HEALTH CARE CHOICE

FOR DIARAHOEA IN

Pri Mipal Investigator

RURAL BANGLADESH.

Non-ill subjects

Minors or persons

Doos the study involve:

Social Risks

to subjects

ject or others

birth or other)

Procedures to be

followed including

Sensitive questions

Right to refuse to

draw from study

incipal Investigator

Benefits to be derived

participate or to with-

Compensation 8/or treat-

Confidential handling

alternatives used

Physical risks

abortus

fluids

fudy

of data

Does the study involve:

subjects

under guardianship

Psychological risks

Invasion of privacy

Discomfort to subjects

Disclosure of informa-

tion damaging to sub-

Use of records, (hosp-

Use of fetal tissue or

Use of organs or body

Nature and purposes of

Are subjects clearly informed about:

ital, medical, death,

Physical risks to the

Appelluation No.

itte of Study

AND DRUG USE

(b)

(c)

(a)

 (\mathfrak{a})

(c)

(d)

(e)

(E)

(b)

(c)

(b)

(c)

(d)

(e)

 $\{f\}$

(g)

(h)

28.02.88

OK 161NAL

ETHICAL REVIEW COMMITTEE, ICODR, B. C. RONSMANS

K2 Mary

Yes

165

Yesi

No

No

No

No

No

NO NA

Yes No

No

No

No

N٥

10

Trainee Investigator (if any)

Supporting Agency (if Non-!CDDR,B)

Project status:

(X) New Study

Continuation with change No change (do not fill out rest of form)

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

Source of Population: Will signed consent form be required: (a) III subjects

No From subjects Yes | No | No

From parent or guardian (b) (1£ subjects are minors) Yes No

Will precautions be taken to protect anonymity of subjects Yes No

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 quest-

ions 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 confidential.

Questionnaire or interview schedule. * If the rinal instrument is not completed

prior to review, the following information should be included in the abstract summary. A description of the areas to be

interview which could be considered either sensitive or which would constitute an invasion of privacy. Examples of the type of specific

covered in the questionnaire or

questions to be asked in the sensitive areas. An indication as to when the question-

naire will be presented to the Cttre. for review.

Trainee

ment where there are risks: or privacy is involved in [NΑ any particular procedure No

(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.

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b.SECTION I - RESEARCH PROPOSAL

1.TITLE

- : Health care choice and drug use for bloody diarrhoea in rural Bangladesh.
- 2.PRINCIPAL INVESTIGATOR: Carine Ronsmans

CO-INVESTIGATORS

: V Fauveau, J Chakraborty, ASG Faruque, A Bari, SA Khan, M Yunus.

3.STARTING DATE

: 1th April 1988

4.COMPLETION DATE

: 31th July 1988

5.(a)TOTAL COST (b)PROBABLE SOURCE OF FUNDING

- : 7956 US \$
- : Belgian Government

6.ACTING SCIENTIFIC PROGRAMME HEAD

: Dr. R Eeckels

This protocol has been approved by the Community Medicine Division.

Staleber

Signature of the Scientific Programme Head

10.3.88

Date

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7. ABSTRACT SUMMARY.

This study proposes to examine the utilisation of different parallel medical systems for children with bloody diarrhoea in a rural community in Bangladesh. Particular attention will be given to the pattern of antibiotic use.

In a community survey a systematic sample of children with bloody diarrhoea since less than 7 days will be visited and the type of health care used will be examined. Age and sex of the patient and treatment provided (name of the drug, dose, route, duration and cost) will be recorded.

In another survey a field worker will visit a random sample of health care providers and ask for treatment for a two year old child with bloody diarrhoea. The advices given and drugs dispensed will be recorded.

Knowledge about the accessibility of appropriate treatment for acute bloody diarrhoea in a rural area will contribute to the improvement of strategies for field management of dysentery.

mprovement of strategies for field management of dys	
.REVIEWS:	
1. Ethical Review Committee	
2. Research Review Committee	

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3. Director's signature -

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e. SECTION II - RESEARCH PLAN

A. INTRODUCTION'

1. Objective

To describe the treatment currently received by village, children when they have bloody diarrhoea.

