient must be informed about the procedure involved in its totality. The risks and benefits involved must also be conveyed. It is not just the conveyance of the complete information that is important in the process of disclosure, but also when and how the information is communicated is as equally important.

Through disclosure, the researcher/clinician can show their respect for the autonomy of the patient. Disclosure of all the necessary information to the participant/patient can be considered as a primary obligation of the researcher/clinician. If the researcher/clinician fails to provide the complete information regarding the procedure involved, then it may be claimed as negligence on the part of the researcher/clinician. Consistent disclosure of all the relevant information on the part of the researcher/clinician will help in building a continuous trust on the researcher/clinician by the participant/patient.

Information can be withheld from the patient in a few exceptional cases. They are:

- When there is an emergency situation
- When the patient/participant expresses his/her wish that he/she does not want to know the information offered
- In situations where the patient is incompetent

The General Medical Council states that:

"You should not withhold information necessary for decision-making unless you judge that disclosure of some relevant information would cause the patient serious harm. In this context serious harm does not mean the patient would become upset, or decide to refuse treatment" (Singer A Peter and Viens A M, 26)

Legal Aspect

Laws regarding disclosure as an important concern for informed consent are different in different jurisdiction. Laws pertaining to the legal right of the patient to know about their healthcare are the strongest in North America, than in any other part of the world (Singer A Peter and Viens A M, 19). But these laws are constantly changing and evolving. The recent trends in the ethical and legal side are leading to increased disclosure of the information as well as increased involvement of the participant/patient in healthcare practices.

Policy

A number of professional bodies give importance to the consent procedure which is focused on the patient. The General Medical Council, United Kingdom states that:

> *"doctor's must take appropriate steps to find out what patients want to know and ought to know about their condition and its treatment"* and that *"existing case law gives a guide to what can be considered minimum requirements of good practice in seeking informed consent from patients"* (Singer A Peter and Viens A M, 26)

How should Disclosure be approached in practice?

The ethical concept of disclosure will ensure that relevant and necessary information has been communicated to the participant/patient to make an informed choice regarding the research/medical practice. The following elements should be included while communicating the relevant information:

- All relevant information regarding the condition of the patient and the inherent risks if the patient remains untreated or if there is any delay in the treatment
- All available treatment options, including their risks and benefits and side effects (which may be reversible or irreversible) if any.
- Any information that the participant/patient specifically asks for
- The clinician's opinion regarding which option should be chosen keeping in mind the patient's values and expectations

For the process of disclosure to be effective, the communication process should be open. This process is not just a neutral communication of information, but rather a situation which is highly complex. A few points must be taken care of while communicating the relevant information. They are:

- Technical language and jargon must be avoided. There should be clarity
- A language which is in par with the participant's/patient's fluency must be used

- After the relevant information is provided, the participant's/patient's reaction must be observed
- Questions from the participant/patients should be encouraged
- The participant/patient should be given the space to share his/her fears and anxieties
- Empathy and compassion should be shown to the participant/patient
- The conveyed information should be again summarized

Disclosure should be considered as a process and not just an individual event.

1.6.1. C Voluntariness

Presented in the context of consent, voluntariness can be defined a participant's/ patient's right to make medical practice decisions and decision and decision about his/her personal information free of any undue influence (Singer A Peter and Viens A M, 31). The participant's/patient's freedom to decide about the medical practice can be infringed upon by internal factors as well as external factors. The participant's/patient's condition may decide the internal factors. External factors may include the ability of a third party to impose control over a participant/patient through means of force, coercion or manipulation. But the concept of voluntariness does not imply that the researcher/clinician should stop from persuading the concerned person to undergo the procedure. In this context persuasion refers appealing to the participant's/patient's reason and trying to help him/her to understand the benefits of the recommendation. Though a researcher/clinician can try persuading a participant/patient to undergo that particular recommendation based on evidences and judgements, the participant/patient has all the freedom to accept or reject the recommendation. But the clinician must be fully aware fully aware of the thin boundary between persuasion and coercion.

Voluntariness is considered to be an ethical requirement for consent to be valid. The concept of voluntariness implies freedom, independence and autonomy.

Legal Aspect

Voluntariness is considered to be a legal requirement for consent to be valid. In some jurisdictions, in some exceptional circumstances, treatment may be given against a patient's will. To substantiate, a person with a contagious disease may be provided treatment despite their refusal as it concerns public safety. Some jurisdictions also allow treatment of individuals without obtaining informed consent if it is impossible to get the informed consent. A topic which has become the centre of ethical and legal debates in the recent past is the procedures which involve minors. Such a position poses extra challenges with regard to the concept of voluntariness. In some cases, the parents of the minors may make the decision on behalf of their children. This may, in some very rare cases, not be in the best interest of the child. Cases have been reported where the parents refuse the necessary treatment for their children as the suggested treatment option may be against their religious beliefs.

Policy

As stated earlier, voluntariness is an important aspect of a valid informed consent. Obtaining informed consent is a policy of the general bodies regulating the clinicians. The General Medical Council of the United Kingdom has created some norms for voluntary decision making. To be given as an example, interaction with the patients regarding informed consent must give a balanced view of all the options available. If there is any conflict of interest, that should also be given clarification. The United Kingdom's Department of Health states that 'voluntary consent to treatment (or refusal of that treatment) requires an absence of pressure and undue influence on a patient and that pressure may come from clinicians, as well as from the patient's family members (Singer A Peter and Viens A M, 33) to avoid the situation the clinicians must make an arrangement to meet the patient in private so that they can make their own decisions regarding their healthcare.

How should voluntariness be approached in practice?

A participant's/patient's decision about a procedure is affected by both internal and external factors the internal factors arises from the medical condition of the participant/patient. The researcher's/clinician's duty is to lessen the potential effects of these factors to the best of their ability. The researcher/clinician, family and friends and the healthcare setting may form the external factors. Problems will arise when family or friends or any other third party exercise excessive control. In the very rare situations where the researcher/clinician has the freedom to use force, a technique which is considered to be the least restrictive should be adopted.

Measures should be adopted by the researcher/clinician to minimise the scope for manipulation. The main reason for this is that the participant/patient can be easily manipulated when they are receiving incomplete information. To avoid such a situation the researcher/clinician should make sure that all the relevant information has been communicated to the participant/patient. Manipulation can also happen when the information is communicated in a biased manner. To avoid this situation the researcher/clinician may ask the participant/patient to review the information given to them in their own words. If a participant/patient accepts the procedure after being fully aware of its inherent benefits and risks, it can be understood that the decision made by the participant/patient is not manipulated.

1.6.2 **Confidentiality**

When a person gives information to another in confidence there is an obligation on the person receiving the information not to disclose to someone else (Singer A Peter and Viens A M, 39). Confidentiality can be either explicit or implicit.

- Confidentiality can be explicit by the provider of information stating that the information must not be shared, or
- Implicit in the nature of the relationship between the provider and the receiver of information.

The concept of confidentiality gives the foundation of trust in the relationship between the researcher/clinician and participant/patient. Great importance is placed on confidentiality by the professional organizations and regulatory bodies. The breach of confidentiality on the part of the researcher/clinician may even lead to disciplinary actions. In some cases, confidentiality cannot be absolute and in those cases it may be legally permitted to breach confidentiality. When a participant/patient has a belief that the information communicated by him/her to the researcher/clinician will remain confidential, the participant/patient will be more open to the researcher/clinician. If they do not possess this confidence, then they may not communicate the important information.

If a researcher/clinician shares a participant's/patient's information to a third party without the participant's/patient's knowledge and consent, the respect for the participant's/patient's autonomy is in question. In a relationship between the researcher/clinician and the participant /patient there is an implied promise from the side of the researcher/clinician that the confidence will be respected. The breach of confidentiality is justified in some situations where there is a chance for serious harm to either the participant/patient or to another third party; "personal freedom may legitimately be constrained when the exercise of such freedom places others at risk" (Singer A Peter and Viens A M, 39). The General Medical Council of the United Kingdom states that

> "*disclosure of personal information about a patient without consent may be justified in the public interest if failure to disclose may expose others to a risk of death or serious harm. You should still seek the patient's consent to disclosure if practicable and consider any reasons given for refusal"* (Singer A Peter and Viens A M, 39).

Legal Aspect

The courts in the United Kingdom have stated that confidentiality should be maintained and if there is any breach of confidentiality in the greater interest of the general public, then both the aspects should be weighed properly. In certain jurisdictions, it is required by the legislation that the physicians should maintain and respect the patient's confidentiality. The jurisdiction in most of the countries defines the legal requirements that is needed for the disclosure of the information regarding the participant/patient.

Policy

The Hippocratic Oath explicitly demands confidentiality in physicians' dealings with patients.

> *"what I may see or hear in the course of the treatment in regard to the life of men, which on no account one must spread abroad, I will keep to myself, holding such things shameless to be spoken about"* (Singer A Peter and Viens A M, 40).

No exception of confidentiality is allowed by the World Medical Association. All the professional bodies states the importance of why further consent should be obtained from the participant/patient before sharing the information of the participant/patient to a third party.

How should Confidentiality be approached in practice?

The participant's/patient's confidence must be respected by the researcher/clinician. If any information of a participant/patient is to be communicated to a third party, then consent should be obtained from the participant/patient before doing so. If the patient is incompetent, then the consent of the patient's representative must be sought. If a situation arises where there is serious harm to a third person(s), there the duty to protect or warn will nullify the duty of confidentiality.

1.7 Present Study

The word autism refers to a distinctive developmental disorder. In the passage of time the word was used in a large number of contexts and as a result of this autism is interpreted in a number of ways. Large numbers of children have been diagnosed with autism in the recent past and a number of therapies are also used for the treatment of autism and the first step in any treatment is to make an assessment about the disease. There are a number of tools for the assessment of autism. But whether the usage of these tools follows the ethical codes is a question to be asked.

1.7.1 Autism

Autism Spectrum Disorder (ASD). The terms Autism and ASD can be used interchangeably. Any developmental disability which is caused by any abnormality in brain comes under ASD. If a person has ASD then he will have difficulty with social skills and communication skills. Such a person will always prefer to stick on to a particular set of behaviours and will resist any change to his/her daily activities, the change be major or minor. The friends and relatives of people with ASD has stated that if the person with ASD is told in advance about the change and he has amble time to prepare for it, the resistance to that particular change will be either completely gone or the level of resistance will be very low.

Autism is always considered to be a complex developmental disability. It is believed that autism presents itself during the initial three years of a person's life. This condition is believed to be the result off a neurological disorder they can have an effect on the normal functioning of the brain. The development of the communication skills and social skill and interactive skills will be affected. Non -verbal communication, social interactions and activities with element of play are also affected. The behaviour of a ASD affected individual with another individual will be very different from how the rest of the people may behave. If the severity of the symptom is less, the person with ASD may sometimes be offensive in his/her behaviour, may seen awkward in the social behaviour and may be out of synchronisation with everything else. If the severity of the symptom is high, the ASD affected person may seen the least interested in other people. It is noted by the friends, relatives and other people who interact the ASD affected individual that they make very little eye contact. However, eye contact among people with autism can be improved too a greater level if the symptoms of autism is detected at an earlier stage and timely intervention is provided.

