



A Relook into Research Involving Children

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Opinion

Research involving children has always been a controversial issue. Various international bodies have issued guidelines on this matter, notable among which are the guidelines by the World Medical Association (WMA) Declaration of Helsinki [1], The Royal College of Paediatrics and Child Health (RCPCH) [2] and the Council for International Organizations of Medical Sciences (CIOMS) [3].

Data from research involving children is very scanty as children are often glossed over in any research considerations due to a long standing belief that they are vulnerable group, unable to give consent and are thus naturally excluded.

The exclusion of children from clinical researches can be a major setback especially in understanding natural course of diseases and exploring therapeutic strategies. Extrapolating miniaturised' data from findings in adult studies risks serious problems as metabolic differences in adults and children would surely make the extrapolation potentially dangerous. Often this approach of 'miniaturising' of data is simply not possible as some diseases are exclusive to children, such as diseases affecting preterm babies and those affecting babies in utero.

Another possible consequence of not doing research in children is that, there will be serious gaps in knowledge related to understanding of various aspects of developmental psychology and physiology. This aspect of research affects clinical trials as the physiological differences at various stages of development have major implications to the pharmacokinetics of drug metabolisms.

Serious neurodevelopmental disorders such as autism may remain understudied if the current age barrier affecting researches in children remain. These researches often rely on identification of children at risk, careful tracking of behavioural manifestations and sometimes on genetic information. Similarly the study into childhood cancers will be seriously affected if researches involving genetic predisposition, clinical trials of chemotherapeutic agents and in particular the detailed understandings of their pharmacokinetics are restricted by the age barriers. Epidemiology of these domains will be affected if children are broadly classified as 'vulnerable' and hence, researches on them are considered inappropriate. The repercussions from this could be serious especially in a less developed country where there is a lot of reliance on research findings done elsewhere in more developed countries and are less

likely to have the flexibility in approach especially in the areas of research.

It is well known that the main contributor to child mortality in any countries is death during the infancy stage. Hence the need to undertake research into all the contributing factors become more pressing, not only on the deceased child where sampling of body tissues could possibly be done, but also on siblings and relatives. Public policy discussions and epidemiological studies are also the natural outcomes of careful research, many of which will involve children and young adults. Such studies range from social issues such as delinquent behaviours, crime, drug taking and alcoholism and learning disabilities to other core issues such as understanding adolescent and pre-adolescent diseases. The barriers affecting children research will come into play should this issue remain unattended and not re-examined.

There is also a need to examine innovative drug delivery methods for children. Ineffective and age-inappropriate drug delivery will result in wasted resources from unfinished medication usage, dosing errors, poor absorption and unacceptable methods of deliveries that will lead to refusal.

Data protection and protection of personal and sensitive data especially in children has also affected research in children. This sensitive data, if kept unsecured and unencrypted will seriously compromise confidentiality of children and is especially relevant if the data involves audio-visual recording of children.

In short, the challenges of research in children stem from vulnerability and concerns of data protection and if unresolved, will continue to create gaps in knowledge, some of which will be detrimental.

Future for research in children

Bearing in mind the above need to have more research data in children and the serious constraints faced by researchers, newer innovative methods are needed in order to reduce the vulnerability of the young children and provide them with a better data protection for them and their families.

Invasive techniques for sampling of body fluids and tissues should be replaced by technologies using micro sampling of blood samples, or usage of sampling methods from secretory

and excretory body products such as sweat, urine and stool, body integuments such as hairs, nail clippings and skin swabs. The use of topical analgesia should make it possible for any blood taking or biopsies be done painlessly. Innovative drug delivery method such as that through mucosa, eye drops, or sprinkling methods should enable drug pharmacokinetics be studied in a better and a more pleasant environment. High resolution ultrasound and radiological procedures should enable close examination of body tissues without the need for tissue biopsies. Invasive electrophysiological and biosensor recordings should be utilized and supplemented by the use of WIFI or Bluetooth sensors, capable of sending research data collected in a non-invasive manner to a data repository.

A research needing visual and audio recording should be done discreetly using close circuit television, capable of recording long hours of data, without interfering with the child's natural environment and activities. Such method will prove to be useful in collecting data on behaviour of children and making early diagnosis of neurodevelopmental disorders that would benefit

from early intervention and rehabilitation. Current available technologies should enable a child's clothing be incorporated with necessary recording and biosensors to enable recording and recording of a child's data in a non-intrusive manner. The challenge is for researchers to work across disciplines, combining state-of-art technology with current knowledge of diseases affecting children and designing acceptable research protocols so that gaps in data on diseases affecting children could be filled without disturbing the comfort and dignity of children.

References

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