Attachment 1.
(FACE SHEET)

Date 12/05/91

ETHICAL REVIEW COMMITTEE, ICDDR,B.

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Principal Investigator DR A.M.M ANISUL ALWAL
Application No. PCC/004/91
Title of Study THE NEONATO-MATERNAL RELATIONSHIP IN THE POPULATION OF A VARYING GRADES OF IODINE DEFICIENCY AND RANKING OF SOME INDICATORS.

Trainee Investigator (if any) _____
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 — (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
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.

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

Principal Investigator

Trainee

B. SECTION 1 : RESEARCH PROPOSAL

1. Title of the proposal: THE NEONATO-MATERNAL RELATIONSHIP IN THE POPULATION OF A VARYING GRADES OF IODINE DEFICIENCY AND RANKING OF SOME INDICATORS.

2. Principal Investigator : **Dr. A.M.M. Anisul Awwal**
Division Chief, Field
IPHN.

3. Co-investigators : **Mr. M.A. Wahed**
Head, Bio.& Nutrition, LSD, ICDDR,B
Dr. Udoy S. Anwar
M.O., Community Health Div. ICDDR,B

4. Consultants : **Dr. Md. Jahangir**, Director, IPHN
Prof. Peter Heywood,
Director, Community Nutrition prog.
Queensland University,Australia.
Prof. Andrew Tomkins,Director
Dept. of International Child Health
Institute of Child Health, London,UK.
Dr. George Grimble, Sr. Biochemist
Dept. of Gastroenterology & Nutrition
Central Middlesex Hospital,London UK.

5. Starting date : 1st June,1991.

6. Completion date : 28th February,1992 (Total 8 months).

7. Total direct cost : US$6000 (six thousand US$ only)

8. Recommendations :

Md. Jahangir 12-5-91
(a) Director,IPHN.

14/5/91
(b) Associate Director, LSD, ICDDR,B.

9. Abstract Summary:

This research is a cross-sectional study involving mothers, neonates and the women of child bearing age (WCBA). The field research will be done in Rangpur, Rajshahi, Barisal and Dhaka and would continue for 8 months from the date of commencement.

0.25ml venous blood would be taken from the mothers as well as WCBA. Two drops of left out cord blood would also be required. Filter paper method (FPM) would be used to collect the blood. Ten ml (10 ml.) urine would be taken both from the mothers and the WCBA. Toluine would be used as preservative.

This research aims to see the neonato-maternal relationship with respect to T4, TSH, Urinary iodide and goiter in the population with varying grades of iodine deficiency.

The other aims of the research are a) to see the incidence of neonatal chemical hypothyroidism (NCH); b) to see the prevalence of biochemical hypothyroidism amongs the pregnant women and the WCBA; c) to determine the best indicator of iodine status and rank the indicators on the basis of their practical and scientific utility and d) to see whether the iodine status of the WCBA can be used as an alternate approach for assessing the iodine status of the community.

C. SECTION II. RESEARCH PLAN:

1. AIMS OF THE RESEARCH PROJECT:

a. GENERAL AIMS:

1. TO SEE THE NEONATO-MATERNAL RELATIONSHIP WITH RESPECT TO T4, TSH, URINARY IODIDE (UI), AND GOITER IN THE POPULATION WITH VARYING GRADES OF ICDINE DEFICIENCY.

2. TO SEE THE INCIDENCE OF NEONATAL CHEMICAL HYPO-THYROIDISM (NCH) IN THE POPULATION WITH DIFFERENT GRADES OF IODINE DEFICIENCY.

3. TO SEE THE PREVALENCE OF BIO-CHEMICAL HYPOTHYROIDISM AMONG THE PREGNANT WOMEN, AND WOMEN OF CHILD BEARING AGE (WCBA) OF THOSE IODINE DEFICIENT AREAS.

4. TO DETERMINE THE BEST INDICATOR OF IODINE STATUS AND RANK THE INDICATORS ON THE BASIS OF THEIR PRACTICAL AND SCIENTIFIC UTILITY.

5. TO SEE WHETHER THE IODINE STATUS OF THE WCBA CAN BE USED AS AN ALTERNATE APPROACH FOR ASSESSING THE IODINE STATUS OF THE COMMUNITY.

B. SPECIFIC AIMS :

1. Examination of the thyroid gland to detect the presence/absence of the goiter on the basis of WHO classification.

2. Sample collection and laboratory analysis.

3. Identification of the Iodine status of individuals, and the groups.

4. Incidence and prevalence of biochemical hypo-thyriodism among the neonates, and mothers in the study areas respectively.

5. Prevalence of biochemical hypothyroidism among the WCBA of those areas.

6. Determination of the biological relationship of the neonates and their mothers with respect to T4, TSH, UI, and Goiter in the population with varying grades of Iodine deficiency.

7. Determination of the best indicator of Iodine status and ranking of the indicators on the basis of their practical and scientific utility.

8. Developement of a new and sensitive method for measurement of urinary iodide.

C. SIGNIFICANCE: EXPECTED CONTRIBUTION OF THE PROPOSED RESEARCH:

The research is expected to contribute :

1. To know, for the first time, more clearly the impact of Iodine deficiency on the mothers and the neonates simultaneously, and the relationship between them in different grades of Iodine deficient areas.

2. To determine the relationship of the incidence of NCH with varying grades of Iodine deficiency.

3. To determine the relationship of the prevalence of biochemical hypothyroidism among the pregnant women and WCBA with different grades of Iodine deficiency.

4. To determine the best indicator of Iodine status at the community level and rank the indicators in order of their merits.

