OVERVIEW OF PROTOCOL

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In June of 1992 a five day workshop was held at Tufts University in Boston under the auspices of the United Nations University to discuss methodological problems in using the IUNS protocol. All participating centres attended (Australia, Greece, Sweden, China, Philippines), as well as centres which intended to take part in the study (Indonesia, Guatemala, Costa Rica). A total of 8 sites were studied: 2 Greek (Spata, Greece and Melbourne, Australia), Melbourne Anglo-Celtic, Swedish, 3 Chinese (Beijing and 2 in Tianjin) and Philippino. Experts on conducting epidemiological studies on food habits and health were also invited to obtain a critical appraisal of the protocol. Views were heard from researchers that had already used the IUNS protocol as well as problems foreseen by researchers that wished to administer the protocol in their country. In summary, the major issues raised at the workshop for various aspects of the IUNS protocol were as follows.

2.1 GENERAL

Cross-sectional studies cannot prove causality, so this study has power only for associations. Causality can only be inferred by longitudinal, prospective data or data from intervention studies. It is intended to make the IUNS study longitudinal by going back to communities studied after 5 years and ascertaining change in health and function of study subjects (or cause of death) and changes to dietary habits.

Sampling elderly survivors is significant. In this study both industrialised and non-industrialised countries are included. In the former both 'weak' and 'strong' survive due to access to medical care and thus the protective or restorative effect of food may be weak or unapparent. Where as in the latter only the 'strong' survive enabling food-health relationships to surface. Thus, it is important to include developing countries in such studies.

In developing countries it may be best to begin with a study in an institution for the elderly to get background information and experience before moving into the community.

Selective mortality is the grim confounder of cross-sectional studies. It makes the decile approach (taking the upper decile of the population when it is not possible to obtain enough

subjects aged over 70) a fallacy because it may be quite different in a community that has experienced a catastrophe compared to an unscathed community. Thus, the top decile may mean quite different things in different populations.

In some communities age is not accounted for until the completion of the first year. This needs to be specified and adjusted for.

Food habits of the elderly may not be reflecting recent trends but rather more traditional practices.

It is important to note the effect of rapid change, for example, in Sweden ten years ago only 20% had a deep freeze where as today 90% have this facility. The study only describes prevailing conditions at the time of interviewing.

Data collected are not representative of countries but only of sites.

It is important to take the communities studied as a unit of observation and recognise how different they are from each other.

What constitutes rural, semi-rural or urban communities needs to be further defined in protocol.

It is important to put equal emphasis on negative as well as positive findings with due allowance for type 2 errors.

The presentation of the data need to have not only the means but also the distribution to illustrate cases of marked skewing. The median may be better than the mean if there is marked skewing.

2.2 QUESTIONNAIRE

2.2.1 Adaptation

It is important to review the questions carefully before applying them to a community because there is difficulty in comparing items for studies in developed countries to studies in developing countries. Each question had to be adjusted to the individual populations. Many questions were wholly irrelevant, not feasible or not culturally appropriate.

In order to make the questionnaire culturally sensitive to the community being studied, the following should be asked for each question:

1. Is the information sought relevant?
2. Is the question feasible and culturally appropriate?
3. What would be the reliability of the question?

4. What would be the validity of the question and answers?

In developing countries the list of health conditions in the questionnaire will need to be extended to include more communicable diseases since the non-communicable diseases such as heart disease are just becoming major health problems in these countries.

Cognitive function was one of the more difficult areas to deal with. Questions were not found to be cross-culturally appropriate and language based questions were not useful. It is an important area but the study does not have a satisfactory methodology. This will need to be resolved by some other body and their recommendations utilized.

2.2.2 Administration

There was a need to ask tactful probing questions about certain topics, for example, to obtain information on socially unacceptable food and drink behaviour which might not otherwise be admitted.

RAP methodology was useful for probing and checking what study subjects actually do as opposed to what they say they do, although subjects can still deceive observers.

RAP can be used for:

1. background data
2. appropriate questions
3. testing, checking, cleaning, monitoring
4. evaluation, follow-up

The interviewer selected for the study can make a big difference in the results obtained. If the right persons are not selected to do the interviews, there can be a lot of misinformation obtained. Selection should not depend upon disciplinary background but on sensitivity, community experience and attitude. It is very important for the interviewer to understand the culture of the community with which they will be dealing.

The gender of interviewer may also influence answers obtained on some questions (for example, prostate problems). Also researchers need to decide whether interviewers should be 'insiders' or 'outsiders' of the community being studied. 'Insiders' may try to shape the outcome of the study to their liking or advantage.

There needs to be an awareness of cross-cultural differences in the interpretation of specific questions and answers, for example, cultural differences in subjective criteria for 'health', 'active', good sensory function (vision, hearing), or good memory.

There is a need to consider food that is given to the elderly but is not actually consumed by the individual.

Need to look at relation of size of household to intake of the elderly, for example, food that is reported may actually be eaten by others.

The study should look for specific types of social activities (such as those geared to seniors) as well as others that are substitutes or equally important. Therefore, each centre should include activities relevant to their study community as well as including open ended questions to avoid missing other activities.

Social contact questions (visits, phone calls) can be biased by lack of memory of these contacts, or they may be so normal, that they are not reported as special events, therefore a little probing may be needed. What is important here is the quality of contacts and their impact.

2.2.3 Intrepretation

Cultural differences in educational systems can often make cross-country comparisons difficult.

