Library (2)

Attachment 1.

ICDDR,B LIBRARY
DHAKA - 12

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Date 21/5/87

Principal Investigator Dr Iqbal Kabir

Application No. 87-012

Title of Study Nutritional management of post-shigella growth faltering in children with a high-protein diet.

Trainee Investigator (if any) 2

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 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.

(PTO)

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

Kabir
Principal Investigator

Trainee

MAY 25 1987

37-012

21/5/87

SECTION I : RESEARCH PROTOCOL

1.	Title	:	Nutritional management of post-shigella growth faltering in children with a high-protein diet.
2.	Principal investigator	:	Dr Iqbal Kabir
	Co-investigators	:	Drs A. Islam, S.A. Sarker, A. Briend
	Consultant/adviser	:	Prof. Roger Eeckels Director, ICDDR,B Prof. John Banwell Dr T. Butler Case Western Reserve University Cleveland, USA
3.	Starting date	:	July 1987
4.	Completion date	:	June 1989
5.	Total direct cost	:	US $61190
	Source of fund	:	To be submitted
6.	Scientific programme	:	This protocol has been approved by the Clinical Sciences Division.

Signature of the Acting Associate Director, Clinical Sciences Division

Date: 13 April 87

7. ABSTRACT SUMMARY

Previous studies in Bangladesh showed an interruption of linear growth in children with shigellosis. Catch-up of growth following loss due to infections in children has been advocated with higher protein diets, but such diets have not been tested following shigellosis or other infections for an effect on linear growth rate or weight gain. Fifty-four children with culture-proven Shigella dysentery in Bangladesh will be randomly assigned to receive either a diet with a standard amount protein (5 percent of calories as protein) or a high protein diet (15 percent of calories as protein) for 21 days in the hospital. The diets will be isocaloric and provide abundant calories at a level of 150 kcal/kg/day. Heights and weights will be recorded before and after feeding the diets and every month after discharge for 6 months. Serum concentrations of prealbumin, as indicators of rates of protein synthesis, will be measured before and after 21 days of feeding. If the high protein diet supports faster growth during convalescence from shigellosis, a follow-up study will be designed to provide protein supplements to home-based diets in order to achieve similar catch-up growth in a feasible manner for developing countries. The duration of the study will be two years.

8. Reviews:

1. Ethical Review Committee:_____
2. Research Review Committee:_____
3. Director, ICDDR,B:_____

SECTION II : RESEARCH PLAN

A. INTRODUCTION

1. Objectives:

The objective of the study is to evaluate the effectiveness of a short-time dietary intervention with a higher amount of protein in reducing subsequent morbidity and growth faltering in children with shigellosis.

2. Background:

Children in developing countries show slower growth rates than children in developed countries, and many are stunted when they reach adulthood. A large part of this growth retardation is caused by malnutrition due to decreased intake of food during infectious diseases. Scrimshaw (1) has attributed the decreased intake/utilization of calories during infection to a combination of anorexia, fever, withdrawal of solid food by parents, impaired intestinal absorption, and nutrient losses in body fluids. The effects of diarrhoeal infections on growth of children in Bangladesh was studied prospectively by Black et al (2), who concluded that shigellosis had a significant impact on linear growth and diarrhoea due to E. coli had a significant impact on ponderal growth. Diarrhoeal illnesses, respiratory tract infection and skin infection accounted for 90% of all illnesses. Shigella had a longer duration than other type of diarrhoea with 16% episode lasting for more than 20 days (2). Prolonged diarrhoea associated with deep ulceration of colon follows acute shigellosis in a proportion of patients. Besides the other effects of diarrhoea shigellosis also cause loss of blood and mucus and cause enteric protein loss (3,4). Study of Kabir et al showed that patients with shigellosis had bulky stool for several days during recovery from acute shigellosis (5). The relationship between diarrhoeal diseases and growth increment in total body length and weight were investigated in Gambian and

Guatemalan children (6,7). In these studies days ill with diarrhoeal diseases were found to be significantly associated with reduced growth in length and weight.