5. To recommend the area specific, and cost- effective appropriate interventive programs for Bangladesh.

2. Ethical implications:

This research is a cross-sectional study involving mothers, neonates and the women of child bearing age (WCBA). The field research will be done in Rangpur, Rajshahi, Barisal and Dhaka and would continue for 8 months from the date of commencement.

0.25ml of venous blood would be taken from the mothers as well as WCBA. Two drops of left out cord blood would also be required. Ten ml (10 ml) urine would be taken both from the mothers and the WCBA.

The confidentiality of the subjects involved will be maintained. There is no risk of physical or mental trauma to the subjects and he/she will have the right to withdraw his/her name from the research any time. Informed consent would be obtained from the WCBA, the pregnant mothers and the legal guardians of the neonates.

There would be no negligence in the treatment if anybody refuses to participate in the research or withdraw from the research at any time.

BACKGROUND INFORMATION:

About one billion people of the world are at risk of Iodine deficiency disorders (IDD), most of them are in the developing countries (39). Iodine deficiency impairs mental and physical growth and development. The most serious consequences of Iodine deficiency is on the developing brain of the fetus and the infants which leads to endemic cretinism and sub- clinical cretinism (2-4,6,10,15,16,18,30,36,40,42).

Some of the consequences of Iodine deficiency are not reversible, but virtually all can be completely prevented by easily available techniques of Iodine supplimentation. Strategy of Iodine supplimentation depends on the extent and severity of Iodine deficiency in the environment and the population. Endemic cretinism is common where Iodine deficiency is severe with very high incidence of neonatal chemical hypothyroidism (NCH)(2-4,6,9-13,16,20,33-36,39,40).

Direct biochemical screening of the neonates for NCH involves some critical issues which are indeed very difficult to overcome. As a result , community nutrition scientist are trying to device some alternate method(s) of approach for the prediction and prevention of NCH.

In severe environmental Iodine deficiency what should be the most logical approach to determine the extent and severity of NCH? Are there any alternate method(s) for the assessment of iodine status of the community and predict the incidence of NCH? If any, how strong is the association between the alternate method(s) and the neonatal thyroid status? These are the issues yet to be solved and are the burning questions to the researchers

today. The purpose of this research is to find out the relationship between the thyroid function of the fetus and that of the mother and the women of child bearing age (WCBA) in different grades of iodine deficiency.

CONSTRAINTS PECULIAR FOR NCH SCREENING AND THE ALTERNATE METHODS:

The technology for prevention of neonatal chemical hypothyroidism (NCH) are available but are definitely not very suitable for the developing countries (13,39). According to N. Kochupillai et al (13), and J.T.Dunn et al (39) the constraints peculiar for the implementation of screening program for NCH are considered to be the following:

1. To organise a sophisticated screening program like NCH in endemic goitrous region due to their socio economic backwardness and sometimes geographical isolation .
2. To obtain blood samples from the new borns.
3. Poor coverage of births by hospitals especially at village level.
4. Lack of training, skill and knowledge of traditional birth attendants (TBA).
5. Lack of financial and logistic support.
6. Lack of an appropriate, and cost effective RIA technology for the NCH screening program.

To overcome these constraints, the researchers are looking forward to findout alternate approach(s) which will reflect more of the community rather than the individuals. These methods would assess directly the iodine status of the community as a whole and can be used with reasonable confidence as an 'indirect' reflector(s) of neonatal iodine status and other parameters of thyroid functions as well.

T4, TSH, and Urinary iodide are the most commonly used biochemical indicators of Iodine status. Inter-relationship of the neonatal biochemical status with these common indicators of mothers and the women of child bearing age would be addressed critically in this researcg on the basis of the grades of iodine deficiency.

SIGNIFICANCE OF NCH:

Epidemiological application of the concept of NCH has two sharply defined levels:

1. At individual level and

2. At community level.

The core significance of screening for the NCH lies in its unique opportunity of diagnosing the thyroid status of a neonate within a few days of the birth of the child (individual level). Another important aspect of NCH involves its use as a highly valid indicator of Iodine status of the community (community level). The constraints peculiar for the screening program for NCH in Iodine endemic area has limited the use of its application at individual level. Present use and application of neonatal screening is limited in epidemiological monitoring (39).

FUNCTIONAL DEVELOPMENT OF THE HYPOTHALAMO-PITUITARY-THYROID AXIS IN THE FETUS AND THE FETO-MATERNAL RELATIONSHIP:

A.J.Winters et al (26) measured Thyrotropic releasing hormone (TRH) and Leutonising releasing hormone (LRH) in methanolic extracts of brain tissue from human fetuses as early as 4.5 weeks after conception. The time of emergence of these hormones are of special interest. The brain of the human fetuses aborted 4.5 weeks after conception contained concentrations of LRH and TRH which did not increase with age. They have found that the great-

est concentration of TRH was in the hypothalamus, where as the lowest was in the cerebrum. The concentation of TRH in the whole brain was 4 times that of LRH.

In the study with human fetal pituitories (n=40) of 8-32 weeks gestation, M.Fukuchi et al (24) detected Thyrotropin as early as 12 weeks of gestation by radioimmunoassay. They found that the content increased progressively with fetal age and reached about 1/10 of thyrotropin content in the adult pituitory gland at about 32 weeks gestation. Thyrotropin content /gm of fetal body weight was calculated and found to be maximum at 12-17 weeks gestation. In this study they did not found TSH activity in 11 weeks gestation or less. In addition, Iodination of protein in the human thyroid begins at 11 weeks gestation (47). From these findings, it is evident that 11-12 weeks gestation is the most important stage for fetal pituitory thyroid relationship and its function.