An ASD affected person will often miss clues that individual give each other when somebody's attention is to be attracted. A person affected with ASD might not even understand that somebody wants to talk to them. Such a person may show extreme interest to talk to a particular person or to a group , but may not possess the same skills as others in the group to become completely involved. To be more precise they lack the playing and talking skills.

1.7.2 Causes

Abnormal chemistry and biology in the brain are the factors that are linked to the physical condition of autism. The root causes of these abnormalities still remain unknown, and this very fact has been the causes of autism a very vibrant area of research. A combination of factors is considered to lead to autism. One important factor is genetics. To substantiate the chances for identical twins to be autistic are much more than the chances for fraternal twins or siblings to be autistic. Likewise language abnormalities are more commonly seen in relatives of children who are affected with autism. Other neurological problems and abnormalities in the chromosomes are more commonly seen in families with autism. A lot of other possible causes have been speculated, but not proven. They are :

- Diet
- Poisoning through mercury
- The improper use of vitamins and minerals by the body
- Changes in the digestive tract
- Sensitivity to vaccines

1.7.3 Symptoms

When a child is eighteen months old and if the child is autistic the parents may feel that something is wrong and they may seek the help of a clinician by the time the child is two years of age. The areas in which an autistic child will have difficulties is :

- Communication, both verbal and non-verbal
- Pretend play
- Social interaction

Some autistic children may appear to be normal before they are one year or two year and in suddenly they may regress and loose all the language skills and social skills which they gained during the initial years of their life this is known as the regressive type of autism.

Other symptoms which the people with autism exhibits include :

- Repetition of the body movements
- Overt attachments to objects
- Severe resistance when there is a change in the routine
- Highly sensitive in touch, smell, taste, sight and hearing.

The other symptoms may vary from sever to moderate. The problems faced by an autistic child in each of the developmental phase is given bellow

Problems in communication:

- Difficulty in starting or maintaining a social conversation
- Problems in communication with gestures instead of words
- Language is developed slowly or no development at all
- Will have problem in focusing at objects that others are focusing at
- Repetition of words or passages
- Usage of nonsense rhyming
- Reference to self will not happen (the child might say 'you want water' instead of 'I want water')

Problems in social interaction:

- Cannot make friends
- Problems involving in interactive games
- May appear to be socially withdrawn
- Problem in making eye contact and very little or no response to eye contact and smiles
- Other individuals are treated as objects

- Will not be able to show empathy
- May spent time alone rather than with others

Play:

- Not able to perform prudently or imaginative play
- Won't be able to imitate the action of others
- Prefers games that can be played alone

Behaviour:

- May throw severe tantrums
- Will have very little attention span
- Will show very narrow interest
- May be either overactive or passive
- May show self aggression or aggression to others
- Body movements will be repeated
- Shows a strong inclination for sameness or routine
- May keep on doing a single task for a long time.

1.7.4 Test and Exams

All children should undergo routine exams and test to check their development by a recognised paediatrician. If the doctor or the parents feels that there is some developmental problem then further testing should b e done. The test should be done if a child does not attain any of the given language milestones

- Babbling by the age of one year
- Gesturing by the age of one year

- Uttering single words by sixteen months
- Uttering toward phrases by the age of two years
- Loss of any language or social skill at any stage.

If any of the problems is seen in a child then assessment procedures for autism should be done.

1.7.5 Treatment

A timely and appropriate intervention program will create a difference in children with autism. A treatment can be the most successful when it focuses on the child's particular need. Most intervention programs will be built on the child's interests. Visual aids are also proved to be helpful. A verity of therapies is available. Some of them are mentioned bellow.

- Applied Behaviour Analysis
- Physical therapy
- Speech language therapy
- Music therapy
- Medications.

Medication is used to cure the behavioural problems of autistic people. These behavioural or emotional problems may include:

- Anxiety
- Aggression
- Attention seeking problem
- Mood swings
- Difficulty in sleeping
- Tantrums

Other approaches:

There are a number of treatments for autism that is not proved scientifically. Various reports on 'miracle cures' have also come out. These treatment options and reports are not to be believed. If a child is autistic then the parents are advised that they communicate with parents of other autistic children and people working as interventionists of autism (http://www.nlm.nih.gov/medlineplus/ency/article/001526.htm)

1.8 Review of Literature

Not much of work is carried out in the area of assessment procedures for autism. However a number of works on the current knowledge about autism has been undertaken in the past few years. One of the works which deals with the assessment procedures for autism are the National Initiative for Autism: Screening and Assessment. This work provides information about autism and about the various approaches towards autisms and it also evaluates the efficiency of approaches towards teaching children with autism. A research team at the National Centre of Autism Studies provided evidence on the effectiveness of the intervention programmes and assessment procedures. The evidence on the effectiveness of the intervention programmes and assessment procedures was based on the concepts of understanding and social interaction, group play and behaviour approaches.

All the important works that have come up about autism specifies the need for early intervention and this intervention should be carried out in a consistent manner. Most of the works claims that the intervention should be carried out in an informed way. The longer the time gap between the identification of the disorder and the intervention the more expensive and ineffective will be the intervention. If the parents have any concern about the development of their child at any stage, then the child should be taken for proper check up.

Most of the works on autism claims that if timely assessment and intervention is given to a child, then it can lead to great improvement in the behavior of the child. But to what extent can these assessment procedures and intervention programs can be successful is a fact that remains unknown. It is a widely noted fact that any assessment procedure or intervention program that involves social understanding can be more successful than any other assessment or intervention program.

Most of the works on autism deals the basic understanding of that disorder. An introduction to the developmental disorder called autism, its causes and symptoms, assessment procedures that can be used for autism, intervention programs that exist for treating autism and how the person should be accepted in the society forms the basic concept in the majority of works on autism.

The book written by Deborah Barnbaum, 'The Ethics of Autism, Among them but not of them' provides a great insight into the real life situation of the autistic patient's. The author herself was an autistic patient. She with the help of proper and timely intervention programs coped up with her situation. She has written about how the autistic patients sees and feels the things around them and how that thinking and cognitive procedure is normal for them. This book has been a major benchmark and it stands to be different from all other works on autism because of the fact that the author has a thorough understanding about how the autistic patients feel as she herself has undergone that phase.

Quite a number of works has been come out regarding ethics and its different aspects. The major work among all those books is 'The Cambridge Textbook of Bioethics'. The Cambridge Textbook of Bioethics gives a very detailed account on bioethics, the history of bioethics, different concept of bioethics. Each of the above mentioned aspects is discussed in detail in each chapter of the book. But an aspect that has not been dealt with the book is that how does some of the aspects of bioethics gives negative effects. For example, there was a news sometime back in the United States. The news reported that a mother of an autistic child did not want the concept of disclosure to be practiced. The reason she gave for not wanting to know about the details of the disorder and her child's condition was that is she knows that her child's condition in problem then that information can cause serious mental breakdowns. She was not able to cope-up with the situation when the information regarding her child was conveyed to her.

The above mentioned book discusses such situations, but what ought to be done in such a situation that can prevent mental breakdowns on the side of the parents is not discussed in the book.

Works that deal with both the assessment procedure and the ethical concepts involved in those assessment procedures in not available till date.

1.9 Scope and objective

The main objective of the study is to find out the ethical issues involved in the assessment procedures for autism. When a pilot study was done to study the same, it was found out that the information regarding the assessment procedures used was not communicated to the parent/guardian of the patient. This is a violation of the principle of disclosure, which forms a key concept of ethics in medical practices and research. It was also observed that informed consent in writing was not obtained from the parent/guardian of the patient. Another observation that was made was that the patient information was communicated to a third party without obtaining further consent from the patient. In two institutions the patient was let to know that the basic information regarding them was communicated to a third party and the consent of the patient was obtained orally. As informed consent and disclosure form two important aspects of ethics, this can be considered to be a violation of the principles of ethics and this formed the basis for the research hypotheses.

Research hypotheses are -:

1) The consenting process is not done in a proper manner

2) Proper disclosure of all the information regarding the assessment procedures used are not conveyed to the patient or to the guardian. The inherent risks or alternatives to the proposed assessment procedures are not completely disclosed. Disclosure if practiced, depends on the capacity of the parent/guardian

3) The patient information is shared to a third party without taking further consent from the patient, thus violating the principle of confidentiality

4) The patient is not given the freedom to practice voluntariness

1.10 Background and Justification

Background & Justification – a lot of study has been done regarding the assessment procedures for autism. Aspies for Freedom (AFF is a solidarity and campaign group which aims at raising awareness of the autism rights movement) claims that the most common therapies for autism are unethical. But no study has been conducted to understand the ethical issues involved in these assessment procedures. This study aims to do that.

[i] The Nuremberg Trial Code – a series of military tribunals conducted in the cities of Nuremberg, Bravia and Germany in the time period of 1945-46, post world war 11. These trials exposed the German scientists who used human subjects in experiments which often turned out to be ghastly.

[ii] The Tuskegee Syphilis Study – this study was conducted in Alabama in the US during the mid 1930-1970's to know the advancement of syphilis patients. This was done by withholding all treatment to syphilis patients. The subjects here were rural black men.

[iii] Code of Hammurabi – is a Babylonian law code and one of the oldest decrypted writings of significant length, which dates back to about 1772BC. The code was ordained by Hammurabi, the sixth Babylonian king. The code is comprised of 282 laws.

[iv] The Hippocratic Oath – taken by physicians and other healthcare professionals affirming to practice medicine ethically. Hippocratus, the father of modern medicine, is believed to have written this code.

[v] The Universal Declaration of Human Rights – the Universal Declaration of Human Rights was put forward by the United Nations General Assembly in 1948. This was a direct outcome of the experiences of the Second World War. This is the first international expression of the rights of human beings.

[vi] Right to life – right to life upholds the belief that a human being has a right to live and especially the right to not to be killed by another human being.

[vii] 93rd United States Congress – the 93rd United States Congress was a meeting of the legislature of the federal government of the United States comprising both of the United States Senate and the United States House of Representative.

[viii] 93rd United States Congress – the 93rd United States Congress was a meeting of the legislature of the federal government of the United States comprising both of the United States Senate and the United States House of Representative.

[ix] Charaka Samhita – a textbook of medicine dating back to 200 BC

[x] Sushruta Samhita – a textbook of surgery dating back to 200 AD

CHAPTER 2

Methodology

2.1 Brief account of the classification of different types of Research

The two syllables ‘re’ and ‘search’ constitute the word research. The prefix ‘re’ implies again or anew and the word search means to seek or inquire into. These two syllables together form a noun which implies a systematic investigation in any field of knowledge to establish certain facts. A research should be a structured enquiry which uses a set of established methodology.