Optimal feeding practices during acute diarrhoea has been controversial and was reviewed recently by Brown and MacLean (8). The theoretical advantages of delayed feeding include the avoidance of increased fluid loss in stool, of acidosis, and of mucosal injury caused by certain foods. The advantages of continued feeding during diarrhoea are to prevent weight loss and protein deficits, to maintain and repair the injured mucosa, and to sustain the benefits of breast feeding. The World Health Organization has opted for continued feeding during diarrhoea, stressing that breast-feeding should continue and weaning diets should be continued as previously except that cow's milk and formula feedings be diluted at least two-fold (8). These recommendations apply mainly to watery diarrhoeas that affect the small intestine. Less attention has been given to shigellosis and other infections that affect the colon (9), and no recommendations are available for intensive feeding during the recovery period.

It should be desirable during and after acute infections of children to try to catch-up lost growth, but no study has been carried out to show whether growth catch-up is possible. Whitehead (10) has made theoretical calculations what the energy and protein requirements should be doubled for catch-up growth. For a 7 kg child the calories required are about 25% higher than for normal growth, or about 150 kcal/kg/day, and the percentage of calories as protein is nearly doubled to more than 11 percent. In Jamaica, Golden (11) estimated the minimum amount of protein to maintain lean body weight in malnourished children was about 3 percent of calories as protein and minimum total caloric intake to maintain lean body weight was 96 kcal/kg/day. The required duration of intensive feeding for growth catch-up should be about three

times longer than the preceding acute disease because of the assumption by Scrimshaw (1) that the anabolic phase of recovery will last three times longer than the catabolic phase of disease.

In addition to growth impairment, infections and malnutrition lead to reductions in serum protein concentration. In Bangladesh, serum protein concentrations in children with severe shigellosis are about half of the normal values (12). In severe malnutrition, depressed serum albumin concentrations are instrumental in lowering plasma oncotic pressure and allowing the edema of kwashiorkor to develop (13). Diets with higher protein content may have a beneficial effect to increase the rate of albumin synthesis, thus raising the serum albumin and protecting children against symptoms of malnutrition. On the other hand, any effort to promote protein synthesis and growth during recovery from shigellosis may be opposed by the acute phase reaction of inflammation. During acute inflammatory reactions, the liver shifts to synthesizing the acute phase reactant proteins, which include the C-reactive protein, and decreases synthesis of other proteins, including albumin and prealbumin (14). Thus, the hypoalbuminemia and impaired growth rates associated with acute infections may be, to some extent, refractory to dietary treatment.

To detect a dietary effect on the rate of protein synthesis, the serum prealbumin concentration is more responsive to energy and protein in the diet than is the albumin concentration because prealbumin is a high turnover protein with a half life of 1.9 days, contrasted to albumin with a high-life of 12-21 days (15). In Egyptian children with kwashiorkor, the serum concentration of prealbumin increased significantly 2-4 weeks after dietary treatment (16). In American premature infants, the serum prealbumin was a more sensitive indicator of nutritional intake than was the serum albumin (15).

3. Rationale:

Malnutrition and growth faltering have been observed as a consequence of diarrhoeal illness in developing countries. In addition to other effects of diarrhoea shigellosis also result blood and mucus loss and can cause serum protein loss in the stool. For children with a marginal diet, this loss must be compensated by increase protein intake for optimal growth to occur. It is obvious that the magnitude of protein loss in the stool in shigellosis is much more than in other diarrhoeal stool. High fever, anorexia, abdominal pain and discomfort, food withholding in these children will make the situation more worse. Early intervention with a diet rich in protein may have some positive impact on subsequent morbidity and nutritional status in these children. This study will help us to find out whether a diet of higher amount of protein for a short period will be able to counteract the growth faltering in children with shigellosis.

SPECIFIC AIMS

1. To study the effects of a defined diet with higher amount of protein in children with shigellosis; to achieve a rapid catch-up growth.
2. Whether the same diet has an impact in reducing further morbidity in these children?

