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## Ethical Challenges And Modifications In Research Methodology Related To Pediatrics

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### ABSTRACT:

Pediatric subjects are included in vulnerable population and according to ICMR ( Indian Council for Medical Research) they also have equal right to be included in research so that benefits occurring from the research can apply to them as well. There are some ethical issues which arise during research conducting on such population like *availability and access, vulnerability to harm or damage, informed consent, confidentiality, exploitation, compensation etc.* The researcher must take care of these all ethical issues while involving such subjects in the researches. ICMR has laid down some guidelines for research on such type of subjects like these population should be included in the research only when the research is directly answering the health needs or requirement of the group. Further benefits of the research should out weight the risk to the population. The Ethical Committee should determine the vulnerability and ensure that additional safeguard and continuous monitoring mechanisms are established. It is also mandatory for the researcher to be well trained and competent in his work to maintain safety.

**Key Words.** *ICMR, vulnerability, informed consent, exploitation, ethical committee etc.*

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## INTRODUCTION:

To conduct research in pediatric subjects is important because by only research we can develop new modalities of diagnosis and advanced and upgraded treatment protocols. Research in pediatric subjects is being conducted everywhere now a days but the research process in such age group is crucial because there are many factors which are troublesome in conducting research in the age group like informed consent issues, vulnerable age, difficulty in explaining and understanding the questioners and answerer.

As we know the pediatric patients are too young to understand the annoyance of treatment as well as outcomes of conducting research on them so one has to be very careful while dealing with this subset of population.

The fundamental challenge in conducting research in pediatric age group is their vulnerability and risk. **ICMR( Indian council for Medical Research)** laid down some guidelines for human research as well as for pediatric research. According to ICMR guidelines there is need of additional safeguard in conducting research of and review of research carried out on vulnerable population including children. Benefit of research carried out in adults cannot be applied to children as the dose, duration of therapy, pharmacodynamics and adverse effects of drugs in children vary from adults.

It is very difficult to decide that up to what level, subject can be exposed to risk. The subject himself/ her- self might not be able to explain the suffering. So who can decide the level of exposure to the risk.

Access to such subjects is also a big issue because none of the parents are easy to make ready for allowing their children to be part of research so taking consent from the parents becomes the important issue. Further if any health related problem arises, then who will pay for managing the problem is also a big issue.

**Ethical Principles:** An Ethics is a moral principle which guides a man while dealing with the others and so the medical ethics which guide a medical man while in dealing with the patients. As India is multi-religious, multicultural, multiethnic and yet a secular country so there are diverse ethical issues in different states.

## **MATERIAL AND METHOD:**

**There are some ethical issues which arise during medical research in pediatrics-**

- **Availability and access to the subjects:-**

Availability of pediatric subjects for clinical research is first and foremost issue. It is very hard to convince the parents to allow their kid to be a part of clinical research because we have to take informed consent. And when we explain the

possible bad outcome and risk, if any, to be subjects, the parents are not willing to give consent. The big question which comes in mind is that who will be the guardian for giving consent for subjects to be available for consent subject for clinical research can be made available from school, children home, slum areas etc. It is easier to make pediatric subjects from slum areas to be available for research by giving some money or other benefits of their interest.

Another factor is time when a researcher can approach to the subjects. For example if an in-charge of children's home sets a particular time to meet the children, it's also acting as a barrier to approach the subjects.

In some research a sample is to be taken at a particular time like fasting blood sugar, cortisol level, thyroid sample etc. These all need a sample to be taken in the morning so if school authority or in-charge of children's home somehow, not allowing the researcher to meet the children at that particular time then a sample could not be taken.

So for a researcher it is important to carry out research and sampling during the free time or time when subjects are available for question answer or giving during or taking sample. The researcher must ensure the authorities, of children's home or principle of a school or parents that during their research the comfort, play activity, rest or teaching or study of the children's wouldn't be affected. So researcher has to decide that what type of research should be carried out at what subject group.

- **Autonomy and Informed consent-** Autonomy is right of each individual to take decision about his own health. Children are too young to understand the various fact about treatment outcome or research conducted on them so informed consent from the parents or guardian becomes the solution for this issue. A valid informed consent must contain all the **five component** i.e. **disclosure** of the information, **comprehension** of the information, **absence of any outside control**, **competency**

(age>12yrs for GPE and >18 year for **surgery** or any invasive procedure) and **actual consent**.(written and witnessed)

- **Informed consent:-** Informed consent is very important part of any research process. Many research processes have potential risk to health or even risk of death of the subject. So it is compulsory to take informed consent because only informed consent is legally regarded valid. An informed consent must be having all the five essential component to be fulfilled. these are as follow-
  - **Disclosure:-**It means transmission of information regarding the procedure.
  - **Comprehension:-** It means understanding of the information provided to the subject.
  - **Absence of any outside control over the decision.**
  - **Competence:-** decided by his/her age for giving consent.
  - **Actual consent.-** Written and witnessed consent.

