

## STRUCTURED, HOLISTIC APPROACH FOR RESEARCH PLANNING (SHARP)

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The SHARP method is a structured approach for developing a research proposal that can be used by individuals or by teams of researchers.<sup>1</sup> SHARP encourages the drawing together of researchers from interdisciplinary sciences with different experience and expertise. The method comprises eight consecutive steps:

1. Set up a causal model
2. Establish a fact-hypothesis matrix
3. Develop a variable-indicator-method matrix
4. Select the study design
5. Define the sampling procedure and calculate the sample size
6. Select the statistical methods
7. Consider the ethical aspects
8. Set up an operational plan.

The key terms of the SHARP approach are participation, visualisation and documentation. This participatory and visualisation process was followed by group members at the Urban Nutrition Action workshop. A report of the outcomes is given below.

### REPORT OF GROUPWORK, DURBAN, 6 MARCH 1999

Participants introduced themselves and explained their nutrition-related interests. Each group member had previously written one or more ideas of a research topic related to urban nutrition on a card. The majority of the cards identified topics on infant-related nutrition, health or disease. Group members were again asked to formulate one idea for a research study, which led to the following research questions and remarks:

- What is the most cost-effective way of improving nutritional status of infants?
- What is the best way of determining weaning practices and how does it influence growth?
- What are the proportions of energy and micronutrients in diets of children in the age group 4 - 60 months?

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- If weaning is done at an early stage at least the diet should be good.
- There is a need to establish accessible facilities to support working breast-feeding mothers.
- How can good lifetime eating habits be developed at the time of weaning?
- How can child (and adult) health be promoted through appropriate transition from breast-feeding?
- What is the association between weaning and eating practices in childhood and later development of lifestyle diseases?
- What is the most cost-effective method to increase breast-feeding practices?
- Does breast-feeding promote seroconversion of HIV infection in infants of HIV-positive mothers in cities?

### Establishing a causal model

The group proceeded to establish a hierarchical causal model (frame of thinking) by identifying all relevant variables associated with the topic of infant nutrition (each factor was written on a separate card and pinned to a board). The purpose of the causal model is to establish a logical framework of causal influence that will allow the identification of a central hypothesis for the study. The causal model originally identified 'biomarkers of non-communicable diseases' as the outcome of the study, and therefore this card was placed at the apex of the 'tree' (Fig. 1). Physical activity, nutritional status, infection, environmental factors and genetics were identified as the key causal factors.

Time constraints did not allow for the development of a complete causal model. Therefore, a decision was taken to concentrate and expand on one branch of the model, i.e. nutritional status. After much discussion and debate, variables in the causal model were rearranged to reflect logical associations between the variables, using directional arrows (Fig. 2).

### Identifying the research question

A research question then had to be defined. All group members were again asked to brainstorm and submit one research question, which resulted in the following questions and the subsequent addition of 'HIV status' to the first level of the causal model.

- Does strengthening social support networks and treating maternal depression improve breast-feeding practices?
- How can child nutrition be maximised through appropriate feeding?
- Does breast-feeding increase seroconversion of HIV in infants of mothers who are HIV-positive?
- Breast-feeding and weaning practices in relation to later