METHODS

Sample size calculation

From the Harvard Standard of children between 30 and 50 months of age (12), the mean monthly increment in height is 6.4 mm with a variance of 0.8 mm. To achieve an alpha error of 0.05 for a worthwhile difference between the diets of 3 mm a month in height, the sample size is 2 (1.96 x variance/worthwhile difference)^2 = 54 patients.

Patient selection and management

Fifty-four children between 3 and 5 years old who present to the ICDDR,B clinic with dysentery and have a stool culture positive for Shigella species will be selected. Approximately one patient per week will be selected during a one-year period. To be eligible the patients' parents or guardians must consent to remain in the hospital for 21 days, they should live within 3 miles of the hospital for easy follow-up, and they must agree to receive one of the two diets by randomization. Excluded will be patients with third degree malnutrition, i.e. who have body weights less than 60 percent of the Harvard Standard of weight for age (17). Any patient with nutritional edema or other signs of kwashiorkor will be excluded. Patients with complicating illnesses viz. pneumonia, tuberculosis, septicemia, heamolytic-uremic syndrome, or any other associated diseases will be excluded. Children who are breast-fed, have chronic dysentery also be excluded. Clinical cure will be determined by absence of fever, tenesmus, straining during defecation and reduction in stool frequency.

All patients will be given effective antimicrobial treatment for 5 days, chosen on the basis of in vitro sensitivity testing of individual Shigella isolates. During these 5 days of treatment, the standard hospital diet will be provided and, because of anorexia that usually accompanies acute shigellosis, no attempt will be made to push intensive feeding.

Randomization and dietary treatment

At the end of the 5 days of treatment, and after clinical cure patients will be randomly assigned to one of 2 diets using sealed envelopes that contain cards designating diets in an order obtained from a table of random numbers. The diets will be called "standard protein" and "high protein". Both diets will be isocaloric and contain a high caloric content of 150 kcal/kg body weight per

day, which was calculated by Whitehead (5) to support rapid weight gain for catch-up growth. The standard protein diet will contain 5 percent of total calories as protein and the high protein diet 15 percent of total calories as protein. The diets will be comprised of locally obtainable foods that are proven to be acceptable by the people. The bulk of calories will be obtained from rice and bread. The protein sources will be eggs, chicken, and dried skimmed milk. The caloric value and protein content of sample diets will be tested by bomb calorimetry and nitrogen content will be measured by microkeidjal-method. These assays are currently available at the ICDDR,B Biochemistry Department. The patients will be treated with these diets in the hospital for 21 days. Nurses will record portions of food uneaten and any meals vomited.

Food will be given ad-libitum at a regular time intervals.

	Study diet (150 kcal/kg/day with 15% protein)	Control diet (150 kcal/kg/day with 5% protein)
07 a.m.	Bread + milk + suzi	Bread + milk
10 a.m.	Milk + suzi	Milk + suzi
12 noon	Rice + chicken	Rice + chicken
03 p.m.	Milk	Milk
06 p.m.	Rice + chicken	Rice + chicken
09 p.m.	Milk	Milk

Adjustment will be made on concentration of different nutrients to make it isocaloric.

Research measurements

Before the start of the test diets, patients will be weighed to the nearest gram and height measured to the nearest mm on a stand-up scale. Blood will be obtained for serum albumin and prealbumin, as measures of the rate of proteir synthesis. The serum prealbumin measurements will be done by radial

immunodiffusion assay. At the end of the 21 days of dietary treatment, the weight and height measurements and serum protein levels will be repeated. Serum total protein, albumin and prealbumin will be done at 3 months and 6 months.

Home follow-up measurements

To test the possible beneficial effects of the high protein diet on subsequent growth and health, monthly home visits will be made for every 15 days. A portable scale will be used for weight and height. Recurrences of diarrhoea or occurrences of other diseases will be recorded during the follow-up visits.