2. Background

In rural Bangladesh, most of the people have little access to health care facilities (4,7).This government mean, however, that the rural people have no access at all to kind of health care. A variety of health care providers ranging from village practitioners who use allopathic drugs, to spiritual healers who heal through ritual chanting, amulets and charms are dispersed over the villages. Their type, distribution characteristics have been studied mostly within the social The private health practitioners are usually divided sciences. into 8 categories: 1. Qualified practitioners with M.B., B.S. degrees or Medical Board Licenses (LMF, National Pass and Medical 2. Semi-qualified village doctors who received a Assistants), one year health training from the government (palli chikitshoks), Practitioners without medical degree providing allopathic drugs, 4. Practitioners using homoeopathic medicine, 5. Ayurvedic (kobiraj) or Unanic (hakim) practitioners, 6. Spiritual healers, Traditional midwives and 8. Others who do not fall above categories . It should be mentioned that some practitioners use different systems of health care but most retain a reputation in one or another form of treatment. A few authors tried to quantify the proportion of each type, but figures vary widely: proportion of "allopathic practitioners" represented from 15% (192/1292) village communities varies in conducted by Sarder in Matlab (1) upto 39% (821/2120) randomly selected sample of Bangladesh described by Claquin The factors influencing the choice of a health care provider by a patient are complex and depend on a great variety of factors such as the type and severity of illness, gender and age of patient, relative proximity of the healer, cost of health care, past experience, etc. (4, 5, 7, 8, 9, 10).

The allopathic system seems to gain popularity in Bangladesh (7,8). Although the most expensive, it dominates medical care, a fact illustrated by the number of allopathic pharmacies even in small localities. Those private pharmacies are the predominant drug dispensers. A study conducted in Matlab reports that 95% of 261 drugs taken by a 1.5% random sample of the population were obtained from private pharmacies (3). Sometimes ,one qualified pharmacist or doctor is registered as the owner of the pharmacy. In reality, untrained attendants "diagnose" and "prescribe" at the same time. A fixed treatment scheme is usually not followed. For a specific disease a variety of tablets or syrup may be advised, depending on the severity of the complaint, the economic

situation of the patient and the range of available medicines. Which medicines the patient gets is often the outcome of a process of negotiation (10).

Diarrhoea seems to be one of the diseases for which people prefer the allopathic system (1,10). Antibiotics and other drugs, are still commonly used for treatment of diarrhoea and it is rare full course of therapy is purchased at a time (1,2,3). that a This was clearly illustrated in a study where 25 pharmacies each of 3 different countries were visited (Bangladesh, Sri Lanka Yemen Arab Republic) and the pharmacist was asked provide treatment for an 11-month-old child with watery diarrhoea (6). Fifty-nine (79%) of the pharmacies, including 19(76%) of in Bangladesh, prescribed unnecessary medications. The most commonly prescribed medications in Bangladesh were furazolidone metronidazole . In another study, 83% of the unqualified allopathic practitioners reported the use of tetracycline treatment of diarrhoea (2).

None of those studies, however, have drawn much attention to problem of dysentery, where appropriate antibiotic treatment both justified and important. Antibiotic treatment for bacillary dysentery reduces duration and severity of illness and is assumed to reduce mortality (18). In endemic areas dysentery accounts for majority of deaths associated with diarrhoea (13,14). demographic data from the Matlab Demographic Surveillance' System for 1984 show that dysentery was related to 129 of the 727 (18%)occurring that year in under-five children (15). deaths deaths were more common than the "diarrhoea" death's which numbered 55 for the same year. The higher risk of death related to dysentery has also been reported elsewhere (16,17). One reason might be that rural people in Bangladesh have no access facilities providing appropriate antibiotic treatment dysentery.

Not much is known, however, about where village people go to when they have diarrhoea and what type of treatment they get. One study reports that 51 % of persons who died of cholera had been treated by village practitioners, another 20 % had been attended by qualified doctors and 8 % had had no medical care (11). A few authors described the advices given and drugs dispensed for diarrhoea by private practitioners (1,2,3,6), but only one of them examined the patients' choice of health care for dysentery village practitioners were more often consulted for dysentery than for watery diarrhoea (12). The treatment provided, however, was not examined.

3. Rationale

Knowledge about the accessibility of correct treatment for acute diarrhoea and the irrational use of antibiotics for bloody diarrhoea will strenghten the development of programmes for control of diarrhoea concentrating on field management of dysentery.