To understand the mechanism of high serum level of fetal reverse triiodothyronine (rT3), I.J.Chopra et al in their study (27) found the mean fetal metabolic clearence rate of T3 (MCR-T3) was significantly lower than that in the adult sheep, and the mean fetal production rate of rT3 (PR rT3) significantly higher. The mean fetal MCR-T3 was higher than, and PR-T3 similar to that in the adult sheep. The mean fetal MCR-Thyroxin (MCR-T4) and PR-T4 were both significantly higher than the corresponding values in adult sheep. Their findings are consistent with the findings of D.A.Fisher et al (50). Their results suggest :

a. elevated serum rT3 in the fetus is due to its decreased clearence and increased production by mono-deiodenation of T4.

b. low serum T3 in the fetus is due to its increased clearence and decreased production by mono-deiodenation of T4.

These findings are consistant with the findings of G.A. Medeiros et al (34). They studied with human cord blood and found that the cord blood rT3 and T3 are significantly higher and lower respectively than their mothers. These studies support the functional autonomy of fetal thyroid.

Studies showed that the fetal pituitary-thyroid system differentiate in the human fetus and appears capable of functioning by the end of the first trimester of gestation (47). However, Fisher et al (45), in their study found that the secretion of the thyroid stimulating hormone (TSH) and of T4 prior to midgestation appears to be minimum or undetectable. Serum level of these hormones remain very low until mid-gestation. Evans et al (48) found that the uptake of radio iodine by the fetal thyroid gland also is relatively low at this stage of development.

D.A.Fisher (49), Fukuchi et al (24) in their study found that near mid-gestation, there is a progressive increase in the pituitory TSH concentration and content. By 22-26 weeks mean fetal serum TSH levels consistently exceed maternal value (45,49).

All these above findings when compiled, suggests that the fetal hypothalamic-pituitory thyroid control system begins to mature at about 20 weeks. The events in the maturation are not clear (43) and may involve

a. increased secretion of thypothalamic thyrotropin releasing factor (TRF).

b. increased pituitory TRF responsiveness and/or

c. decreased hypothalamic and/or pituitory sensitivity to thyroid hormone feedback.

Numerous investigations have been carried out in a number of living species including human, have supported the conclusion

that the placenta is relatively impermeable to thyroid hormones. Recent studies in sheep have shown little or no transfer of labelled T4 or T3 in maternal-fetal or fetal-maternal directions (50,51) or at best limited transfer (52).

FETO MATERNAL RELATIONSHIP IN IODINE ENDEMIA:

Iodine is essential for the normal growth and development of human being (1,37). The thyroid function is particularly dependent on the serum iodide concentration. Low iodide concentration of serum leads to decreased production of serum T3 and T4 (15). As a consequence of sub optimal level of iodide in the serum, TSH secretion increases to stimulate the thyroid to produce optimal level of iodothyronine. These biochemical hormonal parameters (T3,T4, and TSH) are used to screen, diagnose, and treat an individual with hypo/hyper thyroidism.

Failure for plasma thyroid hormone to increase during pregnancy due to lack of iodide or other reasons is accompanied by an increased risk of frank retardation or sub-normal intellectual development (3,6,10,15-17,31,32,36,37,42,44). Placental transfer of T3 and T4 is severely limited in both fetal to maternal and maternal to fetal direction (23,43).

When there is severe iodine deficiency, serum levels of T3 and T4 falls producing biochemical hypothyroidism in mother. Moreover, there is a competition between the mother and the fetus for iodine for normal thyroid function (18). Iodide is readily and actively transported if available. There appears to be no evidence regarding possible adoptive changes in placental transport of iodide when there is iodine deficiency (18). As a consequence of this phenomenon, fetus suffers more than mother due to lack of

vailability of iodine. In such situation, thyroid function of the fetus dramatically falls below the physiological level pro ducing NCH.

NEONATO-MATERNAL RELATIONSHIP IN IODINE ENDEMIA:

The hypothesis that the NCH results from perinatal hypothyroidism recently received further factual support from the fact that there is a statistically significant correlation between the thyroid status of mothers and that of the fetus and neonates in an iodine endemic situation (2,3,34).

However, under the physiological condition, the indicators of thyroid function, in the neonates, show no correlation with those of the mother (18,21,43,45,46). In such condition fetal hypothalamus-pituitary-thyroid system is autonomous.

Biochemical correlation between the parameters of thyroid function of mother and neonate has been successfully depicted by using T4 and TSH (2,3). Their findings underlines the fact that, both in mothers and newborns,TSH concentration increases as T4 concentration declines. But the increase in the TSH level in the neonate is relatively much higher than that of the mothers.

It also reveals that when the maternal serum T4 levels are low, serum T4 of the neonates in the corresponding newborns are even lower. These classic findings depicts clearly that the neonate suffers more than their mothers and proves the existence of a correlation between the values of these biochemical parameters in mothers, and their newborns in Iodine endemia.

Highly significant inverse correlations ($r=-0.79$, $P<.001$) were observed between the serum T4 and TSH level of mother and neonate (2,3). The TSH concentrations are similar to those observed in definite cases of hypothyroid cretins living in the same endemia

(19). Many researchers pointed out that a substantial number of clinically euthyroid mothers are in fact biochemically hypothyriod and they have described this condition as 'compensated hypothyroidism. G.A.Medeiros-Neto et al in their study in Brazil found a significant association between the serum T4 of cord blood and that of the mothers blood (n= 38) at delivary (34). Findings have not been expressed sufficiently with statistical support. As a result, the correlation coefficient of the biochemical parameters of thyroid function between mothers and the neonates is virtually absent.