Morbidity data

Questions will be asked about whether the child developed diarrhoea, character of stool (watery, dysentery, bloody), running nose with or without purulent discharge and without respiratory distress (will be graded as URTI), fever, cough with respiratory distress (will be graded as LRTI), skin infection, scabies, impetigo etc. However, all these patient will be given proper health education in respect to personal hygiene. They shall be asked to report to the hospital for any illness or will be transferred to the hospital if detected during follow-up visit for better management and diagnosis. For diarrhoeal illness if patient cannot be taken to hospital a stool specimen will be brought to hospital laboratory for diagnosis. For validation of field data on weight and height every 4th patient will be brought back to hospital every month for accurate measurement of weight or height.

Data analysis

Monthly increments of heights and weights of the patients will be calculated and compared to the Harvard Standard (12). The means of the increments of height and weight during each month and the means of serum protein concentrations will be compared between the two dietary groups by Student's t

test. Rates of recurrence of diarrhoeal disease and other infections will be compared using Fisher's Exact Tests and Chi-square tests.

COLLABORATIVE ARRANGEMENTS

This study will be carried out in collaboration with Case Western Reserve University. Dr. John Banwell in the Division of Gastroenterology and Nutrition, Dr. Thomas Butler in the Division of Geographic Medicine, and Dr. Harold Houser in the Department of Epidemiology and Biostatistics will participate.

REFERENCES

1. Scrimshaw NS. Effect of infection on nutrient requirements. Am J Clin Nutr 1977;30:1536-1544.

2. Black RE, Brown KH, and Beeker S. Effects of diarrhoea associated with specific enteropathogens on growth of children in rural Bangladesh. Paediatr 1984;73(6):799-805.

3. Sarker SA, Wahed MA, Rahaman MM et al. Persistent protein losing enteropathy in post-measles diarrhoea. Arch Dis Child 1986;61:739-743

4. Rahaman MM, Wahed MA. Direct nutrient loss and diarrhoea. In: Chen LC, Scrimshaw NS eds. Diarrhoea and malnutrition: interactions, mechanisms, and interventions. Newyork, Plenum, 1983:155-160.

5. Kabir I, Butler T, Khanam A. Comparative efficacies of single intravenous doses of ceftriaxone and ampicillin for shigellosis in a placebo-controlled trial. Antimicrob Agents Chemother 1986;29(4):645-648.

6. Rowland MGM, Cole TJ, et al. A quantitative study into the role of infection in determining nutritional status in Gambian village children. Br J Nutr 1977;37:441.

7. Martorell R, Yarbrough C, et al. Diarrhoeal diseases and growth retardation in pre-school Guatemalan children. Am J Phys Anthropol 1975;43:341.

8. Brown KH, MacLean WC. Nutritional management of acute diarrhoea: an appraisal of the alternatives. Pediatr 1984;73:119-125.

9. Butler T, Speelman P, Kabir I, Banwell J. Colonic dysfunction during shigellosis. J Infect Dis 1986;1545:817-824.

10. Whitehead RG. Protein and energy requirements of young children living in the developing countries to allow for catch up growth after infections. Am J Clin Nutr 1977;30:1545.

11. Golden MHN. Protein deficiency, energy deficiency, and the oedema of malnutrition. Lancet 1982;1:1261-1265.

12. Butler T, Islam MR, Azad AK, Jones PK. Risk factors for development of the hemolytic-uremic syndrome during shigellosis: role of antimicrobial treatment. J Pediatr 1987 (in press).

13. Coward WA, Fiorotto M. The pathogenesis of oedema in kwashiorkor - the role of plasma proteins. Proc Nutr Soc 1979;38:51-59.

14. Dickson PW, Howlett GJ, Schreiber G. Metabolism of prealbumin in rats and changes induced by acute inflammation. Eur J Biochem 1982;129:289-293.

15. Moskowitz SR, Pereiva G, Spitzer A, Heaf L, Amsel J, Watkins JB. Prealbumin as a biochemical marker of nutritional adequacy in premature infants. J Pediatr 1983;102:749-753.