The age for giving consent for any procedure or research process which has potential risk of physical injury, harm or risk of death is equal or more than 18 years.

So in such cases consent is being taken from guardian or parents or principle of school or

any in- charge of children's home. When we explain the risk to the health during research

process, parents, guardian or any in-charge of children's home may not be agree to give

consent. So making research to be easier the ethical committee or law enforcing agencies

should confide some negotiation for criteria for informed consent like negotiation in age of

consent. Further a researcher can counsel and convince the parents about the benefit of

research and ensuring them that they can withdraw their child any time from the research

process, if child feel uncomfortable or if harmed in any way.

Consent issue may also arise in some families where three

generation are residing together like families with grand-parents, parents and children in a single home, In such families some time parents give consent but grand parents don't. So it is also important to counsel such family members otherwise they can interrupt in midway of the research process.

For researches not having the risk to the health 12 yrs of age of child is sufficient to give consent but still parents, guardian or in-charge of children's home or principle of school must be informed.

It is also important to take additional consent to publish photograph.

Most importantly child's interest must also be considered. If the subject is not interested to be involved in research that subjects must not be included in the research process because such subject will not cooperate in the research process and can withdraw anytime during research process.

Lastly the consent must be witnessed.

- **Safety and monitoring of the subjects:-** As we know the pediatric age group is very prone to any harm, disease or death. So this issue is also very important while initiating research in pediatric subjects.

For a researcher it is not easy to make ready the subjects, its parents or guardian to be involved in research, if the process has any risk to health. many drugs have potential side effects further a slight increase in dose of any drug can harm the subject since in pediatric drugs we always give drug by considering the weight of the subject and weight is continuously changing variable in this age group so *researcher must be very careful in changing the dose/or initiating the dose of a drug.*

So while initiating research on pediatric subjects important factor in counseling of guardians or parents about the safety.

Further special care has to be taken while involving the children in research by considering their weight and other health problems. All the measure

regarding safeguard of subject must be taken into account.

Researcher can also seek advice of international agencies like **UNICEF**, “**save the children**” before embarking of data collection on sensitive issues.

So regarding safety and vulnerability research on pediatric subject must only be carried out only it is responsive to their health needs and priorities and if there is reasonable likelihood that pediatric subject stands to benefit from the research.

Lastly the researcher must be well trained and competent enough in his work to minimize or avoid the risk to the health of the subjects and evaluation must be done at all stages.

- **Issue of Privacy, confidentiality exploitation, and compensation:-** For any research it is important to keep identity and record of participants confidential as far as possible for confidentiality the children needed to be explained as well. The researcher must also take care of non-exploitation of the

subjects, by physically, mentally or financially.

Since pediatric age group is very soft target for any physical or sexual harassment so this is also a big issue apart from safety or healthy.

Many parents might not be agree to give consent of allowing their adolescent girl to be the part of any research project.

For poor subjects some kind of compensation in the farm of money should be given and also this can be a good step for making any pediatric subject to get ready for being part of some research project. If some health related problem arise, the accountability must be of research conducting authority and necessary measures to be taken along with compensation

**Anonymity** is also an issue in research some children often wish to have their own names to be used. So reason for anonymity needs to be explained to such children

**Dissemination:-** This is another issue, how will the result of research should be disseminated to the children involved, whether it would be verbal presentation, written

material or any other format this must be considered in the beginning of the research.

**Non-maleficence:** The principle of "*Primum Non Nocere*" means firstly do no harm to the patient. This ethical concept protects the patient from being harmed in any way or there should be balance between harm and benefit provided by any treatment modality.

## CONCLUSION

The medical facilities advanced on one side improved the patient care on the other side it raised new ethical challenges as well. Developing countries like India has special challenge of **distributive justice**(Justice ensures the fairness of treatment as well as availability of treatment to all needy patients without any discrimination). In the context of research it's our moral duty to conduct research in children as well to develop better and advanced diagnostic procedures as well as treatment modalities and draw attention to implement better care facilities for this vulnerable age group. Since pediatric age is a vulnerable groups for research so high standard of ethical issues must be taken care like selection and

access, consent, confidentially, compensation and frequent monitoring, during research. It must be taken into account that the beneficial outcome must outweigh the possible risk, and research must be conducted by competent and well trained researcher only. So for taking care of the important ethical issues ICMR guideline must be followed strictly

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