Research can be classified from three different perspectives

2.1.1 Application of research study

2.1.2 Objectives which lead to the research

2.1.3 Mode of inquiry employed

On the basis of the application of the research study a research can be either a:-

2.1.1. a. Pure research – here theories and hypothesis are developed. These theories or hypothesis will be reflectively challenging to the researcher but it may not possess any application in the near future or even in the present scenario.

2.1.1. b. Applied research – an applied research is where the research is undertaken to find answers to some specific questions. This kind of research will usually be of the exploratory kind.

Based on this division the study that is undertaken here falls into the category of applied research. The aim of this study is to find out the ethical issues involved in the assessment procedures for autism.

The objectives that lead to the undertaking of the research gives rise to four types of research.

2.1.2.a. Descriptive research - in a descriptive kind of research a situation or a problem is described in an organized manner. It may also include the description of attitude towards an issue.

2.1.2.b.Correlational research – a co relational research attempts to establish the interdependence between various aspects of a phenomenon.

2.1.2.c. Explanatory research - this kind of research tries to explain how and why there exist a relationship between two or more aspects of a phenomenon.

2.1.2.d. Exploratory research – as the term signifies, an exploratory research explores a field about which very little is known. It also explores the possibilities of undertaking a particular research study.

A research undertaken need not necessarily fall into one particular division. Certain studies will turn out to be a combination of two or more kind of study as is the case with this particular study. Here, this study can be a combination of both descriptive research and exploratory research. This study is considered to be descriptive as it tries to describe the ethical problems involved while making assessment about autism. The study tries to make an exploration into the lesser known areas regarding the ethical issues involved in the assessment procedures for autism.

The mode of enquiry employed can differentiate a research from qualitative approach and quantitative approach.

2.1.3.a. Structured approach – a structured approach is often classified as a quantitative research. Everything that forms the research process is decided beforehand. The samples and the questions are also pre-determined.

2.1.3.b. Unstructured approach – this is qualitative research. This kind of research allows more flexibility in all the aspects than in quantitative research.

Under this classification the study undertaken is qualitative and unstructured.

2.2 Scope and Objective

The main objective of the study is to find out the ethical issues involved in the assessment procedures for autism. When a pilot study was done to study the same, it was found out that the information regarding the assessment procedures used was not communicated to the parent/guardian of the patient. This is a violation of the principle of disclosure, which forms a key concept of ethics in medical practices and research. It was also observed that informed consent in writing was not obtained from the parent/guardian of the patient. As informed consent and disclosure form two important aspects of ethics, this can be considered to be a violation of the principles of ethics and this formed the basis for the research hypotheses.

Research hypotheses are -:

1) The consenting process is not done in a proper manner

2) Proper disclosure of all the information regarding the assessment procedures used are not conveyed to the patient or to the guardian. The inherent risks or alternatives to the proposed assessment procedures are not completely disclosed. Disclosure if practiced, depends on the capacity of the parent/guardian

3) The patient information is shared to a third party without taking further consent from the patient, thus violating the principle of confidentiality

4) The patient is not given the freedom to practice voluntariness

2.3 Methodology Undertaken for the study

As a first step, the tests used for the assessment of autism were taken into note and those tests were studied in detail to understand what the shortcomings in those tests were. The tests studied were:

- Childhood Autism Rating Scale (CARS)

- Autism Diagnostic Interview – Revised (ADI-R)
- Autism Behaviour Checklist (ABC)
- Checklist for Autism in Toddlers (CHAT)
- Pre-linguistic Autism Diagnostic Observation Schedule (PL-ADOS)

2.3.1 Childhood Autism Rating Scale

The usage of Childhood Autism Rating Scale (CARS) helps to identify the presence of autism in children. The Treatment and Education of Autistic and Communication Handicapped Children (TEACCH)[i] program staff developed CARS. CARS is a behaviour rating scale. Here fifteen domains related to behaviour are rated. The rating is done on a scale from one to four (1-4). The fifteen domains are :-

a) Relating to people
b) Imitative behaviour
c) Emotional response
d) Body use
e) Object use
f) Adaptation to change
g) Visual response
h) Listening response
i) Fear and anxiety (nervousness)
j) Verbal communication
k) Non-verbal communication
l) Perceptive response (taste-smell-touch response and use)
m) Activity level
n) Level and consistency of intellective relations

o) General impressions

The above mentioned fifteen domains is rated using a scale of 1-4. 1 signifies that the child's behaviour is normal for the child's age. 2 signify mild abnormalities. 3 is given to children exhibiting moderate abnormalities and 4 signifies severe abnormality. The total score obtained from all the fifteen domains generally helps in assessing a child as either non-autistic, or mild-moderately autistic or severely autistic.

2.3.2 Autism Diagnostic Interview – Revised (ADI-R)

The Autism Diagnostic Interview – Revised is a semi-structured interview. It is a revision of the Autism Diagnostic Interview (ADI)[ii]. The ADI-R is to be used with the child's parents or principle caregiver. This is more precise and appropriate to be used with children than the ADI. The ADI-R can be used with small children with a biological age of 2 years and a mental age of eighteen months. The ADI and ADI-R concentrates primarily on three areas and try to get the required information from the parents or caregivers about these three areas. They include:-

a) Communication and language

b) Reciprocal social interaction

c) Repetitive and stereotyped behaviour

The ADI-R is considered to be one of the better standardized instruments which are available now for diagnosing Autism.

2.3.3 Autism Behaviour Checklist (ABC)

The ABC was published in 1980. It forms the part of a bigger tool which is known as the Autism Screening Instrument for Educational Planning (ASIEP)[iii]. The Autism Behaviour Checklist is considered to be a general measure for autism. It is considered not to be as reliable as ADI-R and CARS. The CARS could identify 98% of the autistic subjects as autistic and 69% of the possibly autistic was identified as autistic where as the ABC could identify 88% of the subjects as autistic, while 48% of the possibly autistic was identified as autistic. The ABC is constituted by a 57 item questionnaire which is to be completed by the parent or the care-giver. The ABC is divided into five (5) sub-divisions. They are:-

a) Sensory behaviour

b) Body and object use

c) Language and communicating skills

d) Social relating

e) Social and adaptive skills

The ABC has a lot of drawbacks. In two separate studies, it failed to reveal a common set of characteristics of high functioning autistics disorder individuals. ABC also proved to be the least useful in identifying children under the biological age of three (3). ABC is primarily useful to be used with school population children. When used along with other assessment tools and screening instruments, ABC may show some usefulness as a symptom inventory which is to be completed by parents or caregivers and this can be used by the clinicians to structure their evaluation.

2.3.4 Checklist for Autism in Toddlers (CHAT)

This is a screening instrument that aims to identify possible autism in toddlers. CHAT was published in 1992. It is the least time consuming screening tool as it takes only five-ten (5-10) minutes to administer and score. CHAT is designed in such a way that it can be used with kids as young as eighteen (18) months of age. This consists of nine (9) yes or no questions which is to be answered by the child's parents. The questions involve the following areas:-

- Specific behaviour
- Social play
- Social interest in other children
- Joint attention
- Pretend play
- Pointing to how interest in something
- Pointing to ask for something
- Motor development

- Function play
- Rough and tumble play

The CHAT also provides an opportunity for the examiner to have five (5) brief interactions with the kid to verify whether the child's actual behaviour is in accordance with the parent's reports. It is always advisable to diagnose Autism as early as possible. CHAT can be used as a first level platform to screen children under the biological age of eighteen – thirty six (18-36) months at which level there can be any possible concern of Autism. If the screening hints possible autism further assessment will be prescribed to diagnose autism. If there is a possibility for autism it is the best to continue the screening at different levels as all children with autism cannot be identified early because the onset and severity of symptoms will vary in each and every child.

2.3.5 Pre – linguistic Autism Diagnostic Observation Schedule (PL-ADOS)

This is a semi-structured observation scale. This is used to diagnose children who have not yet started using phrase speech and hence is suspected of having Autism. This is administered with the help of the child's parent. This instrument consists of eight (8) tasks out of which four gives importance to social behaviour and the other four focuses on communicative behaviour. It takes less than 30 minutes to administer this.

Some assessment procedures involve structured observation. Here the examiner observes the child playing by himself/herself or with someone else. In certain other cases the examiner plays with the child to get an understanding of specific skills. A single assessment tool may not be sufficient to make a proper assessment.

After a review of these tests, three hospitals in Kerala was visited to study whether the key concepts of ethics were being maintained or not, while conducting the assessment procedures. The following aspects of ethics were given special attention.

- Consent – whether a signed consent form is obtained from the patient or guardian of the patient.

- Disclosure and capacity– whether all the details of the assessment tool have been explained to the patient or guardian of the patient. Without accurate information, they are less able to give all the information needed for the accurate assessment.

- Confidentiality – information disclosed to a health professional should remain confidential. If the information is to be shared with someone else then the clinician should get consent from the patient before doing so. An attempt was also made to understand whether a further consent is obtained from the patient or the parent/guardian of the patient before sharing the information about them to a third person.

- Voluntariness – whether the patient was forced to answer any question. If a response is forced out of a patient, then it may lead to a negative result or inaccurate assessment.

These aspects were studied through the process of naturalistic observation. A total of twenty-five subjects were studied. Ten patients from one clinic, eight from another clinic and seven from the other clinic were involved in the study. Observation was made when a child was brought to the clinic and assessment for autism was done. The patient was observed in its natural environment. There was little intervention or manipulation from the side of the researcher. The environment was neither manipulated nor created by the researcher. In this method there was no pressure on the respondent as he/she is not directly asked for the response. Also personal interview with people working as clinical psychologist and interventionist for autism was also done because the information thus received from that person facilitated a more strong insight into the reality of the situation.

The following table was used to record the observations. The code assigned for each patient was noted along the vertical line. Along the horizontal line, the key concepts of ethics

were written. Notes were made against each subject's name while they were undergoing the assessment procedure as to whether the concepts of ethics were maintained or not.

Patient name/code	Informed consent	Disclosure	Confidentiality	Voluntariness

Additional notes were made during the observation to know to what level are the information regarding the assessment procedure were conveyed to the parent/guardian of the patient. Also it was noted that what information about the patient was communicated to a third party with or without the consent of the patient.

The study undertaken was a cross sectional one as children of different age groups were observed.

A more detailed review of the earlier mentioned assessment tools is discussed in the next chapter. The information gathered during the visits to the clinics about whether the ethical norms were maintained is also discussed in the following chapter.

[i] TEACHC – (Treatment and Education of Autistic and Communication Handicapped Children) is an intervention. This was developed at University of North Carolina. TEACHC provides services and training to help the autistic children and their families to cope up with their situation.