16. Smith FR, Goodman DS, Zaklama MS, Gabr MK, El Maraghy S, Patwardhan VN. Serum vitamin A, retinol-binding protein, and prealbumin concentations in protein-calorie malnutrition. Am J Clin Nutr 1973;26:973-981.

17. Jelliffe DB. Assessment of nutritional status of the community with special reference to field surveys in developing regions of the world. WHO Monograph Series No. 53, 1966:221-232.

ABSTRACT SUMMARY FOR ETHICAL REVIEW COMMITTEE

1. Fifty-four children atged 2-5 years with bacteriological proven shigellosis will be given a diet containing higher amount of protein or regular amount of protein for 21 days. Both the study patient and control patients will be followed up for 6 months at their home. The impact of supplementing higher amount of protein on their nutritional state and further morbidity will be evaluated.
2. Patients with severe malnutrition and other complicating illnesses will be excluded.
3. There is no potential risk involved in the study, every precaution will be taken to safeguard the interest of the patient.
4. All the records will be kept strictly confidential and will remain with the investigators.
5. Informed consent (signed or thumb impression) will be obtained from the guardians or parents. There is no procedure in this study which may unmask the privacy of the subject.
6. Interview will be taken only to the history of illness and is needed only for clinical management of the disease.
7. The patient will benefit from the treatment of diarrhoeal illness. General benefit to the community include to set a policy, whether short-term nutritional therapy with a diet with higher amount of protein is effective in reducing further morbidity and growth faltering in children with shigellosis.
8. The study will require rectal swab for bacteriological culture on admission and venous blood samples for prealbumin.

SECTION III : BUDGET

A. Detailed budget

PERSONNEL SALARY

Name	Position	% of effort	Annual salary	Project requirement (US Dollar)
Dr I. Kabir	Pr. investigator	50	5760	2x2880 = 5760
Dr S.A. Sarker	Co-investigator	20	4920	2x984 = 1968
Dr A. Islam	Co-investigator	10	5760	2x576 = 1152
Medical Officer (to be named)		20	4200	2x840 = 1680
Field workers (to be recruited)/GS 3		100	1440	3x2x1440= 8640
Sub-total:				19200

SUPPLIES AND MATERIALS

Dry skimmed milk, chicken, egg	900
Office supplies	300
Sub-total:	1200

CAPITAL EXPENDITURE

Weighing machine, scale, caliber	1000

OTHER COST

Rent, communication & utilities	50
Printing and publication	500
Service charges	50
Sub-total:	600

INTERNATIONAL TRAVEL

For attending conference/seminar	2000

INTERDEPARTMENTAL SERVICES

Computer (for data analysis)	2000
ICDDR,B transport (Dhaka): 54x6x10 = 3240 mile x Tk.12	1296
Xerox and mimeography	200
Laboratory investigation (Pre-albumin, fat, protein, CHO analysis of diet)	500
Patient hospitalization (Tk.500/day x 21 x 54 pts)	18900
Medical illustration	50
Sub-total:	22946

B. SUMMARY BUDGET

	Amount ($)
1. Local salaries	19200
2. Supplies & materials	1200
3. International travel	2000
3. Other costs	600
4. Interdepartmental services	22946
Total direct cost	45946
Plus 31% overhead	14244
	60190
Capital expenditure	1000
	61190

Follow-up MORBIDITY form

POST-SHIGELLA FEEDING STUDY

Patient identification ___/___/___/

Name_____ Sex _____ Age _____

Date of interview ___/___/___/___/___/___/ Week of follow-up _____

Date of previous interview ___/___/___/___/___/___/

Address _____

Previous 15 days symptoms:_____

	1st fortnight					
Diarrhoea						
Stool character: Watery						
Mucoid						
Bloody						
Vomiting						
Loss of appetite						
Fever						
Cough						
Skin rash						
Nasal discharge						
Purulent cough						
Hurried respiration						
Discharge of pus from ear						
Skin infection						