Due to the functional maturity of the mothers tissue and thyroid, fetus suffers more from Iodine deficiency than mothers, which is usually detected by the screening tests for cord serum TSH, and T4. Fetal TSH remains significantly higher than that of the mother. In this study, the cord blood as well as the maternal blood T4 is relatively high than what is usually found in severe Iodine endemic area (10,13,20). At the same time, the cord blood TSH level though high, is also relatively low for that endemia. Homoki et al. found neonates with decreased thyroid reserve may manifest T4 levels within the normal range with increased TSH concentration (41,43). Proportion of mothers and the neonates detected biochemically hypothyroid has not been addressed.

RELATIONSHIP BETWEEN PREGNANT WOMEN, WCBA, AND THE NEONATES IN IODINE ENDEMIA:

A. Based on hormonal levels:

In southern Tanzania, researchers have observed that the blood spot TSH levels in newborns from mothers without iodine supplementation were above 12 mU/L in 45% (n=69) where as it was only 21% in the neonates of the supplimented group of mothers (4). These group of neonates showed definitely higher range of TSH

value (12-200mU/L) and classified as chemically hypothyroid. At the same time, serum level of TSH of the pregnant and non-pregnant women were done.

This study clearly shows that the prevalence of biochemical hypothyroidism is more prevalent in the pregnant women than in the non-pregnant women.

In an area of endemic goitre and endemic cretinism, serum concentration of thyroid hormone and iodide is already very low among the pregnant women and WCBA. Moreover, there is a competition for the serum iodide, whatsoever the amount is, between the mother and the fetus. As a result, the fetus suffers more from iodine deficiency which is reflected when screening is done for the detection of NCH (3).

In the Jimi river valley of Papua New Guinea, biochemical measurements of thyroid function were made on the women of child bearing age (5) and the out come of pregnancy were assessed. No biochemical assessment of the thyroid function of the neonates/children of this group of mothers were done. Still birth, infant death and endemic cretinism were very high among the offsprings of women who showed the biochemical evidence of iodine deficiency without clinical evidence of hypothyroidism.

BASED ON URINARY IODIDE:

Virtually no methodical research work has been carried out to see the direct relationship between the urinary Iodide and the incidence of NCH. Though the quantitative measurement of urinary Iodide has long been used as one of the most valid and reliable indicators of Iodine intake (and thus thyroid function) of the community, its role in the prediction of NCH has never been tried.

There are plenty of literature which are based on urinary Iodide. Most of the data of these works were obtained by cross-sectional study design (10,11,13,36). Unfortunately, very little is mentioned about the sampling design, and the subjects. How the chance, bias, and the potential confounding variables were controlled has not been addressed.

In the study of Iodine deficiency and neonatal hypothyroidism, N.Kochupillai et al (36), found a wide range of variation in the prevalence of NCH with Follis classification of urinary Iodide. Their findings clearly shows that the incidence of NCH increases steadily with the severity of environmental Iodine deficiency (EID). They use Follis classification to relate the incidence of NCH with urinary Iodide and obtained very inconsistant results. Their findings regarding the incidence of NCH varied from 7.5% to 13.3% within the same grade (grade 5) of Follis classification. Source of data regarding the urinary Iodide excretion has unfortunately not been addressed here.

Subjects and the sampling technique could be a potential confounding factor. The conventional method of analyzing the urine for urinary iodide has a lot of constrains to itself. Chances of contamination and variation of the results are very high. However, it can be concluded from their findings that urinary Iodide is not a reasonably good indicator to reflect the incidence of NCH in an Iodine endemia so long the Follis classification is concerned.

From the epidemiological point of view, incidence of NCH has a strong relationship with the Iodine deficiency in the environment. Results from India (11) says that when the mean urinary Iodide was 48 ugm/gm of creatinine, incidence of NCH 0.2%. and when the incidence of NCH was 4.2%, the mean urinary Iodide was

as low as 20 ugm/gm of creatinine . This inverse relationship is invariably present between these two indicators of Iodine status .

This study, in fact, does not focus whether the relationship between urinary Iodide and the incidence of NCH is linear or not, but it clearly shows that the incidence of NCH increases with the severity of Iodine deficiency.

RATIONALE:

There is a strong association between the biochemical parameters of thyriod function of mothers and the neonates in an environment where severe Iodine deficiency exists. Even the clinically normal newborns from areas of environmental iodine deficiency shows mean cord blood T4 significantly low (10,35). Demonstration of severe hypothyroxinaemia in the neonatal cord blood among a significant number of newborns from iodine deficient environments indicate high incidence of intra-uterine hypothyroidism in such environment (2-4,6,34).

A small proportion of thyroxine deficient neonates in severe iodine deficient environment continue to remain hypothyroid throughout the critical period of post-natal brain development resulting in endemic cretinism and sub-cretinism (6).

A significant proportion of the apparantly normal children of Iodine endemia show a shifting of IQ to the left and conductive deafness as well. These facts when taken into consideration, can be interprated that environmental iodine deficiency (EID) is causing much more brain damage than is evident by overt endemic cretinism in millions of people living in the iodine deficient environment. No study has yet been done to see the relationship

of the neonates with their mothers in different grades of iodine endemia.

In severe environmental iodine deficiency, the biochemical relationship with respect to T4, TSH, UI, and Goiter among the women of child bearing age (WCBA) and the pregnant women (mothers) is yet to be understood. Also the biological relationship among the mothers, neonates and the WCBA is to be explored in different grades of iodine endemia.