[ii] ADI – Autism Diagnostic Interview – published in 1989, ADI was primarily aimed for research purposes, providing behavioural assessment for children with a biological age of five and a mental age of 2.

[iii] ASIEP – The ASIEP is a very reliable and valid instrument to diagnose Autism and related behaviors. This was developed to identify individuals with autism and to help in developing and planning appropriate educational programs for them. Five main standardized components are used to collect data for this. They are autism behavior checklist, sample of vocal behavior, interaction assessment, education assessment and prognosis of learning rate.

CHAPTER 3

Assessment Procedures for Autism and Ethical Considerations

A topic which has gained significant interest of the research community, especially in the recent years, is the development of different standardized tests for the assessment of autism. In the recent past there has been an exponential growth in the reference standard for derivative assessment. Special vehemence has been placed on defining and better delimiting the symptoms of the disorder in relation to other forms of Autism Spectrum Disorder (ASD) and other intellectual disability (ID) and also to identify the condition at the possible earliest age. This has also been at the centre of argument, debate and research ever since it was first described by Kanner. Kanner, in one of his early papers states that, the main referral was because of the fact that children were assumed to be 'severely feeble minded' (Kanner, 1944). Since that time, a considerable amount of research was done. In the present scenario, autistic children are not considered to be intellectually disabled (http://ees.elsevier.com/RASD/default.asp)

3.1 Criterions to value the assessment procedures

The general criteria for assessing autism can be divided into several categories. Some questions to be asked regarding the value of the assessment procedures are the following:

1) Is the assessment procedure reliable?

2) Is the assessment procedure valid?

3) Are the parents and clinicians willing to use the assessment procedure?

4) Is the assessment tool sufficient to be done on children as young as possible?

The first question to be asked is regarding the reliability of the test; whether the results given by the assessment tool is correct and accurate. For this, test-retest reliability check can be undertaken. This is a procedure where the same assessment tool is administered two times with a time gap of two-three weeks. Within this period, the subject/patient will not

remember the answers given by him the previous time. This time period is short enough that the symptoms or behavioural patterns will not change. This will help to check the reliability of the assessment tool. Some assessment tools may yield false answers as well. So the reliability of the assessment tool is a question of great importance.

The second question regarding the value of the assessment tool is concerning the validity of the tool and validity may not be of one type. Validity must be checked to know whether the assessment tool is assessing autism based on a hasty review of items. If it is so, then the assessment tool must not be accepted. Validity can be also checked with reference to the differential assessment of the disorder, ie. whether the assessment tool can make proper differentiation between symptoms of autism and other childhood disabilities. Whether an assessment tool is able to identify correctly those children having autism at a very initial and early stage is also important in terms of validity.

The third question is a very matter-of-fact one. Will the assessment tool be accepted by the parents and clinicians? A lot of questions should be answered for taking such a decision. Some example of such questions can be

- Whether the directions and questions in the assessment tool are clear and simple?
- Whether the details of the assessment tool can be conveyed to the parents in a short period of time, such as fifteen-thirty minutes or even less than that?
- Whether the assessment tool is interfering in an offensive manner?
- Whether special space is needed to carry out the assessment procedure?
- Whether the assessment is done easily and rapidly?

The above mentioned five questions can be used to check the reliability and validity of the test as well.

Another question that is of great importance to value the assessment procedure is its ability to conduct assessment on children of a very young age. Until some years before, a general notion that existed among clinicians and researchers was that the clinical pattern of the different symptoms of autism could not be sufficiently recognized until an age of six-ten

years, and this makes a valid and reliable assessment a difficult job (Gillberg, Nordin and Ehlers, 1996). There was also a false notion that no assessment tool was sufficient enough to assess the condition of autism in children as young as six-twelve months of age. It was not long before that clinicians and researchers have debated that assessment can be done in younger and younger children. A reason for this rush was the generally approved fact that the earlier the intervention, greater will be the benefits in later periods like childhood, adolescence and adulthood.

3.2 Developmental History in Assessment Procedures

Autism is defined as a developmental pervasive disorder (Diagnostic and Statistical Manual of Mental Disorders, 4th Edition). If an assessment is to be sufficiently accurate and reliable, then a complete developmental history of the patient/subject is to be included in the assessment procedure. The best advised method to get information on the developmental history is through the parents of the child or care-givers. This can be done through the means of in-person or direct interview. The following points will help the clinician to understand the developmental history of a child/patient, so inclusion of these points in the assessment procedures will make the assessment procedure more accurate and reliable. The points that will help in the gaining information on the developmental history of a child are the following:

- Birth history
- Family history, both immediate and extended
- Developmental disorder
- Genetic disorder
- Medical Disorder
- Medical history
- Medical conditions
- Behavioural disorder
- Emotional disorder

- Learning disorder
- Medication
- Hospitalization
- Problems in vision
- Problems in hearing
- Sensory differences
- Language disorders
- Communication disorders
- Milestones in development
- Interruption in development
- History of premature stoppage in development
- Social aspects
- Problems in motor functioning
- Other diagnosis
- Earlier assessment

All the assessment tools and procedures have included one or the other above mentioned aspects.

3.3 Assessment Procedures for Autism

The development of assessment procedures has gained the attention of clinicians and researchers in the recent past. A major challenge in this area was the development of assessment procedures that can be used in young children as young as twelve months of age. The following are some of the assessment tools used by clinicians and interventionists to assess children with autism. Some of the assessment procedures may involve structured observation, where the clinician or the investigator observes the child play by himself/herself or with another person. In some other cases the clinician or the investigator plays with the child to get an awareness of any specific skill. It is important that a clinician or interventionist using the assessment tools should be experienced in carrying out the assessment procedure and should undergo sufficient training in administering and understanding the assessment tool. A reliable and accurate assessment may not be possible by using one single assessment tool. The following are some of the tests used by the clinicians or interventionists for the assessment of autism.

- Childhood Autism Rating Scale (CARS)
- Autism Diagnostic Interview – Revised (ADI-R)
- Autism Behaviour Checklist (ABC)
- Checklist for Autism in Toddlers (CHAT)
- Pre-linguistic Autism Diagnostic Observation Schedule (PL-ADOS)

A more detailed discussion of these tests is given below.

3.3.1 Childhood Autism Rating Scale (CARS)

The usage of Childhood Autism Rating Scale (CARS) helps to identify the presence of autism in children. The Treatment and Education of Autistic and Communication Handicapped Children (TEACCH) program staff developed CARS. CARS is a behaviour rating scale. Here fifteen domains related to behaviour are rated. The rating is done on a scale from one to four (1-4). The fifteen domains are:-

a) Relating to people

b) Imitative behaviour

c) Emotional response

d) Body use

e) Object use

f) Adaptation to change

g) Visual response

h) Listening response

i) Fear and anxiety (nervousness)

j) Verbal communication

k) Non-verbal communication

l) Perceptive response (taste-smell-touch response and use)

m) Activity level

n) Level and consistency of intellective relations

o) General impressions

The above mentioned fifteen domains is rated using a scale of 1-4. 1 signifies that the child's behaviour is normal for the child's age. 2 signify mild abnormalities. 3 is given to children exhibiting moderate abnormalities and 4 signifies severe abnormality. The total score obtained from all the fifteen domains generally helps in assessing a child as either non-autistic, or mild-moderately autistic or severely autistic.

Among the assessment instruments used today, CARS tends to own an approved combination of virtual, practicality and research support, though very little research is carried out about the use of CARS in children less than three years old. The use of an assessment tool that has some practicality, research support and does rating based on the severity of the symptoms gives way for the collection of information that is consistent.

The CARS has proved useful in the assessment of children with possible autism in a number of situations like initial stage intervention programs, developmental programs before school and diagnostic centres as it gives rating based on the severity of the symptom. Because of this reason CARS has proved helpful for continuous evaluation and monitoring of those children assessed with autism and also for understanding the long-term consequences.

Advantages of CARS

- CARS provides a format that is structured and this helps in proper collection and recording of information
- CARS can be used in children as young as two years of age, though the amount of data that can validate its usefulness in so young children is limited.
- CARS adds on to the evaluation process's consistency, objectivity and standardization to some extent
- CARS helps to identify the severity of the symptoms
- The administration and understanding of CARS can be done easily as training materials are available.

Disadvantages of CARS

- CARS may lead to false positive and negative results
- Assessment of autistic children with mild symptoms may not be possible
- Severity of the symptoms may not be identified if CARS is not used by individuals who are trained to do rating based on CARS.
- CARS may identify children as autistic when in actual case the child may be having severe levels of mental retardation
- The present situation with respect to the social development and cognitive development of the child may not be fully understood.

3.3.2 The Autism Diagnostic Interview – Revised (ADI-R)

The Autism Diagnostic Interview – Revised is a semi-structured interview. It is more of a semi-structured parent interview. It is a revision of the Autism Diagnostic Interview (ADI). It is a newer and shorter version than the ADI. The ADI-R is to be used with the child's parents or principle caregiver. This is more precise and appropriate to be used with children than the ADI. The ADI-R can be used with small children with a biological age of 2 years and a mental age of eighteen months. The ADI and ADI-R concentrates primarily on three areas and try to get the required information from the parents or caregivers about these three areas. They include:-

a) Communication and language

b) Reciprocal social interaction

c) Repetitive and stereotyped behaviour

The ADI-R is considered to be one of the better standardized instruments which are available now for diagnosing Autism. It considers all domains of autism. Both the ADI and ADI-R is designed in such a way that it is advised to be used by trained professionals after wide training. To be used with younger children, the ADI-R is considered to be more suitable than the ADI. The clinicians may prefer to use ADI-R because of this reason. However, proof on the efficiency of the ADI is important as it can work as a supporting factor to understand the usefulness of both the ADI and ADI-R.

ADI-R is more specific. But the ADI-R takes more time and more wide training for conducting the assessment procedure and because of this factor it can prove more useful for performing an in-depth assessment of children for whom other tests or factors implied a high chance of being diagnosed with autism.

Advantages of ADI-R

- ADI-R helps in gathering all types of developmental or historical information. The gathered information is properly organized and interpreted for assessment
- As in CARS, ADI-R also adds on to the evaluation process's consistency, objectivity and standardization to some extent.
- ADI-R helps the parents to have a better understanding of the aspects that are taken into consideration for the evaluation so that an accurate diagnosis can be made
- ADI-R has a standard scoring pattern
- ADI-R has a more current knowledge of autism than the ADI
- ADI-R can produce high level of specificity is performed by a well trained individual
- ADI-R focuses on children in the age group of three-five years and is suited for children in the age of two years as well
- Children with mental age of eighteen months can also be assessed using ADI-R

Disadvantages of ADI-R

- As is with the case of CARS, the ADI-R also can produce false negative and positive results
- Extensive and expensive training is required to use ADI-R
- Till date, the ADI-R is used with children in the age group of three years. For children below this age group, other assessment procedures are used
- The ADI-R is time consuming for the clinicians as well as the parents. For the interview alone it may take more than one hour. Additional time will be required for calculating and interpreting the scores.

