



**ORIGINAL RESEARCH PAPER**

**Pediatrics**

**ETHICAL CONSTRAINTS FOR CONDUCTING RESEARCH IN PEDIATRIC AGE GROUP – A REVIEW.**

**KEY WORDS:** Ethics, Child, Children, Pediatric Dentistry, Clinical research.

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**ABSTRACT** Ethical aspect in pediatric dentistry starts when we as a dentist meet a child patient in the clinic, to whom we should provide a dental treatment & oral health needs with taking the patient's point of view into consideration. Thus, with professional ethical codes it is very much concern how we look upon children as individuals and as patients. Clinical Research in pediatric dentistry is incorporated to increase and revise the current knowledge. The aim of this review is improve the concept of clinical research in pediatric dentistry with pertinent ethical concern. In the current times where evidence-based dentistry is known for expertise studies with ethical papers without plagiarism, stress is been emphasized. Proper Knowledge about ethics while conducting a clinical research in pediatric dentistry is propitious to the researcher and also the dental community.

**INTRODUCTION**

Clinical research in knowledge seeking enterprise that is correlated with routine dental care. Over the years there is improvement in the quality of clinical research. Evidence-based dentistry is stressed upon as the need of current times. But the progress that is made is yet not sufficient enough to fill the need of the hour.

The advancement in the pediatric dental research is limited particularly in the area of clinical subjects such as diagnosis, risk assessment, outcomes & treatment.

The evidence that is available is sometimes not sufficient to be implemented in clinical areas due to lack of qualitative research whereas in few clinical cases there is no availability of evidence. This limitations and unavailability of evidence shows that clinical research is deficient as per demands of current time.

The western countries have shown tremendous improvement & advancement in clinical research as compared to Asian countries. The Asian countries still face problems in conducting qualitative clinical research due to limitation of resources and underdeveloped technologies.

Ethical solicitude have become a chief part of dentist's work, especially when dealing with the child patient who needs some extra notice where we have to ensure that their point of view is also recognized. For pediatric dental professionals, there is an important responsibility to implement the justice based on the ethical framework for children's oral health.

**WHAT IS ETHICS?**

The word ethics is derived from the greek word 'ethos' meaning personality. Ethics is science of morals [1]. It can also be interpreted as directive of behaviour based on ideas about what morally is right or wrong.

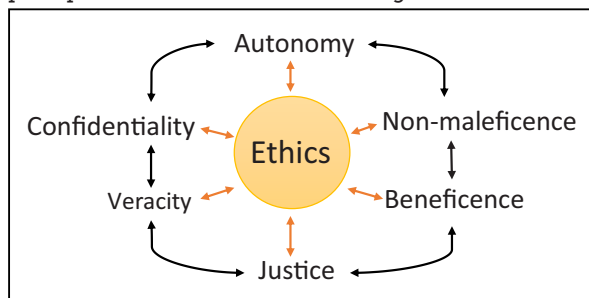
Ethics can also be described as a collection of moral principles, mainly ones relating to or affirm a specified group, field, form of conduct. The basic question ethics asks are how a man should act, especially when the actions have direct or indirect effect on others.

**DENTAL ETHICS**

According to Indian dental association- code of ethics, ethics is primarily a matter of knowing whereas morality is a matter of doing [2]. Morality can be expressed as "impartial, answerable, nobility and principles concerning what is good and bad or right and wrong behaviour. The proximate relationship between ethics and mortality contributes to the rational criteria for individuals to determine or act in appropriate manner.

**PRINCIPLES OF ETHICS**

The ADA Code of Ethics includes five principles: patient autonomy ("self-governance"), non-maleficence ("do no harm"), beneficence ("do good"), justice ("fairness") and veracity ("truthfulness")[3]. With these five principles we can also incorporate "Confidentiality". The above mentioned six principles of ethics are shown below in figure no. 1



**Figure 1: Principles of Ethics.**

The main general rationale in any clinical research project with minors is "first, do not harm"; in other words, children must be protected from unnecessary risks of harm[4].

**1. Autonomy**

The principle of autonomy explains that the children , parents or the legal guardian must be inform about the detailed research or study objective & course of procedure to be conducted together with the probability of risk of unfavourable outcome or discomfort involved. Informed consent should be entirely optional & the participants shall be

given freedom to decline from participating in the research or draw out from the study at any point of time.

**2. Beneficence and Non-maleficence**

Beneficence simply means “doing good” and non-maleficence means “not to do harm”. To study probability of risk & benefits to the child, a previous analysis is necessary. All trials must be conducted by scientifically qualified and clinically proficient pediatric dental researcher to minimize the risk of damage & to protect the subject’s integrity. The participants should not be compelled to essentially involve themselves in the study.

**3. Justice**

The selection of subjects should be carried out & justified for scientific and ethical reasons with assurance by investigators that the outcome produced during the research are equally distributed amongst the participants irrespective of their individuality such as ethnicity, race, status or gender. To assure justice each participant should receive equal part, requirement, attention, social benefaction or merit.

**4. Veracity**

Veracity basically means accuracy or honesty. The participant-researcher association is built upon mutual trust. The contenders anticipate the researcher to be honest about the details of the study.

**5. Confidentiality**

The confidentiality should be maintained between the:

- Investigators & researcher.
- Researcher & publisher.
- Investigator & publisher.