B. SPECIFIC AIMS.

- 1. To describe the choice of health care made and the drugs received by rural people when their children have bloody diarrhoea.
- 2. To describe the knowledge of various types of health care providers about the treatment of bloody diarrhoea.
- 3. To provide the Matlab MCH-FP project with relevant information necessary for designing interventions aimed at reducing infant and child mortality from diarrhoea, particularly dysentery.

·C. METHODS

The study consists of 2 separate surveys to be conducted in the Matlab area: (i) a community survey aimed at describing the health care choice and drugs used for bloody diarrhoea; (ii) a survey of health care providers concentrating on the pattern of drug prescription for bloody diarrhoea.

1. Community survey:

During a 2-month period 480 families with a child having bloody diarrhoea will be visited once and questioned about the type of health care received.

Study area. The study will be conducted in the Matlab-MCH-FP area and a defined area in Chardpur district. Two separate study areas have been chosen because of their difference in facilities available for treatment of bloody diarrhoea: people living in the MCH-FP area have easier access to appropriate treatment for dysentery through the 3 ICDDR'B treatment centres. The Chandpur area, on the other hand, might be more representative for the whole of Bangladesh and might thus allow extrapolation upto national level.

The patients will be identified by the community health workers (CHW) or health assistants (HA) according to the following criteria:

- a child five years of age or less.

- the child still has or had bloody diarrhoea and the diarrhoea started between 2 to 7 days prior to the visit of the CHW or HA.

Diarrhoea will be defined as perceived by the mother: any child reported as having blood in the stool will be enrolled.

In the MCH-FP area randomly 20 CHWs will enroll the first 12 children encountered during their regular fortnightly home visits, meeting the enrollment criteria. In the Chandpur area each of the 6 HAs will enroll the first 40 children identified during weekly home visits.

Sample size. The number of diarrhoea patients required is about 240 for each area. This has been calculated by standard sample size calculation formulas; based on the assumption that only 10 % of patients with dysentery receive appropriate treatment , a significance level of p < 0.05 and a precision of 5%.

For each child identified, the following information will be recorded (see questionnaire on page 13):

- -age / sex / arm circumference
- -type and duration of diarrhoea
- -type of practitioner chosen
- -treatment given
- -reasons for seeking help from a practitioner
- -maternal education

The type of practitioner will be defined according system of health care used, namely allopathy, homoeopathy, kobiraj, unani, religous or magic healing and others. Allopathic and homoeopathic practitioners will be defined as qualified, semi-qualified and non-qualified. "Qualified doctors" refers all those persons who have passed a formal, institutionalised recognised programme of medical study. "Semi-qualified doctors" refers to those who have received a short training course in either a regional or local institution. Usually these receive a certificate indicating their passing particular programme or study. "Non-qualified doctors" refers employ who the techniques $\circ \mathbf{f}$ their respective specialisation although they have never received a degree license in the field. In the Matlab MCH-FP area all the practitioners residing in the area have been identified recently through a survey conducted by the CHWs; the CHWs will able to identify 'he type of practitioner. In Chandpur no extended survey has been done; the HAs will therefore visit any health practitioner not known to them and ask for his her qualification.

Only allopathic treatment will be recorded in detail. For each drug prescribed, name, dosis, duration of treatment and frequency and route of administration will be recorded. To report the names of the drugs as accurately as possible, a pre-survey will be conducted to draw a list of the different brands of antibiotics currently dispensed by the local pharmacies. An estimate of the total cost of the treatment including transport, consultation fee and cost of the drugs will be recorded as well.

If the child still has diarrhoea at the time of the visit, it will be referred to the Matlab treatment centre.

Training. The CHW's in the MCH-FP area and the HA's in the Chandpur area have sound knowledge about management of various types of diarrhoea. During the first month of the study both groups will receive supplementary training on types of health care providers and drugs used. The training will be given by a Field Research Officer under supervision of the PI.

Data analysis. (1) The treatment given by different practitioners and the reasons mentioned for chosing a certain type of practitioner will be described. (2) The influence of age, sex , duration of diarrhoea and maternal education on the choice of a particular type of practitioner will be evaluated through comparison of different groups using standard chi square tests (or Fisher exact test). (3) The proportion of children who have access to correct treatment will be compared between the two study areas using standard chi square tests.