3.3.3 Autism Behaviour Checklist (ABC)

The ABC was published in 1980. It forms the part of a bigger tool which is known as the Autism Screening Instrument for Educational Planning (ASIEP). The Autism Behaviour Checklist is considered to be a general measure for autism. It is considered not to be as reliable as ADI-R and CARS. The CARS could identify 98% of the autistic subjects as autistic and 69% of the possibly autistic was identified as autistic where as the ABC could identify 88% of the subjects as autistic, while 48% of the possibly autistic was identified as autistic. The ABC is constituted by a 57 item questionnaire which is to be completed by the parent or the care-giver. The ABC is divided into five (5) sub-divisions. They are:-

a) Sensory behaviour

b) Body and object use

c) Language and communicating skills

d) Social relating

e) Social and adaptive skills

The ABC, like the other two assessment tools, is an objective standardized tool. But its established specificity was very low in comparison with the other assessment tools while assessing children with autism. Moreover, the questions in the ABC proved to be more appropriate to be used with children above the age of three years. Thus, when compared to other assessment procedures, ABC is less effective in the assessment of young children with autism.

The ABC has a lot of other drawbacks as well. When two studies were undertaken, the common characteristics of high functioning autistic individuals were not identified by the ABC. ABC is best advised to be used with school going children. When ABC was used along with other assessment and screening tools, it demonstrated to be highly useful in identifying the symptoms in which the parents played a pivotal role. This was also helpful for the clinician for a structured evaluation.

Advantages of ABC

- As is the case with the other two assessment tools, ABC also brings in some degree of consistency and objectivity which is helpful in making a decision
- The questions in the tool are framed in such a way that, any person with quite some familiarity with the child, may be a parent or even a teacher or a care-giver, can answer the questions.
- It is not necessary that the assessment procedure should take place in the presence of a trained individual. The test can even be mailed to the parents and completed from home
- ABC is very user friendly
- ABC follows a very organized and structured format for collecting and recording the information.

Disadvantages of ABC

- ABC has proved to be useful only with children above the age group of three years
- The severity of the symptom of autism in the child may not be accurately measured
- ABC might not give accurate results after the assessment procedure also. As per the statistics, ABC fails to recognize the presence of autism in 40% - 60% children
- The tool does not contain questions that will demonstrate the strong side and weak skills of a child.
- ABC also fails to give information about the social development and cognitive development in young autistic children.

3.3.4 Checklist for Autism in Toddlers (CHAT)

This is a screening instrument that aims to identify possible autism in toddlers. CHAT was published in 1992. It is the least time consuming screening tool as it takes only five-ten (5-10) minutes to administer and score. CHAT is designed in such a way that it can be used with kids as young as eighteen (18) months of age. This consists of nine (9) yes or no questions which are to be answered by the child's parents. The questions involve the following areas:-

- Specific behaviour
- Social play
- Social interest in other children
- Joint attention
- Pretend play
- Pointing to how interest in something
- Pointing to ask for something
- Motor development
- Function play
- Rough and tumble play

The CHAT also provides an opportunity for the examiner to have five (5) brief interactions with the kid to verify whether the child's actual behaviour is in accordance with the parent's reports. It is always advisable to diagnose Autism as early as possible. CHAT can be used as a first level platform to screen children under the biological age of eighteen – thirty six (18-36) months at which level there can be any possible concern of Autism. If the screening hints possible autism further assessment will be prescribed to diagnose autism. If there is a possibility for autism it is the best to continue the screening at different levels as all children with autism cannot be identified early because the onset and severity of symptoms will vary in each and every child.

The CHAT is the only assessment tool which was planned to identify autism in young children that has undergone evaluation in relation to scientific studies and has proved to be quite efficient. Statistical reviews suggested that CHAT is an effective assessment tool for identifying children with autism in the group as young as eighteen – thirty-six months. Autism is a relatively rare condition and the usage of CHAT to assess all children for possible autism may not at all be feasible. A more practical approach for the clinicians is to use the CHAT in assessing those children in whom there are some deviations from the normal standards of development. Till date, any negative effects by using CARS are not identified.

If after the assessment procedure, the results suggest that the child may possibly have autism, a more detailed assessment of the autism should be done with the help of other assessment tools and a trained clinician. Likewise, if after the assessment the results are negative it is advised that the child should get further evaluation, be it developmental or health evaluation, to make sure that there is no presence of autism.

The CHAT has proved to be more helpful as a further assessment tool rather than a tool that can establish a particular diagnosis. If it is significantly evident a child may have possible autism and if the clinicians and parents of the child feel that they have necessary information, then they may not use CHAT and move on to a detailed assessment procedure or evaluation.

Advantages of CHAT

- CHAT has proved useful to be used with children as young as eighteen months
- CHAT does not require any trained individual for its administration nor any specific setting is required for using CARS
- CARS is user friendly and is easy to conduct the test and to interpret the scores
- The degree of specificity for assessing children with possible autism is very high

Disadvantages of CHAT

- CHAT may not prove useful in obtaining proper results after the assessment. It is more of a screening tool
- As is the case with CARS and ADI-R, CHAT may also give false results
- CHAT may not be helpful in identifying children in whom the symptoms have not yet began to be manifested or the symptoms are mild
- CHAT may wrongly identify some children with severe delay in development as autistic who actually may not be autistic.

3.3.5 Pre – linguistic Autism Diagnostic Observation Schedule (PL-ADOS)

This is a semi-structured observation scale. This is used to diagnose children who have not yet started using phrase speech and hence is suspected of having Autism. This is administered with the help of the child's parent. This instrument consists of eight (8) tasks out of which four gives importance to social behaviour and the other four focuses on communicative behaviour. It takes less than 30 minutes to administer this.

The PL-ADOS is a detailed assessment tool. This assessment tool has shown to have a greater degree of specificity for assessing children with autism. But the PL-ADOS require trained individuals to carry out the assessment procedure and this can be a major hindrance given particular clinical situations. But the PL-ADOS may prove to be highly helpful when used with other assessment tool for assessing young children with possible autism.

Advantages of PL-ADOS

- Like other assessment tools, PL-ADOS also adds on some degree of consistency and objectivity to the decision making process
- PL-ADOS follows a structured pattern for collecting and interpreting information
- The test is done through the means of direct observation

- PL-ADOS has proved to be useful with children who have not started talking
- PL-ADOS when carried out in the presence of a trained individual can bring in sufficient level of specificity

Disadvantages of PL-ADOS

- Like other assessment tools, the PL-ADOS also may yield false results
- PL-ADOS when compared to other assessment procedures is more expensive
- PL-ADOS has not proved to be useful in assessing autism in verbal children

The administration time that is required by the above mentioned assessment tools are as follows

Childhood Autism Rating Scale	Twenty minutes
Autism Diagnostic Interview – Revised	One – three hours
Checklist for Autism in Toddlers	Fifteen minutes
Pre-linguistic Autism Diagnostic Observation Schedule	Thirty minutes

A number of advantages and limitations of various assessment tools has been brought out by various scale developers. The first step in identifying children with possible autism should be initiated by the parents by checking constantly for any delayed development in the child, and this in turn could lead to further detailed assessment of the child. But if the assessment is done based on a single abnormal development then it may yield false results and the assessment of children with a single developmental delay will not result in a perfect assessment.

3.4 Key Concepts of Ethics

3.4.1 Informed Consent

Consent is defined as the "autonomous authorization of a medical intervention...by individual patients" (Beauchamp and Faden, 2004). In the present day scenario, informed consent is an important step in any research or medical practice. During the procedure of obtaining informed consent, the participant or the patient agrees to become a part of the research or clinical procedure after being fully aware about the way the procedure is carried out, its benefits and advantages and risks (Bulger, 2002). In an ideal situation, after understanding about the research project or clinical practice completely, the participant or the patient gives a full and conscious agreement to the researcher or the clinician to be a part of the procedure. The process of obtaining the informed consent has a lot of ethical concerns surrounding it. The importance of informed consent can be completely understood only if the history that lead to the inclusion of informed consent in research projects is known and this has been discussed earlier in this chapter.

Informed consent was framed to ensure that a research participant or a patient is completely aware of the advantages, benefits and risks that is involved in the procedure and the patient or participant is fully aware of the procedure and how it is carried out. But when it comes to real life situations, it may not be as practical and easy as it seems to be. There is a high chance for misunderstandings as there may be concealed communication barriers between the researcher/clinician and participant/patient. This may not give the participant/patient the privilege to make a decision and give informed consent after being fully aware of the procedure. The barriers between the researcher and the participant can also be because of cultural differences and sometimes because of the differences in the religious practices. The participant's blind belief in science can lead to false expectation and this may also cause a problem. Both the researcher/clinician and the participant/patient must be aware of these barriers. If a participant/patient misunderstands the procedure involved in the experiment/clinical practice, he/she may be unknowingly participating in a procedure which he/she may not approve of. If at a later stage the participant/patient becomes aware of this situation, their physical or psychological well being might be greatly affected. This is one of the reasons for why the researcher/clinician should be ethically obliged to clear all the

misunderstandings and make the participant/patient fully aware of the actual procedure involved.

Consent can be given either explicitly or implicitly. Explicit consent can be in either in written or in words. Implied consent happens when a patient/participant expresses his willingness to take part in the procedure by way or his/her behaviour.

The concept of consent is important as it is based on the principles of patient autonomy (patient's/participant's right to make a fully informed and free decision about his/her healthcare) and respect for persons (avoid conducting unwanted procedures). Obtaining informed consent may be exempted in tow cases. They are:

- Situations where when the truth is told to the patient, it might lead to more harm
- Situations where the patient by himself/herself gives the decision making power to the clinician or another third party.

Legal aspect

In many jurisdictions, getting informed consent from the patient is required by the law. The 'Convention on Human Rights and Biomedicine' states that:

> *"An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks. The person concerned may freely withdraw consent at any time"* (Singer A Peter and Viens A M, 13)

An exception to the necessity of consent is in an emergency situation and this is recognized by all the jurisdictions. This type of emergency can arise when immediate treatment is required to save the life or to sustain the health of a person. This kind of an emergency is given an exception because a delay in treatment may lead to the death of the patient. But a clinician is always advised to get the consent from a person who can act as a substitute decision maker of the patient.

Policy

Almost all the international as well as the national organizations require that informed consent should be obtained from the participant/patient. The World Medical Association's (2005) 'Declaration on the Rights of the Patient' states:

> "*The patient has the right to self-determination, to make free decisions regarding himself/herself. The physician will inform the patient of the consequences of his/her decisions. A mentally competent adult patient has the right to give or withhold consent to any diagnostic procedure or therapy. The patient has the right to the information necessary to make his/her decision. The patient should understand clearly what is the purpose of any test or treatment, what the results would imply, and what would be the implications of withholding consent."* (Singer A Peter and Viens A M, 13)

How should consent be approached in practice?