The confidentiality should be emphasized upon so as to keep the outcome unbiased regardless of the personal characteristic such as age, sex, gender, caste, race & religion. So throughout the complete clinical trial or research which includes children, investigator or any individual involved in the study must comport themselves under three essential ethical principles[5] that are *Autonomy, Beneficence and Non-maleficence & justice*.

**INFORMED CONSENT IN PEDIATRIC DENTISTRY**

Informed consent is most clearly defined in guidelines on consent to medical research, not to treatment."The American Academy of Pediatric Dentistry (AAPD) recognizes informed consent as essential in the delivery of health care[6]. The informed consent guides the child, parents & legal guardians to take part in the pediatric dental care that is provided by the pedodontist.

The pediatric investigator "should adjudge informed consent as a means of succour the patient, not purely as a lawful responsibility, and conversely, shall not use the consent form as a alternative to explain the patient[7].The pediatric dentist should give clear information about the facts, implications and the consequences of the procedure.

According to the current scenario, consent is taken with regards to high risk procedures such as extractions, minor surgery leaving behind low risk procedure such as oral prophylaxis, restorations but it is not preferable to do that. It should be the responsibility of the pediatric dentist to take the informed consent & should not be left upto dental auxiliary. The written informed consent is more advisable than spoken consent as the former can be documented. The documentation will help parents recollect the information.

*Consent form recommended by the American Academy of pediatric dentistry[6]:-*

When a practitioner utilizes an “informed consent” form, the following points should be kept in mind:

1. Name and date of birth of pediatric patient.
2. Name and association to the pediatric patient/lawful basis on which the person is assent on behalf of the patient
3. Description of the procedure in simple terms.
4. Revealing of known unfavourable risk(s) of the proposed treatment particular to that procedure.
5. Qualified or evidence-based different treatment(s) to suggested therapy and risk(s)
6. Place for custodial parent or legal guardian to indicate that all questions have been asked and adequately answered and
7. Places for signatures of the custodial parent or legal guardian, dentist, and an office staff member as a witness.

This informed consent form is an important medico-legal document, which should be implemented in every pediatric dental clinic, study and research.

**CHILDREN AND ASSENT**

Diekema (2003) proposes reasons for obtaining assent from even very young children[11].

- To procure assent is a reminder that the children should be given solemnity & veneration.
- Involving children in the study helps them in their evolution as independent individuals.
- Guardians and investigators should take into consideration that children as an individual is also interested in the study or research.

**RESEARCH ETHICAL COMMITTEE**

Children should not be enrolled in a clinical investigation unless it is scientifically necessary to achieve important information on therapeutics concerning the social or particular oral health and welfare of children[9].

- The Research Ethical Committee must be unbiased throughout the investigation & should not get influenced by any examiner, financier or external bodies. The law & regulations of the country should also be taken into consideration while conducting a clinical research.
- Researchers who intend to conduct a clinical trial must provide the committee with an investigation protocol for its in-depth review[10].

**CONFLICTS OF INTEREST**

As stated by Barnett, “Conflict of interest is a set of conditions in which professional judgment concerning a primary interest (e.g., patient’s welfare or validity of research) tends to be unduly influenced by a secondary interest (e.g., financial gain)[8]”.

- A product developed by a researcher will get more importance than the products which are already in use & this may lead to conflict of interest.
- The examiner may emphasize more on the positive aspect of the research rather than the negative aspect or less effective result and this can lead data manipulation. This may include manipulation of data such as altering results or removing few less favourable points.
- Even if the conflicts of interest are mostly related to circumstances of monetary inducement, there are conditions that are not related to financial aspect and which may upsurge conflicts.
- While, few responses are deliberate and can be altered by monetary co-relations, there may be direct or indirect influence on the person conducting the research or/and the organization.

**THE EQUIPOISE CONCEPT**

The clinical equipoise occurred when newly introduced treatment fails to be more effective than already existing one. Ethics of research involving clinical trials on human beings has drawn attention towards the difficulties associated with equipoise.

The condition of equipoise is constant with the treatment

associated on the part of researcher.

For example , in a study conducted by A.D. Henschel , . In the case of the young David Sackett, equipoise was not satisfied, and although he was aware of his mistake he decided to give the established treatment in addition to the new one. He stated that he had never acted in this way again because he realized that deeds like this may seriously bias the outcome of a trial and in consequence future patients, who were treated according to incorrect conclusions of such trials, could be harmed. His example contributes to the discussion of the importance of equipoise and of who should be in the state of equipoise[10].

Equipoise does not rely on enshroud significant information from investigators unlike individual data observing board. It permits investigator to suffuse subjects, to differentiate proper information received by the clinical group which is not assuring but not persuasive.

The notion of equipoise though conceivably alleviate the modern plight of dependence in the ethics of clinical research. Equipoise remains an ethical condition for clinical research.

### CONCLUSION

In current times, Ethics has become a major part of Dental pediatric clinical research. Paediatric dental investigator should consider all the code of ethics, laws of constitution of the country, consent of the patient, conflicts of interest , equipoise & must accurately represent themselves.

Dental investigation practitioners must consider the already suggested and advocated concept of child-centred-research, in which children are active participants rather than objects during the research development, and so, they can contribute to improve the oral health care process, through valuable information[5].

With the implementation of proper ethical concerns and genuine evidence based- research will benefit the children, the investigators , the research ethical committee, dental students along with the general population.

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