2. Health providers survey.

A field worker (Field Research Officer(FRO)) will visit a stratified random sample of 200 health practitioners providing allopathic treatment in the Matlab DSS area. All the health practitioners residing in the area have been identified recently through a survey conducted by the CHWs.

After obtaining verbal informed consent (see consent form on page 15) the FRO will ask the following question: "I have a 2-year-old child with 3 days of bloody diarrhoea. What treatment would you recommend?" If the health care provider asks more questions about the patient, a clinical picture including abdominal pain and fever will be reported. If drugs are recommended, a structured interview on the name, dosis, frequency, duration of treatment and frequency and route of administration will follow (see questionnaire on page 14). Any other advice given will be recorded as well.

This procedure has been chosen after ethical consideration: though the information obtained by a field worker through informed consent might be biased and might not exactly reflect the real situation we thought this method was the only one that, within ethical limits, would provide us with relevant information on drugs provided for diarrhoea.

This survey will take 2 months and will be conducted during the same period as the community survey.

Data analysis. The appropriate recommendation is considered to be: "Take a 5 day course of antibiotics (Ampicillin 100 mg/kg.d, Nalidixic acid 55 mg/kg.d or Co-trimoxazole 480 mg.d) or consult a doctor". The recommended doses recorded as number of spoons or tablets per day will be translated into the equivalent mg per day. The recommendations given will first be described as such using descriptive statistics and secondly compared to previous surveys (1,2,3) using standard chi square tests (or Fisher exact test).

D. SIGNIFICANCE

Programmes for control of diarrhoeal diseases focus almost entirely on the problem of watery diarrhoea and the use of oral rehydration therapy (ORT). None of those programmes, however, have drawn much attention to the problem of dysentery, where antibiotic treatment is required to reduce both severity of illness and mortality. In a country like Bangladesh, bloody diarrhoea - mostly due to shigellosis - is a major killer of children and interventions should be designed to reduce deaths from dysentery.

This study aims at answering the following question: "What do rural people currently do to treat a child with bloody diarrhoea?". The results of the survey will be used for designing an intervention for treating more appropriately children with bloody diarrhoea.

E. FACILITIES REQUIRED

The facilities of the ICDDR'B in Matlab and Chandpur will be sufficient to conduct this study.

F. COLLABORATION

No external collaboration is required.

d. REFERENCES

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e. ABSTRACT SUMMARY

The study aims to describe the role of private practitioners in treatment of diarrhoea in under five children in rural Bangladesh. Special attention will be drawn to the use of antibiotics for bloody diarrhoea. In a community survey parents of children with bloody diarrhoea will be asked about the health care chosen and the treatment received. In another survey health care providers will be asked to provide treatment for a fictitious case history of a child with bloody diarrhoea.

- 1. Mortality from diarrhoeal diseases is highest in children less than 5 years old and interventions aimed at reducing diarrhoeal deaths should focus on this age group.
- 2. There are no potential risks.
- 3. Procedures for protecting against or minimising potential risks: not applicable.
- 4. To ensure confidentiality all children and health care providers will be given a code number by which to identify them.
- 5. Since the study will be a part of the regular service activities provided in both areas, a specific written informed consent is not necessary. Verbal informed consent will be obtained from parents of children with diarrhoea as well as from health care providers.
- 6. An interview about 30 minutes long will take place in the house to collect information on the type of diarrhoea and the type of health care chosen.

The interview with the health care providers will take place in their place of practice and will require about 15 minutes.

7. Children with bloody diarrhoea will be referred to an ICDDR'B treatment centre. Each child encountered during the visits will be helped if required.

Knowledge about the accesibility and availability of appropriate treatment for diarrhoea for rural children will contribute to the design of new interventions aimed at reducing deaths from diarrhoea in children.