The impact of different grades of environmental iodine deficiency (EID) on mothers, their neonates and the WCBA is not known. This research is expected to explore the impact and find out the best indicator of EID to use at the community level.

Urinary iodide is a good indicator of iodine status of the community when urine is taken from that community from a group of population (39). The conventional method of analyzing the urine for urinary iodide is not very satisfactory especially when the sample size is big. Chances of contamination is also very high in the conventional method. As a result, a new method has to be developed and established (with help of the consultants from U.K.) to analyze the urine for urinary iodide using the COBAS BIOS auto analyzer. The new method would help us to measure the iodine level accurately and see the correlation of the indicators of iodine status.

4.METHODS OF PROCEDURE: RESEARCH METHODOLOGY:

AT A GLANCE:

A. STUDY DESIGN: CROSS-SECTIONAL.

B. SUBJECTS INVOLVED IN THE RESEARCH:

1. MOTHERS
2. NEONATES OF THOSE MOTHERS
3. WOMEN OF CHILD BEARING AGE (WCBA).

C. INDICATORS INVOLVED IN THE RESEARCH:

1. TSH
2. T4
3. UI
4. GOITER.

D. TECHNOLOGY INVOLVED:

1. FILTER PAPER METHOD FOR BLOOD AND
2. COBAS BIOS AUTO-ANALYZER FOR URINARY IODIDE.

E. AREAS INVOLVED IN THE RESEARCH:

1. RAJSHAHI
2. BARISHAL
3. DHAKA
4. RANGPUR

F. PREVALENCE OF GOITER IN THE SELECTED AREAS:

1. RAJSHAHI-2.8%
2. BARISHAL-6.2%
3. DHAKA- 10.09%
4. RANGPUR-27.5%

1. STUDY DESIGN:

Depending on the nature, objectives of the research, limitation of time, financial, and logistic resources, a cross sectional study design has been chosen.

DHAKA	RANGPUR	RAJSHAHI	BARISHAL	DHAKA
10.0%	27.5%	2.8%	6.2%	10.05%

D J F M A M J J A S O N

1ST 6 MONTHS NEXT 6 MONTHS

2. AREA SELECTION:

Four different districts of Bangladesh have been selected on the basis of their grades of goiter prevalence. Selection of these areas are purposive.

2.1. Criteria for area selection:

a. Must provide sufficient subjects,and the samples.

b. Must be accessible.

c. Areas for research have been selected from the following goiter prevalent zones. In Bangladesh, magnitude of the Iodine deficiency have been catagorised in four different grades.

Non endemic area---- 0-5%

Mild endemic area---- 6-10%

Moderate endemic area-11-20%

Severe endemic area---21-30%.

3. SUBJECTS SELECTION:

Pregnant women would be selected from the labour wards of the hospitals of the selected areas.

Neonates of these mothers will be selected to make it a paired sample.

WCBA will be selected from the Maternal and Child Welfare Centre (MCWC) of the research areas.

3.1. CRITERIA FOR SUBJECT SELECTION:

A.

Subjects	Age in years
a. Mothers	15 to 35
b. Neonates	At birth
c. WCBA	15 to 35

This age range (15-35 years) will be divided into two equal parts and equal number of subjects will be selected from each group.

Dummy table:

	Age in years		
	15 to 25	24 to 35	Total
Mothers	150	150	300
WCBA	150	150	300

B. Inhabitants of that area who have lived there for at least five consecutive years.

C. Those who are not using iodized salt.

D. Subjects having education of any level would be covered.

E. For WCBA only: Those who will fit with the conditions laid down in the criteria for subject selection will be selected. In addition to this, following factors will also be considered for the WCBA group of women.

Who:

1. come to the MCWC to consult with the doctors for her child's health.
2. are not mothers, but accompanying the child.
3. who visit the MCWC for some other purposes (family planning advice, collection of contraceptives etc).
4. are apparently healthy.

4. SAMPLE COLLECTION:

Blood (during labour) as well as urine (before labour) will be collected from the mothers and the WCBA where as only left out cord blood will be collected from the neonatal side. No anti-coagualent is required for blood collection. Toluine would be used as preservative of urine.

Thyriod gland of each subject will be examined for the gradation of Goiter.

4.1. Criteria for sample collection:

Blood and urine will be collected on the same day, maintaining the same principle for each subject (both mothers and the WCBA).

Blood: Mothers— at delivery (.25ml)

Neonates— at birth (.25ml)

WCBA —— during their visit to the MCWC.

Urine: Mothers— before delivery

WCBA— urine and blood will be collected on the same day.

Goiter: Mothers— before delivery

WCBA— during their visit to MCWC (same day).

Neonates— after birth, in the labour ward.

Mothers and the WCBA will be divided into two equal sub-age groups, 15-25 years and 26-35 years. Selection of subjects from both sub-age groups will start simultaneously and purposively. It may happen that the required number of subjects of one sub-group is saturated before the other. In that situation, sample collection would continue for the other sub group till collection of required sample size is completed.

5. METHODS FOR AREA AND SUBJECTS SELECTION:

For areas: Purposive

Mothers and Neonates: all pregnant women who meet criteria for subject selection and the neonates.

WCBA: all women who meet criteria for subject selection.

Blood: Mothers— at delivery (.25ml)

Neonates- at birth (.25ml)

WCBA —— during their visit to the MCWC.

Urine: Mothers— before delivery

WCBA— urine and blood will be collected on the same day.

Goiter: Mothers— before delivery

WCBA—— during their visit to MCWC (same day).

Neonates- after birth, in the labour ward.

