CORRESPONDENCE

Ethics in nutrition intervention research: a response

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Several of the investigators who participated in the Narangwal studies during the 1960s and 1970s were recently made aware of the case study, "Ethics in nutrition intervention research" (1) published in the April-June 2007 issue of your journal along with responses from four reviewers (2-5). Although the case study did not explicitly mention the Narangwal Nutrition Study as the basis of the case, for those familiar with field research in India it was not difficult to identify the project involved. We therefore felt it appropriate to respond both to the content of the case study and specific comments by the responders in order to correct any misperceptions or possible errors in fact.

But first, we would like to commend the editors of the Indian Journal of Medical Ethics for their efforts to raise the important issues surrounding the ethics of medical research. It is refreshing to see old studies become subjects of review at a later date - almost 40 years in our case - if only to follow the development and progress of healthcare research over the years and our understanding of the ethical implications of such research.

There are some aspects in the way the case study was presented and in the responses to the case study that were apparent misunderstandings of the original study. We particularly would like to point out the following in both the case study and the responses:

The study was not located in an area with the highest prevalence of malnutrition and infection but in rural Punjab (rather than a poorer state), which had undergone the green revolution and in comparison with just a few years earlier had seen a dramatic improvement in child health as demonstrated by significantly reduced mortality. It was evident that severely malnourished children needed both medical and nutrition care, but that is not much of a guideline on how to approach a population with a high degree of mild to moderate malnutrition in order to prevent and or treat the whole population and avoid progression to severe malnutrition. One fundamental hypothesis of the study was that in the Punjab of the late 1960s the basic problem was the need for better understanding of the child's nutritional needs and the lack of appropriate care of common childhood diseases. The study coincided with the green revolution, so food security played a diminishing role as a factor responsible for malnutrition. In addition, the implications of extreme nutritional deprivation on child survival may have been established earlier, however the relationship between the degree of malnutrition and the risk of death was first and conclusively shown in the 1970's in two projects (The Narangwal Study in India and the Matlab Study in Bangladesh).

The choice of area was made on the basis of a relatively good health services network (Ludhiana Medical College outreach plus Punjab health services). While intervention villages were selected in clusters at a distance from government primary health centres (PHCs), the two villages for the nutrition "control" cell (and the four "control" villages of a parallel population project) were chosen on the basis of the Indian Council of Medical Research (ICMR) requirement that they be in easy walking distance of a PHC, giving them ready access to the services of the PHC. Thus the controls were never a "placebo" group. The leaders and inhabitants of these villages were well aware that they were subject to data collection on child morbidity, child growth and vital statistics only. They also were aware that if one of their children was seriously ill, the child would receive full treatment through the project physician, and alternately, if the parents preferred, through the nearest health centre (or hospitals in Ludhiana). This was in addition to ready access to primary care services from the nearby PHC. The intervention groups in the study were therefore set up to test what more could be done through improved health and nutrition services in comparison with the standard care available at the time.

It is our opinion that at the time of the Narangwal study scientific community health researchers felt the need to rely on "control" groups to differentiate "hypothetical" from "workable" solutions, and such studies were carried out in "developed" and "developing" societies alike. Over the years, many healthcare problems in India have been successfully researched by Indian institutions, using Indian research designs, which were no less solid than, and often not much different from Narangwal's. It should also be pointed out that the Narangwal Nutrition Study was set up at the request of the national government, specifically the minister of health, and the ICMR appointed a very senior committee to endorse and supervise all activities. Throughout the project's existence national institutions and national scientists were intimately involved in all aspects of the research. There certainly is some controversy currently in regard to the use of control areas in community research, but at the time of the Narangwal studies in the 1960s and 1970s, in all countries, the use of control or comparison areas was felt to be essential.

We fully agree with the observation that control communities should not be put at risk, and the benefits of the intervention must be made accessible to them, or there should be a plan to do so. The fact that control villages ultimately did not benefit from the interventions was essentially related to political repercussions following the Indian-Pakistani war of 1971 which brought the study to an abrupt halt in 1974 and with it any chance to initiate "after-project" care. If the study would have had more years of functioning we planned to sequentially initiate the separate interventions in the control villages until each village received the fully integrated package.

We welcome this opportunity to comment on the case study and the responses that were published in your journal. In addition we hope these comments will contribute to the important dialogue on the ethical issues involved that need to be engaged in by all investigators contemplating community based research. We have given, below, some additional references to Narangwal publications (6-14).

Members of the original field team who participated in drafting this response are: ***Dr DN Kakar, Chandigarh, and, in the US and Europe, Drs Bob Parker, Ardy Kielmann, Cecile DeSweemer, Bill Reinke, and Colin McCord.***

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