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Date 18 october 1984

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Principal Investigator BRIEND

Application No. 84-044(P)

Title of Study Evaluation of the risk of death by nutritional status of children admitted in ICDDR,B hosp

Trainee Investigator (if any) J. DYKEWICZ

Supporting Agency (if Non-ICDDR,B) _____

Project status:
( ) New Study
( ) Continuation with change
( ) No change (do not fill out rest of form)

Circle the appropriate answer to each of the following (If Not Applicable write NA).

1. Source of Population:
   (a) Ill subjects (Yes) No
   (b) Non-ill subjects Yes No
   (c) Minors or persons under guardianship (Yes) No
2. Does the study involve:
   (a) Physical risks to the subjects Yes (No)
   (b) Social Risks Yes (No)
   (c) Psychological risks to subjects Yes (No)
   (d) Discomfort to subjects Yes (No)
   (e) Invasion of privacy Yes (No)
   (f) Disclosure of information damaging to subject or others Yes (No)
3. Does the study involve:
   (a) Use of records, (hospital, medical, death, birth or other) (Yes) No
   (b) Use of fetal tissue or abortus Yes (No)
   (c) Use of organs or body fluids Yes (No)
4. Are subjects clearly informed about:
   (a) Nature and purposes of study ~~NA~~ (Yes) No
   (b) Procedures to be followed including alternatives used Yes No
   (c) Physical risks Yes No
   (d) Sensitive questions Yes No
   (e) Benefits to be derived Yes No
   (f) Right to refuse to participate or to withdraw from study Yes No
   (g) Confidential handling of data Yes No
   (h) Compensation &/or treatment where there are risks or privacy is involved in any particular procedure Yes No

NA

5. Will signed consent form be required:
   (a) From subjects Yes (No)
   (b) From parent or guardian (if subjects are minors) Yes (No)
6. Will precautions be taken to protect anonymity of subjects (Yes) No
7. Check documents being submitted herewith to Committee:
   ___ Umbrella proposal - Initially submit an overview (all other requirements will be submitted with individual studies).
   ___ Protocol (Required)
   ___ Abstract Summary (Required)
   ___ Statement given or read to subjects on nature of study, risks, types of questions to be asked, and right to refuse to participate or withdraw (Required)
   ___ Informed consent form for subjects
   ___ Informed consent form for parent or guardian
   ___ Procedure for maintaining confidentiality
   ___ Questionnaire or interview schedule *

* If the final instrument is not completed prior to review, the following information should be included in the abstract summary:
1. A description of the areas to be covered in the questionnaire or interview which could be considered either sensitive or which would constitute an invasion of privacy.
2. Examples of the type of specific questions to be asked in the sensitive areas.
3. An indication as to when the questionnaire will be presented to the Cttee. for review.

e agree to obtain approval of the Ethical Review Committee for any changes volving the rights and welfare of subjects before making such change.

J. Briend — 23 OCT 1984 — Marc ADYKEWICZ

Principal Investigator — Trainee

84-044 (P)
23.10.84

SECTION I - PILOT PROTOCOL

1. TITLE: Evaluation of the risk of death by nutritional status in children admitted in ICDDR,B hospital

2. PRINCIPAL INVESTIGATOR: A. Briend

CO-INVESTIGATOR: C. Dykewicz, Ramendra Nath Majumder

CONSULTANT: M. Bennish

3. STARTING DATE: October 1984

4. COMPLETION DATE: April 1985

5. TOTAL DIRECT COST: TK. 10,700

6. SCIENTIFIC PROGRAM HEAD:

This protocol has been approved by the Nutrition Working Group

Signature of the Program Head:

Date: 15/10/84

7. ABSTRACT SUMMARY:

During a three months peiod, all children admitted in ICDDR,B hospital will be weighed and measured by one of the investigators. Serum protein hemoglobin and serum electrolytes levels will be also recorded. All these variables will be entered in a personnel computer and will be used to assess the risk of death associated with malnutrition in hospital patients. The predictivity of all classical nutritional indices will be also compared.

8. REVIEWS:

(a) Ethical Review Committee: _____

(b) Research Review Comittee: _____

(c) Director: _____

SECTION II - RESEARCH PLAN

A. INTRODUCTION:

Objective:

The objective of this protocol is to determine the relation between the nutritional status of the child as assessed by anthropometry and biochemistry and the risk of death in hospital. It will also determine which nutritional indicator is the best predictor of the risk of death.

Background:

The risk of death associated with malnutrition has been established by several studies in Bangladesh in children living in the community. Paradoxically, a study of the risk of death associated with malnutrition in hospital patients is lacking. Such a study however would rapidly provide information which is difficult to collect from community surveys since very large sample are needed to have a substantial number of deaths to allow a statistical analysis. On the other hand, the routine biochemical tests made for the clinical management of patients makes available for statistical analysis a mass of information which would be ethically difficult to collect from healthy subjects with no medical problems.

Two types of questions can be rapidly answered by a small study in the hospital. First, a multivariate analysis of all the anthropometric variables will indicate which one has the best predictive value to detect the patients with a high risk of death. Most clinicians still rely to assess malnutrition on the weight for age ratio although a same ratio can describe very different clinical situation. The validity of weight for height to predict short term outcome could be tested.

Secondly, the cut off point which is optimal to discriminate the patients with a high risk of death is still an open question in Bangladesh and a study of the relation between anthropometry and mortality in the hospital could give some clues on this point.

These questions which are apparently simple have not received so far an adequate response. One reason for that may be that they involve rapidly complex statistical analysis which until recently could only be carried out with extensive computer facilities. The presence of personal computers in the Centre makes however these analyses possible at almost no incremental cost.

B. PROCEDURE

During the study period, every under 5 child admitted to ICDDR,B Dhaka hospital will have the height, weight, arm circumference, triceps and subscapular skinfold thickness, chest, arm and head circumference carefully measured by one of the investigators. Some of these measurements will have to be made if needed post-mortem if the child dies just after admission. These anthropometric data will be routinely entered in a personal computer with the biochemical parameters known to be affected by malnutrition: total serum albumin, hematocrit, potassium and sodium levels. All these analysis are made routinely for patients and no extra blood sample or analysis will have to be done for the present protocols.

Presence of oedemas and signs of xerophtalmia will also be recorded.

Statistical Analysis

First, all the variables entered in the computer will be compared in an unvariate approach. The variable which will be found to be significantly different between the children who die in the hospital and those who survive will be introduced in a multivariate model: logistic equation or discriminant analysis. This will

determine which variable are the most relevant to predict death.

C. SIGNIFICANCE

This study will provide useful information at two levels. First, for hospital practice, it will provide information on the prognostic value of the different variables which are collected routinely in the hospital. Secondly it will give rapid information on the relation between anthropometry and mortality in the hospital setting which may be useful to know before starting a major survey on this subject in the community.