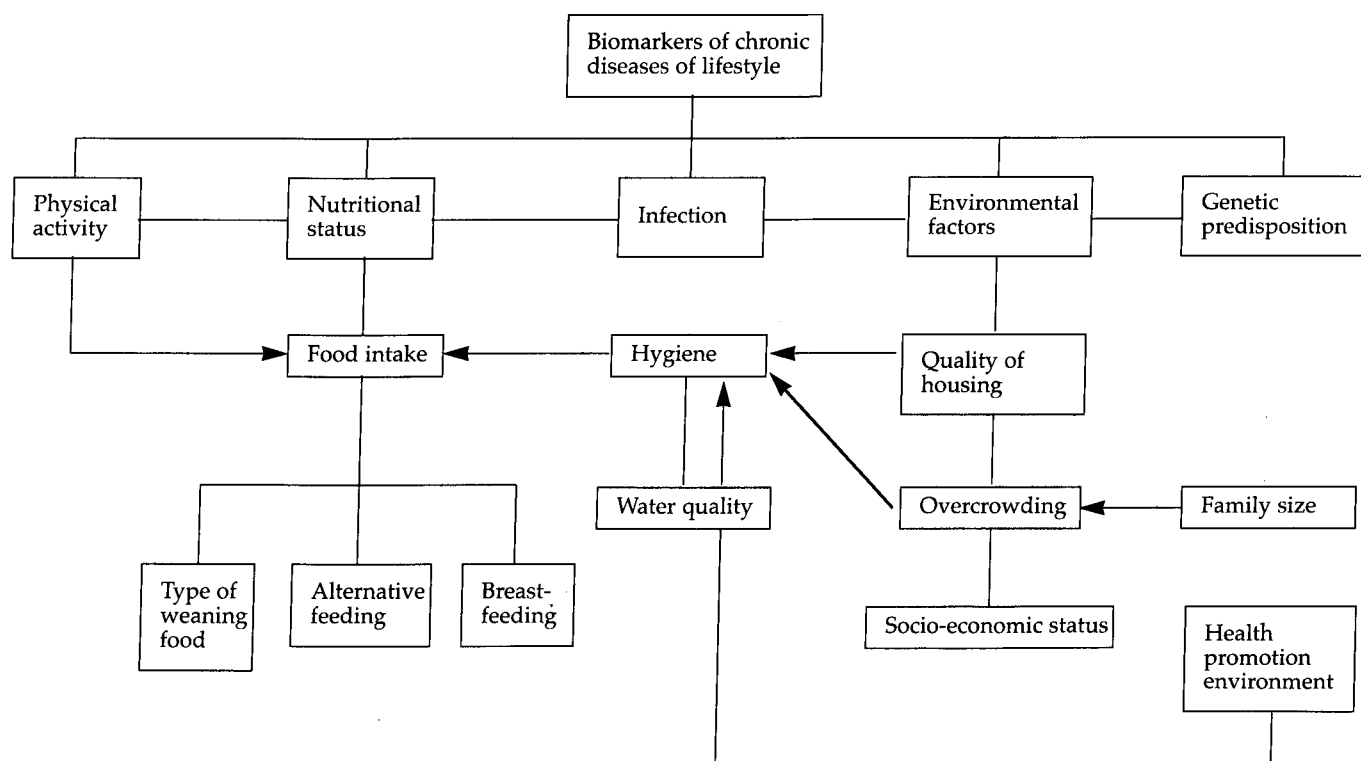


Fig. 1. Causal model – first stages of development.

development of lifestyle diseases.

- How can good eating practices be developed during the weaning period?
- What is the most cost-effective way of improving nutritional status in children younger than 2 years?

After voting, the following final research question was generated: Does breast-feeding of HIV-infected children for 6 months (or other time frame?) increase their lifespan and nutritional status?

### Establishing a variable indicator matrix (VIM)

A variable indicator diagram is a systematic way to organise the relationship between variables of interest and potential indicators for these variables. Each of the variables in the causal model should be transferred to the VIM. Time constraints of the workshop did not allow for the development of a complete VIM. However, Table I demonstrates the process of arriving at the VIM.

The VIM requires a fourth column which lists references for the selected method. Again, time constraints did not allow for consultation of the literature. In some cases, it was felt that the method may need to be developed and tested by the researchers through a pilot study in order to validate the method in the population under study (i.e. existing quality-of-life measures assume certain cultural perceptions and norms).

### Selecting the study design

A consensus on the study design could not be reached without a detailed discussion of ethical issues. Particular areas of concern were:

- Sampling. Subjects to be included in the study are those who are HIV-positive. Routine HIV status testing does not occur in South Africa. Therefore, maternal consent to screen babies is needed before the birth of each infant. Identification of an HIV-positive baby will identify the HIV status of the mother. Many mothers may not wish to know the HIV status of either their babies or themselves.
- Allocation of intervention (method of feeding). Random allocation to intervention group (bottle or breast-fed) removes the choice from the mother. Influence by family members could affect compliance of mothers regarding method of feeding. Even following the recent WHO guidelines, which recommend that mothers of HIV-positive infants should not breast-feed, many women may not be willing to expose their HIV status to other family members and may be pressurised to breast-feed, particularly by older female relatives who are co-residing.
- Treatment of symptoms of HIV-related infection (by the researchers) may affect nutritional status. For example, the treatment of oral thrush may result in better feeding and increased hunger, which may result in bias between the

