CASE STUDY

Ethics in nutrition intervention research

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Common infections precipitate malnutrition, which may in turn reduce resistance to other infections. The 1960s was a period of growing awareness of the interaction between infections and malnutrition. Up to then the research on and organisation of programmes for these two issues were separate enterprises.

A national medical research institute undertook a nutrition intervention study in rural India to address these issues. It was a study with multi-disciplinary participation of scholars/ researchers, and it had financial support from the UN, state agencies and the Indian government. The child nutrition programmes in the 1960s emphasised nutritional rehabilitation, which treated children with severe conditions like marasmus and kwashiorkor. The objective of this study was to examine the synergism between malnutrition and infections, and the implications of these links for policy and programmes for improving children's health.

The researchers felt that one way to examine the synergism between malnutrition and infections in young infants and children was to locate groups with a high prevalence of malnutrition and common infections and study them to explore what happens when efforts are made to selectively reduce each type of condition. The nutrition project was conducted in four clusters of 10 villages in three community development blocks. Comparability between different clusters of villages was ensured, along with sufficient separation in order to minimise communication among villagers who received different service packages.

The four clusters of villages were used for four arms of the interventions. The children in cluster one received only nutrition care (nutrition intervention or NI villages); cluster two had only health care for infection control (healthcare intervention or HI villages); cluster three had both nutrition care and health care for infection control (nutrition and healthcare intervention or NHI villages); and the children in the villages in cluster four were the control group (control villages). The nutritional input consisted of daily food supplements of calorie fortified milk in the mid-morning and porridge made from crushed wheat, milk powder, raw sugar and oil in the mid-afternoon, with a combined nutrient value of 400 calories and 11 grams of protein.

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The researchers sought the cooperation of the villages and negotiated with them until the combination of service interventions assigned to the village was accepted. There was no compulsion for families to cooperate, but all village leaders agreed to help persuade all the families to participate in the survey.

Findings

The study found that nutrition care alone or in combination with health care significantly improved both weight and height of study children beyond 17 months of age. At 36 months, children from the NI and NHI villages weighed, on an average, 560 gms more and were 1.3 cm taller than those in the control villages. A male higher caste child from an NI village or an NHI village averaged about 2 kgs more in weight and 6 cm more in height at 36 months than a female lower caste child from the control village. Peri-natal mortality was significantly reduced in the NI and NHI villages compared with only HI villages (31 v/s 45 peri-natal deaths per 1,000 live and still births) and it was higher in the control villages (57 per 1,000 live and still births). This was due to the supplements of iron and folic acid given to all mothers and additional feeding for mothers at nutritional risk. Neonatal mortality and post-neonatal mortality significantly reduced by one third to half in NI or HI villages vis-à-vis the control villages.

Controversy

About six years after the research was concluded in 1971, some Indian researchers expressed reservations about the idea of undertaking a study in such settings and the ethical justification for continuing to study a control group even though the implications of nutritional deprivation on child survival were clearly established. The study researchers contended that even in control villages, if the health workers found that a child was dying, going blind or suffering from other illnesses that would leave permanent damages, the worker was instructed to call the doctor to start intensive care.

Others have justified the study saying that: (a) in the late 60s and early 70s this was the understanding of scientific and ethical research. The scientists had done their best to ensure scientific validity by conducting and documenting the study carefully and drawing appropriate and cautious conclusions. (b) The study did not cause any additional harm and all that researchers did was to make use of an existing situation.

Questions for discussion

1. Were the researchers justified in using a control group that was selected to ensure a lack of communication between village clusters, and then continuing to maintain a no-intervention strategy while monitoring it?
2. What are the justifications for undertaking such a study? Could the study have been undertaken without a control group?
3. What would be the ethical dilemmas in doing such a study today? If you were asked to design such a study, how would you address these dilemmas?

***(Note:** Cases are fictional but based on real events. Names of individuals and organisations have been changed or masked.)*