Mothers and the WCBA will be divided into two equal sub-age groups, 15-25 years and 26-35 years. Selection of subjects from both sub-age groups will start simultaneously and purposively.It may happen that the required number of subject of one sub-group is saturated before the other. In that situation, sample collection would continue for the other sub-group till collection of required sample size is completed.

5. METHODS FOR AREA AND SUBJECTS SELECTION:

For areas: Purposive

Mothers and Neonates: all pregnant women who meet criteria for subject selection and the neonates.

WCBA: all women who meet criteria for subject selection.

6. SAMPLE SIZE:

The main constraints for the sample size are identified as:

a. Availability of optimum number of subjects/samples.

b. Availability of time.

c. Financial cost.

d. Logistic and practical support.

e. Actual prevalence of the visible goiter rate (VGR).

f. Degree of accuracy.

From a statistical point of view, prevalence of the VGR and the desired degree of accuracy are the main determinants of the sample size. Sample sizes based on the actual prevalence of goiter and degree of accuracy in the areas selected for research are adequate for analysis. Sample sizes for my research have been determined on the basis of the following criteria:

a. Actual prevalence of area specific VGR.

b. Alpha level of .05 and

c. Degree of accuracy 5%.

d. Estimated Mean and SD of Urinary Iodide, T4, and TSH.

All these criteria have been used to obtain the minimum sample size for my research. Two different statistical approaches were followed and the sample sizes were calculated on the basis of the combination of both of them.

1. Formula used for calculation of the sample size:

$$n = \left(\frac{1.96}{\text{Degree of accuracy}}\right) * \left(\text{Prevalence of VGR} * (1 - \text{VGR})\right)$$

Degree of accuracy	Alpha level	Goiter prevalence	Sample size
5%	.05	27.5%	302
5%	.05	10.09	140
5%	.05	6.2	89
5%	.05	2.8	42

2. Determination of sample size for UI, T4 and TSH.

Formula:

For Urinary Iodide:

$\mu_1 = \mu_2 = 60$	LSD of Mean	Sample size
$u = 1.28$	27.48	100
$v = 1.96$		

For TSH:	LSD of Mean	Sample size
$\mu_1 = \mu_2 = 1.6$	.59	150
$u = 1.28$		
$v = 1.96$		

For T4:	LSD of Mean	Sample size
$\mu_1 = \mu_2 = 2$	.74	150

$u = 1.28$

$v = 1.96$

Considering the above statistical formulae and their importance, I have determined the following protocol of sample size for my research.

COMPREHENSIVE TABLE OF THE TOTAL NO. OF SUBJECTS AND THE SAMPLES:

Area	Subjects	Sample size			
		GOITER	T4	TSH	UI
RANGPUR	Mother	300	150	150	100
	Neonate	300	150	150	-
	WCBA	300	150	150	100
DHAKA	Mother	150	150	150	100
	Neonate	150	150	150	-
	WCBA	150	150	150	100
BARISHAL	Mother	150	150	150	100
	Neonate	150	150	150	-
	WCBA	150	150	150	100
RAJSHAHI	Mother	150	150	150	100
	Neonate	150	150	150	-
	WCBA	150	150	150	100

A systematic sub sample would be taken from the mothers and the WCBA group for blood and urine in Rangpur. In other places, a systematic sub-sample will be collected for urine only.

In Rangpur, every 3rd woman (mother or WCBA) will be dropped during sampling for urine. Same principle will be followed for the neonates to make it a paired sample.

From mothers:

Blood: will be collected from every alternate mother from Rangpur. Same principle will be applied for their neonates except urine.

Urine: Every 3rd will be dropped in all the places except in Rangpur where every two subjects will be dropped out from every three subjects examined.

From WCBA:

Blood: will be collected from every alternate WCBA in Rangpur, but at other places, all the WCBA and the pregnant women will be covered .

Urine: Every 3rd WCBA will be dropped in all the places except from Rangpur. In Rangpur, every two will be dropped out of three.

7. INDICATORS OF INTEREST:

Blood for blood spot TSH, and T4.

Urine for Urinary Iodide.

Thyroid for gradation of goiter.

For blood spot TSH and T4: Filter paper method will be used to collect blood from all the subjects. Quantification of the TSH, and T4 would be done by RIA from the Nuclear Medicine center, Dhaka medical college hospital, Dhaka, Bangladesh.

For the measurement of urinary Iodide, a new method will be developed and adopted in the centrifugal analyzer (COBAS BIO) at the Biochemistry and Nutrition lab of ICDDR,B.

8. CUT-OFFS FOR THE INDICATORS:

Standard cut-offs will be used for the biochemical screening and identification of chemical hypothyroidism in the subjects.

a. Blood spot TSH: >= 25 uU/ml.

b. Blood spot T4 : <= 4.5 ugm/100ml

c. Urinary Iodide: <=5 ugm/100 ml of Urine
or <=50ug/gm of Creatinine, and

d. Goiter: WHO classification will be used.

7. CONTROL OF BIAS, POTENTIAL CONFOUNDING AND CHANCE:

These vital aspects of the research would be controlled by using the following components of the research methodology.

a. Method of subject selection

b. Criteria for sample collection and

c. Sample size

Bias:

1. Selection bias: can happen if subjects selected for study differ in some systematic way from those not selected. Possibility of this bias will be controlled by the criteria of subject selection, especially the WCBA from the MCWC. Those not mothers also visit the MCWC to get health service delivery or just accompany the child. These group of women are very vital for sampling. Method of subject selection will also consider this aspect and will help to control bias.
2. Observers bias: Method of subject selection and criteria for sample collection will control the observers bias. The observers will have to measure or assess the goiter only, and rest of the things are the biochemical parameters which would be investigated in the standard laboratories. Nuclear Medicine Center (NMC), Dhaka would do the radioimmunoassay of T4 and TSH, and urinary analysis would be done in the ICDDR,B, Dhaka. A proper training will be given to the observers regarding sample collection and the assessment of goiter grading.