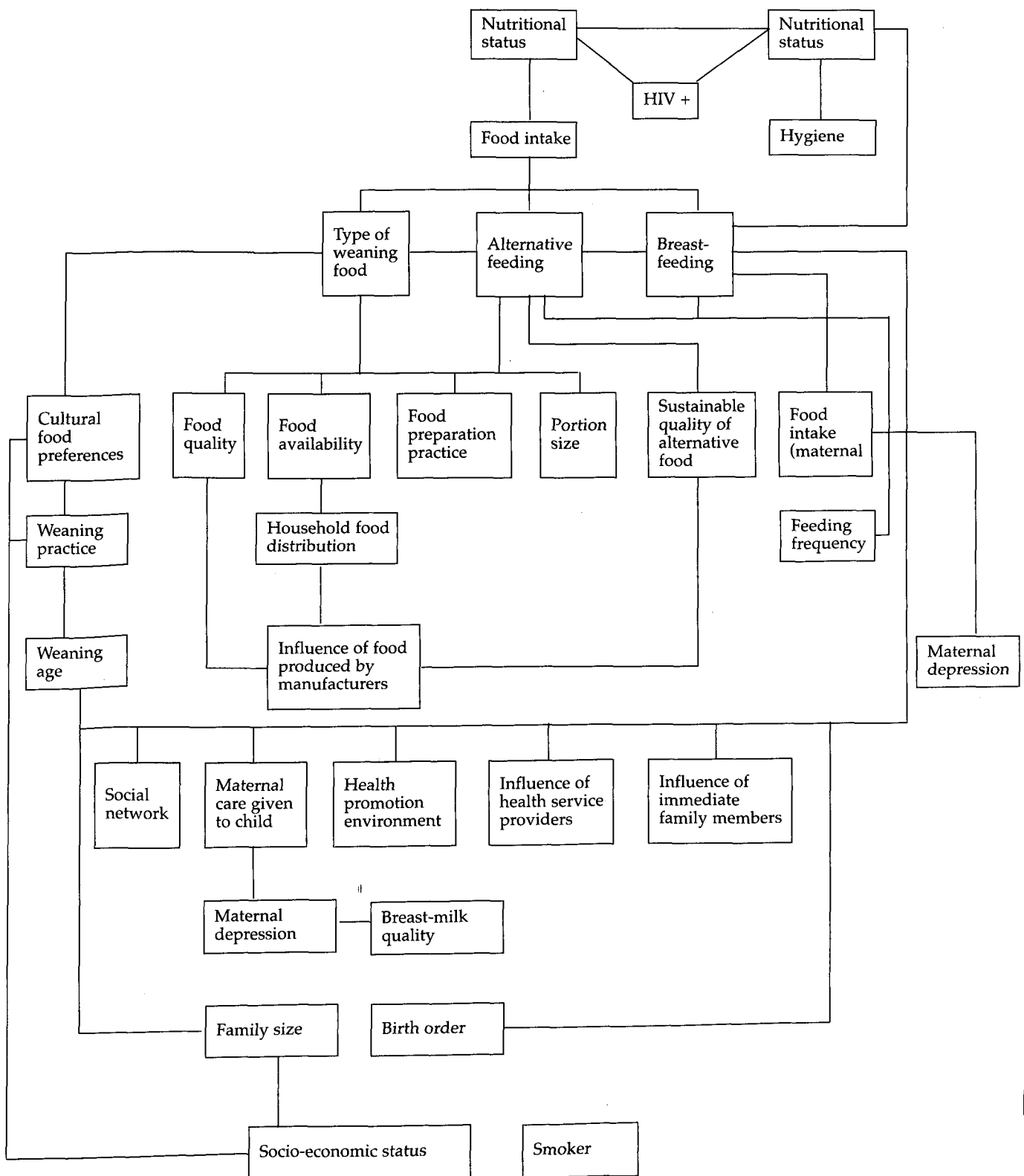


Fig. 2. Expansion of the causal model for 'nutritional status'.

Table I. An example of a variable indicator matrix (VIM)

Variable	Indicator	Measure
Progression to death/lifespan	Age at confirmed death	Birth and death certificates
Nutritional status	Change in: Weight for age z-score Height for age z-score Weight for height z-score	Balance scale, birth certificate (Road-to-Health clinic card), infantometer
<b>Food intake</b>		
Breast-milk	Intake of breast-milk in 12 hours	Repeated 12 h in-home test weighing
Formula	Intake of formula in 12 hours	Disappearance of formula plus repeated test weighing
<b>Quality of food/water</b>		
Breast-milk	Nutrient composition	Chemical analyses
Formula		
Water quality	Bacterial contamination	?
HIV status	Viral counts	?
Quality of life	Maternal-reported symptoms	Questionnaire (maternal reports)
Infectious diseases	Duration and prevalence of acute respiratory infections	Questionnaire, medical reports

study groups. Is it ethical not to treat symptoms? Should mothers not at least be informed about appropriate treatments which affect quality of life and health status of the infant? However, this would affect the outcome of the study.

Inconclusive debate was generated around the issue of whether it was ethical or not to intervene if access to standard treatment was not compromised through the study design.

In addition, the following non-ethical issues related to determining the study design were discussed:

- Exclusivity of breast-feeding
- Dilution of formula feeds
- Study budget
- Duration of feeding as the intervention (1 month versus 6 months)
- Endpoints (difficulty of obtaining death certificates and duration of study).

It was finally agreed that the appropriate study design was a 'randomised clinical trial'. The intervention would be either breast-feeding or formula-feeding during the first 3 months of life of infants who are HIV-infected. No conclusion was reached as to whether the breast-fed children should be exclusively breast-fed or not.

### Statistical methods

Survival analysis is the appropriate statistical method in studies where the endpoint is death.

An operational plan could not be drawn up — at least an additional day would have been required for this.

### CONCLUSION

The SHARP process is designed to be all-encompassing of a particular research area. However, the participants agreed that although expansion of a topic was a valuable exercise, particularly to identify potential confounders, it was necessary to narrow the focus of the question in order to arrive at a feasible research protocol.

The experience of the group was that the democratic process of defining a hypothesis (research question) retarded the progress of the group and that the product of the workshop may have been more substantial if one research question had been agreed upon before moving to the development of a causal model.

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### Reference

1. Gross R, Karyadi D, Sastroamidjojo S, Schultink W. Guidelines for the development of research proposals following a Structured, Holistic Approach for a Research Proposal (SHARP). *Food and Nutrition Bulletin* 1998; 19: 268-282.