

PEDIATRIC RESEARCH: CHALLENGES AND INNOVATIVE MEASURES

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Abstract

Ayurveda is the science which is 5000 years old. In the 21st century, it is the need of the hour to relate ayurveda according to the modern science. This can be made possible only through research. Research in wider aspects had been done in adults. But talking about child, it is totally ignored. Children are the building block of nation. They belong to the vulnerable population. Therefore, in the article we will discuss the challenges faced in the pediatric research and what steps can be taken in the detail.

Keyword: Pediatric, Challenges, Measures, Innovative, Research.

1. INTRODUCTION

Research is the systematic investigation into new or existing knowledge. A research project may also be an expansion of past work in the field. Research Methods refers to the methods / techniques researchers use in performing research operations i.e. research designs, sample, data collection and analysis. In India, there are various vulnerable sections among which children is one of them. Also among them, children with impairments are the most vulnerable. According to the report of The National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research 60% of children did not assent to take part in research, either because they choose not to participate (39%) or did not make a decision (21%)¹. Therefore, to flourish the pediatric branch it is the need of the hour to discuss the challenges and resolve the issues by taking innovative measures in this regard.

2. RESEARCH PROCESSES

1. Observational/ Exploratory

Researcher observes systematically, the disease or its causes or any other parameters, which exist natural. e.g. Prakriti study, behaviour of child in behavioural disorder of child, etc.

2. Survey/ Descriptive (type of observational study)

Asking individuals about attitudes, preferences and behaviour. E.g. Occurrence of a particular disease in a particular area, Immunization status of child, etc.

3. Experimental/ Casual-

Using groups of people to determine cause and effect relationships e.g. clinical trials, animal studies, laboratory studies.

3. CHALLENGES FACED IN PEDIATRIC RESEARCH

1. The assent requirement is one of the principal requirement for pediatric research³
2. Assent – age & ability to decide
3. Children are capable of assent when they become able to understand the research in question and existing data suggest most children develop this ability by approximately age 14.
4. Lack of safe, palatable medications in children lead to more research with children. 70-90% of drugs prescribed in children are off label or unlicensed.
5. Although the demand for pediatric research remains high, the logistical implementation is complex.
6. The fundamental challenge to pediatric research is risk: what is the risk of conducting(or not conducting) the research

4. REASONS FOR LACK OF PEDIATRIC RESEARCH

Many factors have led to a lack of pediatric research, including lack of agreed on end points, informed

consent issues and the general perception are vulnerable subjects. This perceived vulnerability of children is based on several factors:

1. Their decision-making capacity may be immature.
2. Their lives are still subject to the authority of others.
3. Their rights and interests may be undervalued by society.
4. Ethical considerations- Children should not be placed at a disadvantage after being enrolled in a clinical trial, either through exposure to excessive risks or by failing them get necessary health care further after completing trial
5. Parents with lower education levels, and those with lower income status have been reported to perceive lesser degrees of voluntariness associated with research decisions for their children.

These factors make research as part of clinical care in children very problematic.

5. ETHICAL STUDY DESIGN IN PEDIATRICS

1. Targeting the research question- the importance of minimizing risk and maximizing benefit centers on establishing an answerable research question.
2. Control group and placebo group- the choice of an appropriate control group should be based on both scientific and ethical principles.
3. The primary focus should be on using the appropriate comparator to show the safety or efficacy of the intervention e.g. placebo
4. It is commonly thought that the individuals assigned to the placebo group are receiving inferior treatment thereby compromising clinical equipoise.
5. Studies showed that placebo group has better outcomes than the pharmacologic intervention group.

6. NEED OF PEDIATRIC DRUG RESEARCH

1. Acknowledged different drug responses , toxicity and metabolism in adults versus children

2. Discouraged the study of drugs in children
3. Concerns related to ethical issues
4. Fears of harming children
5. Perceived increased liability of testing drugs in children
6. Lacked an incentive for drug companies or institutes to conduct pediatric trials.
7. Lack of potentially beneficial medications for use in children.
8. Treat with medications based on adult studies.

7. MAJOR ELEMENTS OF AN ADEQUATE AND WELL RESEARCH STUDY

1. Study should distinguish the effect of a drug from other influences such as placebo effect
2. Clear statement of purpose i.e. objectives
3. Adequate measures to minimize bias
4. Methods of assessment of response are well defined and reliable
5. Analysis of the results is adequate to assess the effects of the drugs.

8. STEPS TAKEN

1. Improve education
2. Understanding of Rights of pediatric assent
3. Conducting the process in a manner and location that ensures participant privacy
4. Giving adequate information about the study in a language understandable to the participant
5. Responding to the participants questions
6. Ensuring the participant has understood the information provided
7. Obtaining the participants voluntary agreement to participate
8. Continuing to provide information as the participant or research requires

CONCLUSION

It is the need of the hour to encourage researches in pediatric field as children are foundation stone of the nation. Children and families will benefit greatly from advances in research in pediatric field. Research involving children is essential if children are to share fully in the benefits derived from advances in medical science. , Some conditions such as prematurity, genetic disorders such as Phenylketonuria, there diagnosis, prevention and treatment cannot be adequately investigated without studying children. Therefore, it's the symbiotic relationship between parents, child and researchers.

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