The participant's/patient's freedom to give or refuse consent is being widely accepted since the recent past. It is an obligation on the researcher's or clinician's part to help the participant/ patient to practice this right. When a participant/patient is required to give informed consent, it is implied that the participant/patient will be well aware of the available options given by the researcher/clinician. The process by which informed consent is obtained will also help the participant/patient to be a part in the problem solving process and they will also to actively participate in the decision making process and there by authorize it.

When the clinical institutions were visited to get an understanding of how the informed consent was obtained, it was observed that informed consent was not obtained from patients or parents/guardian of the patient before conducting the assessment procedure. When a parent comes to the clinic with his/her child, they were required to tell the symptoms of their child and were made to sit for the test without obtaining any consent from the patient or the guardian/parent of the patient. In the first clinical institution, ten children were observed and informed consent was not obtained from any one of them. In the second clinic eight children were observed and in the third clinic seven children were observed. The situation

was same in both the other clinic as well. The name of the patient/subject is not mentioned due to confidentiality reasons. A code is assigned to each subject/patient.

CLINIC 1

Patient code	Whether Informed Consent was Obtained
MMHM	NO
SNHM	NO
RRHF	NO
CCHM	NO
PRHF	NO
ABHF	NO
DMHM	NO
TTHM	NO
JGHM	NO
AAHF	NO

CLINIC 2

Patient code	Whether Informed Consent was Obtained
NVHF	NO
PKHM	NO
SRHF	NO
LAHF	NO
ASHF	NO
KGHM	NO
AKHM	NO
NJHM	NO

CLINIC 3

Patient code	Whether Informed Consent was Obtained
RRHM	NO
DSHM	NO
RVHF	NO
SKHM	NO
JPHM	NO
NMHF	NO
MJHM	NO

3.4.2 Disclosure and Capacity

Disclosure can be defined as the process during which the researcher/clinician provides the complete information about the research/treatment to the participant/patient. Disclosure forms an important element of informed consent. The patient has a right to the full information available about the proposed research/treatment and then to make a decision. It is the duty of the researcher/physician to let the participant/patient know about the research/clinical procedure and thereby help the participant/patient to decide the best suited option for them. The participant/patient must be informed about the procedure involved in its totality. The risks and benefits involved must also be conveyed. It is not just the conveyance of the complete information that is important in the process of disclosure, but also when and how the information is communicated is as equally important.

Through disclosure, the researcher/clinician can show their respect for the autonomy of the patient. Disclosure of all the necessary information to the participant/patient can be considered as a primary obligation of the researcher/clinician. If the researcher/clinician fails to provide the complete information regarding the procedure involved, then it may be claimed

as negligence on the part of the researcher/clinician. Consistent disclosure of all the relevant information on the part of the researcher/clinician will help in building a continuous trust on the researcher/clinician by the participant/patient.

Information can be withheld from the patient in a few exceptional cases. They are:

- When there is an emergency situation
- When the patient/participant expresses his/her wish that he/she does not want to know the information offered
- In situations where the patient is incompetent

The General Medical Council states that:

"You should not withhold information necessary for decision-making unless you judge that disclosure of some relevant information would cause the patient serious harm. In this context serious harm does not mean the patient would become upset, or decide to refuse treatment" (Singer A Peter and Viens A M, 26)

Legal Aspect

Laws regarding disclosure as an important concern for informed consent are different in different jurisdiction. Laws pertaining to the legal right of the patient to know about their healthcare are the strongest in North America, than in any other part of the world (Singer A Peter and Viens A M, 19). But these laws are constantly changing and evolving. The recent trends in the ethical and legal side are leading to increased disclosure of the information as well as increased involvement of the participant/patient in healthcare practices.

Policy

A number of professional bodies give importance to the consent procedure which is focused on the patient. The General Medical Council, United Kingdom states that:

> *"doctor's must take appropriate steps to find out what patients want to know and ought to know about their condition and its treatment"* and that *"existing case law gives a guide to what can be considered minimum requirements of good practice in seeking informed consent from patients"* (Singer A Peter and Viens A M, 26)

How should Disclosure be approached in practice?

The ethical concept of disclosure will ensure that relevant and necessary information has been communicated to the participant/patient to make an informed choice regarding the research/medical practice. The following elements should be included while communicating the relevant information:

- All relevant information regarding the condition of the patient and the inherent risks if the patient remains untreated or if there is any delay in the treatment
- All available treatment options, including their risks and benefits and side effects (which may be reversible or irreversible) if any.
- Any information that the participant/patient specifically asks for
- The clinician's opinion regarding which option should be chosen keeping in mind the patient's values and expectations

For the process of disclosure to be effective, the communication process should be open. This process is not just a neutral communication of information, but rather a situation which is highly complex. A few points must be taken care of while communicating the relevant information. They are:

- Technical language and jargon must be avoided. There should be clarity
- A language which is in par with the participant's/patient's fluency must be used

- After the relevant information is provided, the participant's/patient's reaction must be observed
- Questions from the participant/patients should be encouraged
- The participant/patient should be given the space to share his/her fears and anxieties
- Empathy and compassion should be shown to the participant/patient
- The conveyed information should be again summarized

Disclosure should be considered as a process and not just an individual event. In the present study, it was observed that the capacity of the parent/guardian played an important role in determining whether the information regarding the assessment tool is to be disclosed to the parent/guardian. If the clinician felt that the parent was educated enough to understand the procedure involved in the assessment tool, then the relevant information was shared with the parent. In the other clinic it was observed that even if the parent/guardian was educated enough, the relevant information was not shared with the parents until the parent/guardian demanded for it. In contrary to this one clinic, made sure that all the relevant information regarding the assessment procedure is shared with the parent/guardian. It was done so in this clinic because the clinician felt that the more the parent/guardian understands the procedure that is followed the more helpful they become in the assessment procedure and more accurate will be the assessment.

CLINIC 1

Patient code	Whether the necessary information was disclosed to the parent/guardian
MMHM	YES
SNHM	NO
RRHF	YES
CCHM	NO
PRHF	NO
ABHF	YES
DMHM	YES
TTHM	NO
JGHM	NO
AAHF	YES

In this institution, the information was disclosed to the parent/guardian, only if the clinician felt that the parent/guardian was educated enough to understand the procedures involved. Not much of an effort was seen on the part of the researcher in trying to make the parent/guardian understand about the procedure involved. If the clinician felt that the parent/guardian was educated enough then they were given a brief introduction about the assessment tool that was going to be used and how are the parents/guardians supposed to be a part of the tests.

CLINIC 2

Patient code	Whether the necessary information was disclosed to the parent/guardian
NVHF	YES
PKHM	YES

SRHF	YES
LAHF	YES
ASHF	YES
KGHM	YES
AKHM	YES
NJHM	YES

In this clinic, all the relevant information was conveyed to the parent/guardian despite their educational qualification. The parent/guardian were made to understand about the assessment procedure that was going to be used, the type of questions that would be asked, why those questions were asked and what could be the possible outcome after performing the test. The parents/guardians were also given information on how could they be helpful while carrying out the test.

CLINIC 3

Patient code	Whether the necessary information was disclosed to the parent/guardian
RRHM	NO
DSHM	NO
RVHF	NO
SKHM	NO
JPHM	YES
NMHF	NO

MJHM	NO

In the third clinic, the concept of disclosure was totally ignored. When the parents came with their children for assessment, they were made to sit for the assessment procedure after hearing the behavioural symptoms. Even if the parents were educated, they did not provide the necessary information regarding the assessment tool until the parents/guardians demanded for it. If the parent/guardian demanded to know about the test, then it was observed that all the relevant information regarding the test was shared with the parent/guardian.

3.4.3 Confidentiality

When a person gives information to another in confidence there is an obligation on the person receiving the information not to disclose to someone else (Singer A Peter and Viens A M, 39). Confidentiality can be either explicit or implicit.

- Confidentiality can be explicit by the provider of information stating that the information must not be shared, or
- Implicit in the nature of the relationship between the provider and the receiver of information.

The concept of confidentiality gives the foundation of trust in the relationship between the researcher/clinician and participant/patient. Great importance is placed on confidentiality by the professional organizations and regulatory bodies. The breach of confidentiality on the part of the researcher/clinician may even lead to disciplinary actions. In some cases, confidentiality cannot be absolute and in those cases it may be legally permitted to breach confidentiality. When a participant/patient has a belief that the information communicated by him/her to the researcher/clinician will remain confidential, the participant/patient will be more open to the researcher/clinician. If they do not possess this confidence, then they may not communicate the important information.

If a researcher/clinician shares a participant's/patient's information to a third party without the participant's/patient's knowledge and consent, the respect for the participant's/patient's autonomy is in question. In a relationship between the researcher/clinician and the participant /patient there is an implied promise from the side of the researcher/clinician that the confidence will be respected. The breach of confidentiality is justified in some situations where there is a chance for serious harm to either the participant/patient or to another third party; "personal freedom may legitimately be constrained when the exercise of such freedom places others at risk" (Singer A Peter and Viens A M, 39). The General Medical Council of the United Kingdom states that

> "*disclosure of personal information about a patient without consent may be justified in the public interest if failure to disclose may expose others to a risk of death or serious harm. You should still seek the patient's consent to disclosure if practicable and consider any reasons given for refusal"* (Singer A Peter and Viens A M, 39)

Legal Aspect

The courts in the United Kingdom have stated that confidentiality should be maintained and if there is any breach of confidentiality in the greater interest of the general public, then both the aspects should be weighed properly. In certain jurisdictions, it is required by the legislation that the physicians should maintain and respect the patient's confidentiality. The jurisdiction in most of the countries defines the legal requirements that is needed for the disclosure of the information regarding the participant/patient.

Policy

The Hippocratic Oath explicitly demands confidentiality in physicians' dealings with patients.

"what I may see or hear in the course of the treatment in regard to the life of men, which on no account one must spread abroad, I will keep to myself, holding such things shameless to be spoken about" (Singer A Peter and Viens A M, 40).

No exception of confidentiality is allowed by the World Medical Association. All the professional bodies states the importance of why further consent should be obtained from the participant/patient before sharing the information of the participant/patient to a third party.

How should Confidentiality be approached in practice?

The participant's/patient's confidence must be respected by the researcher/clinician. If any information of a participant/patient is to be communicated to a third party, then consent should be obtained from the participant/patient before doing so. If the patient is incompetent, then the consent of the patient's representative must be sought. If a situation arises where there is serious harm to a third person(s), there the duty to protect or warn will nullify the duty of confidentiality.