3. Measurement bias: Use of the same standard laboratories of NMC and ICDDR,B for radioimmunoassay and urinary analysis respectively would reduce the chance of bias. Interassay, intra assay and batch to batch variability would be measured during assay.

Confounding:

Time of sample collection from the cord is very vital to get an accurate estimation about the biochemical indicators (TSH, T4) of thyroid function of the neonates. With elapse of time, biochemical parameters start to show some change in their blood level and ultimately sattles within a couple of weeks. This is a physiological phenomenon. To control this potential confounder, samples will be collected from the labour ward just after the child is seperated from the mother (criteria for sample collection).

Age is one of the major confounding factors which influences the grade and the severity of goiter. Division of the age range (15-35 years) of the subjects, into two equal sub-groups (15-25, 26-35 years), and collection of equal no. of subjects from each sub-group will control age as a potential confounder.

Intake of plenty water and consumption of high iodine containing foods have a profound influence on urinery iodide and can change the concentration of iodide in the urine. To check this potential confounder, a high sample size has been selected to determine the urinary iodide.

Chance:

Role of chance will be controlled by the method of subject selection, criteria for sample collection and sample size. Purposive followed by systematic random sampling of the subjects, proper collection of samples and statistically valid sample size will control the possible role of chance.

5. Facilities required:

This PhD research protocol has two laboratory components:

a. Radio immuno assay of T4 and TSH: This will be done in the Nuclear Medicine Center of Dhaka Medical College Hospital, Dhaka. The financial and the logistic support would be provided by the World Health Organization (WHO) for this part of the research.

b. Analysis of Urine for Urinary Iodide: This component of the research requires financial and logistic supports (laboratry facilities) of ICDDR,B. The urine analysis will involve the Cobas Bio cectrifugal autoanalyser of ICDDR,B for accurate measurements of urinary iodide. This portion of the research would be a collaborative work between IPHN and ICDDR,B.

IPHN needs financial and other related support from ICDDR,B for this component of the research work.

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E. Section III : Detail Budget

Personnel

Name	Time required	Honorarium/month	Tk.	US$
Dr AMM Anisul Awwal	100%	--		
M A Wahed	10%			
Dr U S Anwar	5%			
Physicians X 2	20%	1000.00X2	16,000	500.0
FWV X2	25%	1000.00X2	16,000	500.0
		Total:		1000.00

Supplies & Materials

For Cobas BIO:		
Cuvette rotor		
Sample cups		
Sample tips		
Thermal papers		
Reagents & chemicals	3000.00	
Lab Supplies:	600.00	
Test tubes		
Pipettes		
Pipettes tips 5ml & 1ml		
Kimwipes		
Tube racks		
Transportation of materials	1300.00	
Office supplies	500.00	
Printing & reproduction	100.00	
	50.00	
Total	5550.00	
Grand total:	6550.00	

COMMUNITY NUTRITION PROGRAM

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TO WHOM IT MAY CONCERN

This letter is to confirm that Anis Awwal is a PhD candidate at the University of Queensland. On 1 December 1990 he will return to Bangladesh for a period of approximately one year during which he will carry out research on iodine deficiency.

We anticipate that he will return to The University of Queensland, Australia in late 1991 to analyse his results and write a thesis.

Yours sincerely

Peter F. Heywood

Peter F Heywood
Professor and Director

BIO-DATA

1. Name : A.M.M. ANISUL AWWAL
2. Father's name : Late A.K.M. A. Awwal
3. Address
   a. Permanent : House - 23
      Rode - 9/A
      Dhanmondi R/A.
      Dhaka, 1205.
      BANGLADESH.
   b. Present : - DO -
   c. Working : Division Chief Field.
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      Dhaka-1212.
4. Phone : 327594 (R).
      602858 (O).
5. Date of birth : 19/01/57.
6. Marital Status : Married
7. Nationality : Bangladeshi by birth
8. Religion : Islam

9. Educational qualification:

a. Full-time Ph.D student of Queensland University, Australia since April 1989.

b. DMCH & FF (DU) : passed as a regular student in 1984. Stood 2nd

c. MBBS (CU) : passed as a regular student in 1980.

d. HSC (Dhaka Board) : passed in 1st division in 1974.

e. SSC (Dhaka Board) : Stood 7th in 1972.

f. Junior Scholarship (Dhaka Board) in 1969.

10. Professional experience :

a. Division Chief, Field, IPHN from december 1990 till now.

b. On deputation to Australia to do the Ph.D on Community Nutrition from 30/4/88 to 30/11/90.

c. M.O. IPGMR, Dhaka from 22/8/84 to 29/4/88.

d. On deputation to NIPSOM for DMCH & FP from july 1983 to June 1984.

e. M.O. under the disposal of Civil Surgeon, Chittagong Hill Tracts from 22/12/81 to july 1983.

f. M.O. St. Martins Island Teckaf, Chittagong from 26/10/80 to 22/12/81.

g. Inservice trainee in Chittagong medical College Hospital, Chittagong from 26/10/80 to 25/10/81.

PUBLICATIONS

a. Papers and abstracts submitted:

1. Awwal, A.M.M.; Haq, T.; Rezvi, S. Overview of IDDs in Bangladesh and its control mseasures to the Journal of Preventive and Social Medicine, April, 1991.

