Bioethics and Innovation in Pediatric Nutrition Research

Noel W. Solomons

The Innovation Imperative in Pediatric Nutrition Research

Innovation is the process of introducing something new. With a growing population of children across the globe, and threats to food security coexisting with pandemic of overweight, innovative pediatric nutrition is urgently needed. Research in human subjects must take into considerations the rights, welfare and safety of the participants, governed and regulated by a code of bioethics. To the extent that innovative initiatives in the research agenda involve risks or other problems, the issues must be resolved satisfactorily or the innovation may be stifled. This paper reviews considerations on bioethics and innovation from ethicists, researchers and other stakeholders in various national and international contexts.

The Principles of Bioethics and Issues Related to Children

Bioethics is a code or convention for behavior governing interactions among participants in clinical, public health and biomedical research activities. The definitions and distinctions among terms of the Social Compact – values, morals and ethics – should be appreciated in their separate connotations (table 1). Four cardinal principles – autonomy, nonmaleficence, beneficence and justice – are the basis for bioethics (table 1) [1]. The impossibility to avoid all risk and to assure benefit, however, leads to a fifth principle, that of utility (maximizing benefits over risk) [2]. These principles operate in the context of all human research, with children constituting a specially protected group in which issues of and minimization of risk and of consent, assent and dissent are paramount.
Social Values in Setting the Pediatric Nutrition Research Agenda

How the whole community of stakeholders in nutrition research is taken into consideration, given voice and access to benefits is a matter of social values and a stage for international debate. A point of accord is that scientific investment should seek practical knowledge to be applied for human benefit [3, 4]. Technical experts (researchers) are seen by some as having inordinate input into agenda setting [3]. When consulted, other stakeholders voice priorities favoring a criterion of maximum potential for disease burden reduction, or even justice in final equity of distribution of benefit [3]. At the same time, the educational and career training aspects of the scientific enterprise cannot be ignored, while embodying a message that financial and organizational mechanisms that create the private good of products for better health care must address the public health requirements for global development [4].

Common Problematic Areas Related to Bioethics of Research in Children

We can highlight among the problematic areas for bioethics in children: interpretation of ‘minimal risk’ for the participation of healthy
Table 2. Outline of the proposed elements for development of an integrated research ethics system

- Development
- Enabling conditions
- National/regional strategies
- Institutional commitment
- Research ethics review
- Investigators conduct

Modified after Hyder et al. [5].

children in nontherapeutic studies, the use of (non-treatment) placebo controls in designs, and the collection and use of information from genetic biomarkers.

**International Dimensions of Ethics and Morality in Child Research**

Cultural values vary across societies, as do sophistication and power relationships. Harmonizing ethical norms and regulations across nations has been an issue in multi-collaborator research studies. Disrupting cultural patterns by enforcing new behaviors for research purposes can have unintended consequences. Compensating participants in low-income areas with sustained (post-trial) benefits or remunerating participants for the consequences of adverse effects are ethical dilemmas in the transaction with poor communities. Hyder et al. [5] seek to go beyond the narrow confines of ethics review to a more comprehensive strengthening of low- and middle-income societies for an ethics system (table 2).

**Bioethics and Innovation: The Way Forward**

The divergent nature of the considerations should be able to be brought into convergence for the sake of continuing innovation, by following the course of utility [2] to seek the steepest benefit-to-risk ratios with a profound attention toward safety and child welfare, and absolute respect for the subjects’ right of refusal.
References