CLINIC 1

Patient code	Whether confidentiality was maintained
MMHM	YES (oral)
SNHM	YES (oral)
RRHF	YES (oral)
CCHM	YES (oral)
PRHF	YES (oral)
ABHF	YES (oral)
DMHM	YES (oral)
TTHM	YES (oral)
JGHM	YES (oral)
AAHF	YES (oral)

In the first clinic, confidentiality of the patient was maintained to the highest level possible. Before sharing the information of a patient with a third party, they let the patient know about the situation and then only was the information shared. But consent from the patient in this regard was obtained only orally. No written consent was obtained from the patient or the parent/guardian of the patient. The reason the institutions provided for not obtaining a written consent was that only the basic information of the patient was shared. The name and age of the patient and the educational qualification was the information that was asked for. By sharing this information, no harm could come to anyone. When asked for more detailed information like the address of the patient, the institution staff refused to provide it.

CLINIC 2

Patient code	Whether confidentiality was maintained
NVHF	NO
PKHM	NO
SRHF	NO
LAHF	NO
ASHF	NO
KGHM	NO
AKHM	NO
NJHM	NO

In this clinic, confidentially was not at all maintained. The basic information regarding a patient was shared without letting the patient know about it. The reason they gave

for it was that, no harm could come to a patient by sharing his basic information like name, age and educational qualification. When the address of the patient was asked for, they refused it saying that is a confidential detail of the patient and cannot be shared until the patient allows for it.

CLINIC 3

Patient code	Whether confidentiality was maintained
RRHM	YES (oral)
DSHM	YES (oral)
RVHF	YES (oral)
SKHM	YES (oral)
JPHM	YES (oral)
NMHF	YES (oral)
MJHM	YES (oral)

The situation in this clinic is also as same as the first clinic. The consent obtained from the patient or parent/guardian of the patient was only oral. Through this oral consent, only the basic information of the patient was shared to the third party. When asked for the address of the patient, there was little encouragement from the part of the institution.

3.4.4 Voluntariness

Presented in the context of consent, voluntariness can be defined a participant's/ patient's right to make medical practice decisions and decision and decision about his/her personal information free of any undue influence (Singer A Peter and Viens A M, 31). The participant's/patient's freedom to decide about the medical practice can be infringed upon by internal factors as well as external factors. The participant's/patient's condition may decide

the internal factors. External factors may include the ability of a third party to impose control over a participant/patient through means of force, coercion or manipulation. But the concept of voluntariness does not imply that the researcher/clinician should stop from persuading the concerned person to undergo the procedure. In this context persuasion refers appealing to the participant's/patient's reason and trying to help him/her to understand the benefits of the recommendation. Though a researcher/clinician can try persuading a participant/patient to undergo that particular recommendation based on evidences and judgements, the participant/patient has all the freedom to accept or reject the recommendation. But the clinician must be fully aware fully aware of the thin boundary between persuasion and coercion.

Voluntariness is considered to be an ethical requirement for consent to be valid. The concept of voluntariness implies freedom, independence and autonomy.

Legal Aspect

Voluntariness is considered to be a legal requirement for consent to be valid. In some jurisdictions, in some exceptional circumstances, treatment may be given against a patient's will. To substantiate, a person with a contagious disease may be provided treatment despite their refusal as it concerns public safety. Some jurisdictions also allow treatment of individuals without obtaining informed consent if it is impossible to get the informed consent. A topic which has become the centre of ethical and legal debates in the recent past is the procedures which involve minors. Such a position poses extra challenges with regard to the concept of voluntariness. In some cases, the parents of the minors may make the decision on behalf of their children. This may, in some very rare cases, not be in the best interest of the child. Cases have been reported where the parents refuse the necessary treatment for their children as the suggested treatment option may be against their religious beliefs.

Policy

As stated earlier, voluntariness is an important aspect of a valid informed consent. Obtaining informed consent is a policy of the general bodies regulating the clinicians. The General Medical Council of the United Kingdom has created some norms for voluntary

decision making. To be given as an example, interaction with the patients regarding informed consent must give a balanced view of all the options available. If there is any conflict of interest, that should also be given clarification. The United Kingdom's Department of Health states that 'voluntary consent to treatment (or refusal of that treatment) requires an absence of pressure and undue influence on a patient and that pressure may come from clinicians, as well as from the patient's family members (Singer A Peter and Viens A M, 33) to avoid the situation the clinicians must make an arrangement to meet the patient in private so that they can make their own decisions regarding their healthcare.

How should voluntariness be approached in practice?

A participant's/patient's decision about a procedure is affected by both internal and external factors the internal factors arises from the medical condition of the participant/patient. The researcher's/clinician's duty is to lessen the potential effects of these factors to the best of their ability. The researcher/clinician, family and friends and the healthcare setting may form the external factors. Problems will arise when family or friends or any other third party exercise excessive control. In the very rare situations where the researcher/clinician has the freedom to use force, a technique which is considered to be the least restrictive should be adopted.

Measures should be adopted by the researcher/clinician to minimise the scope for manipulation. The main reason for this is that the participant/patient can be easily manipulated when they are receiving incomplete information. To avoid such a situation the researcher/clinician should make sure that all the relevant information has been communicated to the participant/patient. Manipulation can also happen when the information is communicated in a biased manner. To avoid this situation the researcher/clinician may ask the participant/patient to review the information given to them in their own words. If a participant/patient accepts the procedure after being fully aware of its inherent benefits and

risks, it can be understood that the decision made by the participant/patient is not manipulated.

While the present study was done, it was observed that in all the three clinics the concept of voluntariness was given due importance. The reason for this was that, if a patient is forced to answer a question, then the answer given by the patient may not necessarily ne correct and this in turn will lead to inaccurate assessment. So to avoid this situation, all the three clinical institutions observed that the patient had the full right to answer a question only when he wants to do so. In case a patient was not answering a question, then the question was asked at a later point in another way and the answer was obtained.

CLINIC 1

Patient code	Whether the patient was given the freedom to exercise voluntariness
MMHM	YES
SNHM	YES
RRHF	YES
CCHM	YES
PRHF	YES
ABHF	YES
DMHM	YES
TTHM	YES
JGHM	YES
AAHF	YES

CLINIC 2

Patient code	Whether the patient was given the freedom to exercise voluntariness
NVHF	YES
PKHM	YES
SRHF	YES
LAHF	YES
ASHF	YES
KGHM	YES
AKHM	YES
NJHM	YES

CLINIC 3

Patient code	Whether the patient was given the freedom to exercise voluntariness
RRHM	YES
DSHM	YES
RVHF	YES
SKHM	YES
JPHM	YES
NMHF	YES
MJHM	YES

The above given tables can be consolidated into a single one as below.

Serial No:	Patient Code	Informed Consent	Disclosure	Confidentiality	Voluntariness
1	MMHM	NO	YES	YES	YES
2	SNHM	NO	NO	YES	YES
3	RRHF	NO	YES	YES	YES
4	CCHM	NO	NO	YES	YES
5	PRHF	NO	NO	YES	YES
6	ABHF	NO	YES	YES	YES
7	DMHM	NO	YES	YES	YES
8	TTHM	NO	NO	YES	YES
9	JGHM	NO	NO	YES	YES
10	AAHF	NO	YES	YES	YES
11	NVHF	NO	YES	NO	YES
12	PKHM	NO	YES	NO	YES
13	SRHF	NO	YES	NO	YES
14	LAHF	NO	YES	NO	YES
15	ASHF	NO	YES	NO	YES

16	KGHM	NO	YES	NO	YES
17	AKHM	NO	YES	NO	YES
18	NJHM	NO	YES	NO	YES
19	RRHM	NO	NO	YES	YES
20	DSHM	NO	NO	YES	YES
21	RVHF	NO	NO	YES	YES
22	SKHM	NO	NO	YES	YES
23	JPHM	NO	YES	YES	YES
24	NMHF	NO	NO	YES	YES
25	MJHM	NO	NO	YES	YES

From the observations done in the three clinical institutions it was evident that the key concepts of ethics was not given due importance in carrying out the assessment procedures. What can be done to rectify these short-comings? This will be discussed in the following chapter.

Chapter 4 – Summary and Conclusion

4.1 Introduction

Ethics is gaining wide importance day by day in research as well as clinical practices. Clinicians and researchers have to perform so many different roles in their practices. These roles demand various decision making process which requires ethical consideration. But, for a large number of clinicians who interact with their patients on a daily basis, the relationship between the patient and the clinician will decide the ethical concerns.

The three key concepts of ethics namely informed consent, disclosure and confidentiality are related to each other in one major aspect, ie. the way in which information is shared between the clinician and the doctor and how the information is used and shared to a third party. The patient or the guardian/parent of the patient may share the information regarding the symptoms and their concerns to the clinician. The clinician in return should share all the information regarding the options available for the patient. Thus the relationship between a clinician and a patient is formed on the basis of this sharing of information.

4.1.1 Informed Consent

The key concept of ethics is informed consent. A number of regulatory bodies including the ICMR have made it mandatory that informed consent should be obtained from the patient or the parent/guardian of the patient. Informed consent not only implies the acceptance of a suggested option. It also implies a choice between a number of options including the choice to refuse the given option. The concept of informed consent has so much importance in it because the ethical principles of patient autonomy and respect for person form the basis of informed consent. Patient autonomy refers to the patient's freedom to make decisions about his/her healthcare. As it was observed in the present study, obtaining informed consent before the assessment procedure for assessing autism is not practiced in the visited institutions. This in turn implies that the patient or the parent/guardian of the patient is not given any choice regarding the assessment procedures. The parent/guardian is also not aware of the importance of informed consent. This may be because of their total trust in the clinician – a belief that the clinician will come up with the best suited option for them.

A fully informed consent may not be possible in practice. Several factors add to this situation. Cultural difference between the patient and the clinician, linguistic difference, the complexity involved in the medical information, etc. may all add to this hindrance. But given the importance for the freedom of the patient or parent/guardian to decide their healthcare and respect for persons, the clinicians are ethically obliged to get the highest degree of informed consent that can be obtained in the given situation.

4.1.2 Disclosure

Disclosure forms the second key concept of ethics. Before conduction the assessment procedure the clinician has a moral obligation to convey to the patient or the parent/guardian of the patient all the information regarding the assessment procedure to be used. Making the concerned person fully aware about the assessment tool concerned will help in obtaining more accurate answers. The patient must be informed about the procedures involved in the assessment tool. When a clinician discloses all the information regarding a certain procedure to the patient or the parent/guardian of the patient, the expected outcome can be that the patient will also disclose all the information that is necessary for making an accurate assessment. Another added benefit from disclosure of information is the establishment of trust and the full co-operation of the patient in the procedures that follows.

It is made mandatory by the regulatory bodies that information regarding the proposed option should not be withheld from the patient. Some legal exceptions are given to this obligation. They are

- When there is an emergency
- When the patient or parent/guardian demands that he/she does not want to know the details of the proposed information
- When the patient is incompetent to understand the details.