2. Awwal, A.M.M. critical review of papers on IDDs to the Bangladesh Medical Journal, April, 1991.

3. Awwal, A.M.M.; Haq, T.; Rezvi, S. Critical evaluation of IDDs in Bangladesh. Abstract submitted for the 5th National Nutrition Conference to be held in June, 1991.

b. Papers in preparation:

1. Awwal,A.M.M; Haq, T.; Rezvi,S. Critical analysis of IDDs and its control activities.

c. Abstracts published:

Awwal A.M.M, Nutritional status of the children accompaning mothers at BAVS, 1984.

Research works:

Done:

1. Awwal,A.M.M, Nutritional status of the children accompanying mothers at BAVS 1984.
2. Awwal, A.M.M, Patterns of birth weight of the Bangladeshi children, 1986.

On going:

1. Awwal, A.M.M, The neonato-maternal relationship in the populatior of a varying grades of Iodine deficiency and ranking of some indicators.
2. Growth monitoring and its impact on the morbidity and motality- Joint project with National Nutrition Council, Bangladesh.
3. Awwal,A.M.M; Haq, T.,Ishaque, A.M.; Rezvi, S. Community approach to assess the impact of Lipiodol on the newborn.
4. Awwal,A.M.M, Haq, T.;Rezvi,S. Goiter and its implication in the assessment of Iodine deficiency.
5. Awwal,A.M.M; Haq, T.; Rezvi,S. Is urinary iodide the ideal indicator of iodine deficiency?

International seminars attended:

1. 1st Australian tropical health and nutrition conference, held in Brisbane in 1989.
2. Australian tropical health and nutritional conference 1990.
3. Disease in transition 1990, held in Australia.

Hobby:

1. To discuss the common health and health related problems with the people.
2. To discuss about the negative impact of population boom with the people.
3. To travel in home and abroad.
4. To listen songs and music.
5. To watch and participate in drama as an actor.
6. Driving cars.
7. To play table tennis.

Extra curricular activities:

1. An enlisted drama artist of Bangladesh Television.
2. Conductor of some health and family welfare related programs of BTV.

Membership:

1. Bangladesh Medical Association (BMA).
2. Nutrition society Of Bangladesh (NSB)

অবহিত করণ পত্র

আয়োডিনের অভাব জনিত কারণে মানুষের জীবনে নেমে আসে নানাবিধ সমস্যা। মহিলাদের গর্ভধারন ক্ষমতাহীনতা থেকে শুরু করে শিশু মৃত্যুর হার বৃদ্ধি, এ সবই এই সমস্যার অন্তর্ভুক্ত। আয়োডিনের ঘাটতি জনিত কারণে বোবা, কানা, শারিরীক বিকলাংগ এবং পুষ্টি-হীনতা আমাদের অকাল মৃত্যুর দিকে ঠেলে দিতে পারে। বিশেষ করে শিশুদের। গলা ফুলে যাওয়া (গলগন্ড) কর্মক্ষমতা হ্রাস পাওয়া, বুদ্ধিমত্তা কমে যাওয়া এবং কর্মবিমুখ তাই বড়দের মাঝে আয়োডিন ঘাটতির মূল লক্ষণ।

সারা দেশ জুড়ে এক জরীপে দেখা গেছে, আমাদের বাংলাদেশের প্রায় সব অঞ্চলেই আয়োডিনের অভাব জনিত সমস্যা রয়েছে। কোন কোন অঞ্চলে এই সমস্যা মারাত্মক ভাবে জন স্বাস্থের প্রতি হুমকি হয়ে দাঁড়িয়েছে। এই সমস্যাগুলো সমষ্টিগতভাবে আমাদের শারিরীক, সামাজিক এবং অর্থনৈতিক ভাবে পঙ্গু করে দিচ্ছে।

এই সমস্যার গভীরতা এবং ব্যাপকতা আরো বিস্তৃতভাবে পরীক্ষা নিরীক্ষা করার জন্য বিশেষ গবেষণার প্রয়োজন রয়েছে। একমাত্র গবেষণার মাধ্যমে এই মারাত্মক সমস্যাবলী দূর করা যেতে পারে। এই ব্যাপারে আমি আপনার দৃষ্টি আকর্ষণ করছি এবং সার্বিক সহায় সাহায্য কামনা করছি।

সম্মতি পত্র

উপরোক্ত বক্তব্য আমি পড়েছি/শুনেছি। আয়োডিনের অভাব জনিত সমস্যাবলীকে কেন্দ্র করে যে গবেষণার কথা বলা হয়েছে, তাতে আমরা এবং অথবা আমার নবজাতকের অংশগ্রহনের ব্যাপারে কোন আপত্তি নাই। এই গবেষণায় অংশগ্রহন না করলে আমার/আমাদের চিকিৎসার কোন ক্ষতি হবে না, - একথাও আমি জানি। আরো জানি, এই গবেষণায় আমার ২ (দুই) ফোটা রক্ত পরীক্ষার জন্য নেয়া হতে পারে। আমার নবজাত-শিশুর (যদি থাকে) নাভিরজ্জু কাটার পর উচ্ছিষ্ট ২ (দুই) ফোটা রক্তও ব্যবহার করা হতে পারে। এছাড়াও শিশুর প্রস্রাব ও পরীক্ষা করা হতে পারে।

সংগ্রহকারীর স্বাক্ষর

অংশগ্রহনকারীর স্বাক্ষর/
বাম হাতের বৃদ্ধা আংগুলের ছাপ