Answers about income are notoriously difficult; if work earnings in addition to pension is legally limited then true income may not be admitted. It may be more useful to ascertain the source of income to get a qualitative picture of financial status.

Questions on health conditions are intended to be used as point prevalence data (past 12 months) as opposed to period prevalence data (life time) since memory of disease depends on its severity as well as frequency.

The food frequency method was used in the IUNS study. Due to the large number of foods listed it tends to overestimate food intake. Therefore, it is important to recognise that some people are going to be grossly misclassified, but with any dietary method values at the extremes are likely to be artifacts or errors and probably best excluded from analyses.

The decision as to which nutrients to calculate will depend upon the adequacy of food composition data bases in participating countries.

Data on snacking are not amenable to mathematical treatment. However, the impact of snacks on health needs consideration.

Data on the nature of fluctuating food intakes and the cause of fluctuation are important as well as their impact on health. These fluctuations may be due to season, supplies, religious holidays, field work, varying food prices, etc.

It is difficult to determine salt use in cooking. This can be checked by urinary sodium. The prestige of salt may influence reporting.

2.2.4 Limitations

Social networks are very important in health outcomes. However, patterns of social support and ties can be the consequences and not the cause of illnesses. There is a need to adjust for functional health and physical disability. Also, some apparent nutrient effects could be related to social factors responsible for the diet differences. There are some social variables missing from the questionnaire which may have introduced some difficulties in interpretation.

The following issues needed greater depth of treatment:

1. Vulnerability to hunger or food security
2. Focus on isolated individuals
3. Elderly's command over food and resources
4. Eating environment, ascertained by questions such as: With whom do you eat? Who do you see during a day? How many people? The emphasis should be on finding out about 'eating or drinking together' rather than if they 'eat out' or 'eat in'.
5. Social support including emotional, information, material.
6. Depression (which is generally not looked at in enough detail)

Scores were constructed but not tested for robustness cross-culturally for the IUNS study. There were a few concerns regarding the scoring system. In the construction of any score such as the social activity score, the importance of its various components may vary differently among societies, which may need to be weighted by the importance of the component in that community. The scores might not mean what we think they mean. It is important that a score picks up the critical range-- for example does activity in an active culture mean the same as in an inactive culture.

2.3 ANTHROPOMETRY & BIOLOGICAL MEASURES

Although the protocol and manual of operations provided specific instructions on how to perform anthropometry, a central training session was not possible and thus may have contributed to inter centre variations.

The study uses the umbilicus as opposed to the natural waist, as a marker to measure waist circumference, but the shape of men and women is different and thus may bias results. The umbilicus is below the natural waist. Women tend to deposit fat below the umbilicus resulting in higher values than men. Men are more tubular and the difference between measuring at the umbilicus and the natural waist are small. An anthropometric consensus conference recommended the use of the natural waist. In future studies perhaps the natural waist should also

be measured.

Electrical impedance measurements use manufacturers equations and these are not applicable across ethnic groups.

Skinfold values vary with type of caliper used. Each study should specify the type used, preferably Harpenden.

With age there is a loss of height resulting in an increase in body mass index (BMI) even if weight remains stable. Does this mean that elderly should lose weight as they age or should the normal BMI range increase to accommodate loss of height?

The response rate for blood tests was low in most study sites (<60% of sample) and therefore unrepresentative of the total sample. Many of the elderly subjects did not want to have a blood test due to their age or because they had already had blood tested by their own doctor. Furthermore, some elderly subjects felt that too much blood was taken (30-40 ml) and that in their old age this was undesirable. To overcome blood sample problems, new ultra-micro methods or urinary excretion nutrient determinations, should be considered.

When presenting data from blood tests, it may be better to present distributions rather than using cut-off points. If values are below cut-off points but the population is healthy, then this raises the question of interpretation. Furthermore, vitamin supplementation (such as B12 injections) can result in very high blood values, which should be taken into account when presenting and interpreting data.

2.4 SUMMARY

The IUNS study has a cross-sectional design, therefore it cannot prove causality-- it has power only for associations.

It is intended to make the IUNS study longitudinal by going back to communities studied after 5 years and ascertaining change in health and function of study subjects (or cause of death) and changes to dietary habits.

Only a prospective study can tell what nutritional factors earlier in life affected survivorship. However, the way in which food confers ongoing health status on survivors in a cross-sectional study was worthy of enquiry in its own right.

Data collected are not representative of countries but only of sites.

It is desirbale to use anthropological methods (Rapid Assessment Procedures-- RAP) first, to make an initial appraisal of the community (e.g. background data, culturally sensitive/

appropriate questions, inclusion of culture specific foods) in order to make suitable adjustments to the 'core' IUNS questionnaire. RAP is also useful for cross checking data collected by 'triangulation' and for collecting information on food beliefs.

Cognitive function was assessed with the Mini-Mental Status questionnaire (MMSQ) where possible. Questions were not found to be cross-culturally appropriate and relied on subjects being literate. Therefore, the majority of centres cound not use the MMSQ. This will need to be resolved by some other body and their recommendations utilized.

The validated health score from the Philadelphia Multi-level Assessment instrument was used in this study to describe health status. Other scores constructed for the study, but not yet validated, included the following: well-being, memory, social activity, social networks, activities of daily living and exercise. Judgements were not made on the importance of various questions over others i.e weighting of questions comprising a score was not performed.