The clinicians should convey all the information regarding the procedure to the patient. It should be made mandatory that proper disclosure of information is done.

4.1.3 Confidentiality

The third key concept is that of confidentiality. But ever since ethics started to gain importance, it was noted that confidentiality cannot be absolute. In certain situation law requires the breach of confidentiality. When multidisciplinary research is undertaken, the breach of confidentiality poses certain dilemmas. The questions that would pop here will be how much of information of a subject can be shared with the entire team and with whom all in the team can the information be shared.

When a patient is aware that the information shared by him/her will remain with the clinician, the patient will feel to open up with the clinician. If the patient at some point feel that the information given to the clinician may be shared with another person without the knowledge of the patient, then the patient may not open up to the clinician.

A lot of studies were done to understand the patients' awareness about confidentiality and their attitude towards it (Slowther and Kleinman, 46). In these studies it was found out that the patients were unaware about the legal and ethical aspects of confidentiality.

When a clinician discloses any information of a patient to a third person, it is important to take into consideration to whom the information is being conveyed, and how much of the information should be disclosed to the third person. If a clinician is disclosing information to a third person without or with the knowledge of the patient, the clinician should take care and see that the information is shared to a level in which there can be no harm to anyone. But a clinician should always make it a point to obtain the consent of the patient concerned before disclosing any information to any third party.

4.1.4 Voluntariness

Voluntariness refers to the participant's/patient's right/freedom to make decisions regarding the medical practices and to make decision about his/her personal information free of any undue influence (Singer A Peter and Viens A M, 31). If consent has to be valid, voluntariness should be exercised. A participant/patient should not be forced to give consent. This does not mean that the researcher/clinician should stop from persuading the concerned

person to undergo the procedure. Even in such a situation, where the researcher/clinician is persuading the participant/patient to be a part of the recommended procedure, the participant/patient possesses all the rights to accept or reject the recommendation. In this sense voluntariness implies freedom, independence and autonomy.

4.2 An Overview of the Study

The Study undertaken here was to understand the procedures used for the assessment of autism. Attempts were also made to understand how the different concepts of ethics, like informed consent, disclosure of the relevant information to the patient, whether the information regarding the patient was kept confidential and whether the patient was given the freedom to exercise voluntariness, was practiced in different clinical institutions while conducting the assessment procedures.

While a pilot study was conducted, it was noted that the concepts of ethics was not given importance in the clinical practices. No informed consent was obtained from the patient or parent/guardian of the patient. The relevant information regarding the assessment procedure that was to be used was also not conveyed to the parent/guardian. It was also noted that the personal information of a patient was communicated to a third party without obtaining any consent from the concerned person. Voluntariness was one aspect of ethics that was given due importance during the procedure. The patients were not forced to answer a question. Further studies were done to understand the circumstances in other clinical institutions. The methodology adopted for studying the real situations is summarized below.

4.3 Research Hypotheses

The following are the research hypotheses that were derived after the pilot study.

1) The consenting process is not done in a proper manner

2) Proper disclosure of all the information regarding the assessment procedures used are not conveyed to the patient or to the guardian. The inherent risks or alternatives to the

proposed assessment procedures are not completely disclosed. Disclosure if practiced, depends on the capacity of the parent/guardian

3) The patient information is shared to a third party without taking further consent from the patient, thus violating the principle of confidentiality

4) The patient is not given the freedom to practice voluntariness

4.4 Methodological Perspective

The methodology adopted for the study was naturalistic observation. It was a cross-sectional study as children of different age groups were involved in the study. Three clinical institutions in Kerala were visited to get the information needed for the study. Twenty-five subjects were studied in total. Ten subjects from one clinic, eight from another clinic and seven from a third clinic were involved in the study. Observation was made when a child was brought to the clinic and the assessment procedure was done. The subject was observed in his/her natural settings. There was no intervention or manipulation from the part of the researcher, nor was the environment created or manipulated by the researcher. This method was adopted because in this method there would be no pressure on the subject, as he/she is not directly asked for the response.

Personal interview with people working as clinical psychologists and interventionists for autism was also done, because the information thus obtained from them facilitated a more strong insight into the reality of the situation.

The information obtained from the observation was recorded using a table. A code was assigned to each patient to protect the privacy of the patient. This code was noted along the vertical line of the table. The horizontal line was used to note the key concepts of ethics. When a subject was undergoing the assessment procedure, the observations made regarding how each concept of ethics was practiced was marked. A format of the table used is given below.

Patient Code	Informed Consent	Disclosure	Confidentiality	Voluntariness

Additional notes were made during the observation to record to what extend was the information regarding the assessment procedure was disclosed to the parent/guardian of the subject. Notes were also made to record what information about the patient was communicated to a third party without the knowledge of the patient.

4.5 Observations made during the Study

The observations made during the present study with regard to each aspect of ethics are discussed below.

4.5.1 Informed Consent

After observing the situation in three clinical institutions in Kerala, it was found out that before undergoing the assessment procedure, informed consent was not obtained from any of the patients or parent/guardian of the patient. Even the parents were not seen to be aware of the importance of informed consent. The primary concern of the parents was to know whether their child is autistic or not. Even the clinicians did not feel that obtaining informed consent before an assessment procedure was necessary. As stated earlier, informed consent implies the awareness of the patient or parent/guardian about the available options

and awareness about the procedure to be done. The concerned person has all the right to know this information.

4.5.2 Disclosure

In the present study, it was observed that disclosure of information regarding the assessment procedures was not done properly in two of the institutions. Capacity of the parent/guardian to understand the procedures involved played a crucial role here. In the first clinic, the information regarding the assessment procedure was conveyed to the parents only if the parents were educationally qualified so that they would understand the procedure without much explanation from the clinician. In one clinic it was made mandatory that whatever the educational qualification of the parent/guardian, necessary information regarding the assessment procedures should be conveyed. Efforts should be made by the clinician to make the parents fully aware of the procedure to be used. The third clinic was not giving any importance to the disclosure of necessary information to the parent/guardian of the patient. If the parent/ guardian of the patient demanded for an explanation regarding the procedure to be used, the clinician talked about the procedure. If the parents did not ask for it, then they straight away carried on the procedure.

4.5.3 Confidentiality

In the present study it was observed that, two out of three clinics gave due importance for confidentiality. The information regarding the patient was shared to the third party only after obtaining consent from the patient, though the consent was obtained orally. The other clinical institution did not consider it important to let the patient or parent/guardian of the patient know about the sharing of information as the information shared was not of great relevance. In this situation there is serious breach of confidentiality. The clinician is morally and ethically obliged to inform the patient before sharing the necessary information about the patient to a third party. Confidentiality should be maintained even if the sharing of information does not result in any harm. If a clinician shares the information of the patient without the patient knowledge, then there is a betrayal of trust.

4.5.4 Voluntariness

Voluntariness was practiced in all the three institutions. If the patient was not willing to answer a specific question asked to them, then they were not forced to give the answer. But the same question was asked at a later stage in a different manner and thus the answer was obtained from the patient. The clinician made sure that the answer would be obtained from the patient at some point as that particular answer may play a crucial role in resulting in an accurate assessment. But the answer was never forced out of the patient, as the clinician was fully aware that if the patient is forced to give an answer, then he/she may give a false answer and this may lead to inaccurate assessment of the patient.

4.6 Discussion

The first hypothesis was proved to be correct. Informed Consent was not obtained from any of the patient in any clinical institution. Ensuring that informed consent is obtained from the patient or parent/guardian of the patient would also ensure that all the relevant information about the assessment procedure involved was communicated to the concerned person. But as the situation was that informed consent was not obtained from the patient or the parent/guardian of the patient, the case was that not all the information was communicated to the concerned person. This is a serious violation of the ethical aspect.

The second hypothesis was proved partially correct. One of the clinics had made it mandatory that all the relevant information should be communicated to the patient or parent/guardian of the patient before undergoing the assessment procedure. The other two clinics did not consider it important to convey the information. The clinicians in those two clinics felt that the information regarding the assessment procedures need to be conveyed only if the parent/guardian of the patient is educated enough to understand it. They also felt that they don't have the obligation to convey the information if it was not asked for. A fact that is forgotten by the clinician here is that, if the patient or parent/guardian is told about the assessment procedure in detail, then it will help in an more accurate assessment as the parent/guardian know what it is all about.

Regarding the principle of confidentiality, it was observed that confidentiality was maintained to a higher degree. The clinician's made sure that the information of a patient is shared with a third party only after letting the patient know about this. But in this situation also the consent was obtained orally. One among the three clinics did not consider confidentiality to be important as they felt that the information that was shared about the patient was not very relevant and the sharing of that information could not lead to any harm.

Voluntariness was one aspect of ethics that was practiced in all the three clinics without fail. As stated earlier if the patient was not willing to answer a specific question asked to them, then they were not forced to give the answer. But the same question was asked at a later stage in a different manner and thus the answer was obtained from the patient. The clinician made sure that the answer would be obtained from the patient at some point as that particular answer may play a crucial role in resulting in an accurate assessment. But the answer was never forced out of the patient, as the clinician was fully aware that if the patient is forced to give an answer, then he/she may give a false answer and this may lead to inaccurate assessment of the patient.

Even in the present day situations, when ethics is considered important in almost all the fields, it can be observed that the key concept of ethics is not given due importance in clinical institutions where ethics has great importance. The regulatory bodies have to come up with measures that can make sure that the clinician is ethically obliged to the patient. The regulatory bodies may make it mandatory to make the common people who come to the clinics, to be aware about the importance of informed consent, confidentiality and disclosure. This can be done through putting up posters or notices regarding the importance of the key concept of ethics in the clinical institutions and hospitals. It can also be made mandatory that the test sheet of the assessment tools should contain space for obtaining informed consent from the patient or parent/guardian of the patient. It should also have space for the patient or the parent/guardian of the patient to give in undertaking that all the information regarding the assessment procedure to be used has been conveyed to them and their doubts, if any, has been clarified by the clinician. It should also have a space for the clinician to undertake that the information regarding the patient will be conveyed to any third person only after obtaining further consent from the patient or the parent/guardian of the patient.

Through these measures the shortcomings of the existing system can be rectified to a small level. Following the ethical concepts can only add to the well-being, betterment and upliftment of the patient.

4.7 Scope for Further Research

Ethics has started to gain wide importance in the clinical and research practices in the recent past. The topic of bio linguistics is becoming more and more research oriented. In this area of bio linguistics there is immense scope for research. A lot of studies are being done in the present situation in this area as ethics has started to be an important aspect like the treatment itself. Still, there are many topics concerning autism and its ethical aspect that is left unattended. Works may be done to understand more about the treatment and therapies used for autism and what role can ethics play there. In a more general sense the role played by ethics in any assessment procedure or treatment of any disease can be studied and should be studied intensely.

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