Others

Feeding history ___/

Formula milk ___/

Animal milk ___/

Rice ___/

Rice suzi ___/

Chapati ___/

Meat/fish ___/

Egg ___/

SKFT (mm) ___/___/

Wt (kg) __/__/.__/__/

MAC (cm) __/__/.__/__/

Length (cm) __/__/.__/__/

Others (specify) _____

Medicine _____

CONSENT FORM

Post-shigella feeding study

Your child is suffering from blood dysentery. The present knowledge from different studies suggests that due to profuse loss of blood, mucus, and high fever children can develop malnutrition and growth faltering. To counteract this problem we are investigating whether a diet with higher amount of protein supplementation is helpful to improve the nutritional status and further morbidity in these children. If you agree to participate into the study, your child will have to stay at hospital for additional 21 days after treatment with appropriate antibiotic. Your child will receive either a regular hospital diet or study diet which contain higher amount of protein. Your child will be discharged after 21 days, and 5 ml of blood will be taken from your child on admission and on discharge to see the change in protein status in your child. Your child will be visited by field worker every month and body weight, height, and mid-arm circumference will be measured. You will be also asked about any history of illnesses on each visit and proper treatment will be provided.

If you agree to participate and agree to comply with follow-up please sign here. You may withdraw your child anytime and proper care will not be altered by that.

Signature of investigator

Signature/Thumb impression of guardian

Date: _____

সম্মতি পত্র

শিগেলা-পরবর্তী খাবারের গবেষনা
(Post-shigella feeding Study)

আপনার শিশু রক্ত-আমাশয় ভুগছে। বর্তমানে বিভিন্ন গবেষনায় দেখা গেছে যে, প্রচুর রক্ত-পাত, শ্লেষ্মা, এবং উচ্চজ্বর-জনিত কারনে শিশুর পুষ্টিহীনতা এবং বৃদ্ধি বাঁধাপ্রাপ্ত হতে পারে। এই সমস্যার পরিপ্রেক্ষিতে আমরা বেশী আমিষ সমৃদ্ধ এমন একটি খাবার আবিষ্কারের জন্য গবেষনা করেছি, যে খাবার শিশুর পুষ্টিহীনতা দূরীকরনে সহায়ক হবে। যদি আপনি এ গবেষনায় অংশ গ্রহণে রাজী থাকেন তবে আপনার শিশুর প্রয়োজনীয় ওষুধ দ্বারা চিকিৎসার পরও আপনাকে আরো ২১ দিন হাসপাতালে থাকতে হবে। হাসপাতালে থাকাকালীন সময়ে আপনার শিশু হাসপাতালের সাধারন খাবার অথবা বেশী আমিষ সমৃদ্ধ খাবার পাবে। ২১ দিন পর আপনার শিশুকে হাসপাতাল থেকে ছুটি দেয়া হবে। আপনার শিশুর শরীরের আমিষের পরিবর্তন দেখার জন্য ভর্তির সময় এবং ছুটির সময় তার শরীর থেকে ৫ সি: সি: পরিমান রক্ত নেয়া হবে। প্রতিমাসে একজন মাঠকর্মি আপনার বাড়ীতে গিয়ে শিশুর ওজন, উচ্চতা এবং অন্যান্য মাপ নিয়ে আসবে। তাছাড়া আপনার শিশুর শারিরীক অসুস্থতা সম্বন্ধে আপনাকে জিজ্ঞাসা করা হবে এবং প্রয়োজনীয় চিকিৎসাও দেয়া হবে।

আপনি যদি গবেষনায় অংশ গ্রহনে রাজী থাকেন তবে নিম্নে স্বাক্ষর দিন। আপনি যে কোন সময় আপনার শিশুকে গবেষনা থেকে প্রত্যাহার করে নিতে পারবেন তাতে তার চিকিৎসার কোন ব্যাঘাত ঘটবে না।

গবেষকের স্বাক্ষর

তারিখ

স্বাক্ষী :- _____

অভিভাবকের স্বাক্ষর/বৃদ্ধাঙ্গুলের ছাপ।