8. No samples will be taken.

f. SECTION III - DETAILED BUDGET

PERSONNEL REQUIREMENT

NEW RECRUITS

<u>Job</u>	<u>Level</u>	No	<u>Man</u> mo	\$/mo	Amount(US\$)		
Field research off	GS5	2	7	352	2464		
Health ass. Chandpur	GS3	6	18	219	3942		
				1	6406		
SUPPLIES AND MATERIALS	<u>}</u>						
Drugs					50		
Stationery and office	supplies	;			200		
			·		250		
OTHER COSTS							
Printing and publicati	on				100		
Per diem for investiga	100						
Service charges	-		,		100		
	,				300		
INTERDEPARTMENTAL SERVICES							
Transport Dhaka-Matlab	300						
Transport Matlab-Chand	300						
Water transport-Matlab	250						
Xerox					100		
Medical illustration					50 		
•					1000		
			<u>1</u>	COTAL	<u>7956</u>		

QUESTIONS TO BE ASK	(ED -TO THE MOTHER	UF EACH UHILD	IN THE STUDY	
Name of the child:	was one out that pass one upo one limb one and take one our tire the	and the control of th	.a. 1000 ABIN AND	
Census No.(only for	- Matlab)	/		,
Date of visit		<u> </u>		
1.Study No.			/	/
2.Study area	1=Matlab 2=Chandpur			
3.Age of the child	(months)		, <u> </u>	/ :
4.Sex of the child	1=female 2=male		MM-1	
5.Mother's educated	on (years of stuc	(y)		/
6.How many days and	o did the diarrho	ea start?	### ***	/
7. Who treated this diarrhoea?	8.How many days after onset of diarrhoea?	diarrhoes	10.Treatment provideo?	
FIRST	wa am am am wa	<u></u>	cade cross care	
SECOND				. >
THIRD			Lagge Mayor paints	
FOURTH	160 W. 161 W. 481	*****		
(7) 1=no treatment 2=mother 3=relative or (4=allopath qua 5=allopath sem. 6=allopath non- '=homoeopath 8=herbal 9=religuous or 10=other	neighbour I lified i-qualified -qualified	.=bloody diarrho :=watery diarrho :=non-watery,noo diarrhoea	oea -	1=aliopathy 2=allopathy and other 3=nomoeopathy a=home prep. 5=herbal b=other 7=don't know
12. If home remedy	has been given,	give a descrip	tion: .	

13. What mad	e you decide	to seek the help of this health care provide	r?
FIRST _		if other:	· ==#
SECOND _	/	if other:	
THIRD _		if other:	4 1400
FOURTH _		if other:	AMMI
2=exces . 3=extre ! 4=prese	ssive vomiting eme weakness ence of blood lous advices h		24h)
Name		sentation 16.Dosis 17.Frequency 18.Du	ration
(1/) no ot	no of tabl tabl/day	- syrup - IV - IM no of bottles - total number of injections/day - no of spoons/day - no of injections/day scribed in days	ctions
		total cost of the treatment? (ee, cost of the drugs)	inclu
FIRST SECOND THIRD FOURTH		-Taka -Taka	

QUESTIONS	TO B	BE ASKED	TO	THE	HEALTH	CARE	PROVIDERS
-----------	------	----------	----	-----	--------	------	-----------

What type of health care do you provide? Give by order of priority: 1.
 2.
 etc.

Possible answers will be: allopathy / homoeopathy /ayurvedic / unanic / spiritual / other.

2. What is your qualification and training?

Possible answers will be: MBBS, LMF or Medical Assistant / a training course in a regional or local institution (how many years of study?) / apprenticeship with another practitioner (how many years?) / no formal training

3. I have a 2-year-old child with 3 days of bloody diarrhoea. What treatment would you recommend?

Possible answers will be: no treatment / consult a doctor or another health worker / home preparation / allopathy / homoeopathy / herbal / magic, religuous or other / a combination of different types

4. Write down additional questions if asked by the health care provider.

QUESTION

ANSWER GIVEN

1/ 2/ 3/

5. If you recommend drugs, give for each drug:

<u>Name</u>	Presentation	Dosis	Frequency	<u>Duration</u>
	(tabl, susp, IV,	(no of tabl.	(no of tabl	(days)
	IM, powder)	bottles, etc.)	spoons, etc.	
		•	per day)	

1.

2.

etc.

Other advices (nutrition, home remedy etc.):

CONSENT FORM 1

HEALTH CARE CHOICE AND DRUG USE FOR DIARRHOEA IN RURAL BANGLADESH.

(This statement will be read to the <u>mother</u> before obtaining verbal consent)

Your child has diarrhoea now or had diarrhoea during the last week. We know that there is a wide variety of doctors in the village who treat diarrhoea and we would like to know more about them, especially about the type of treatment they provide. If you agree to participate in this study, we would like to ask you some questions about the treatment your child received for this diarrhoea; but you are free to refuse. All of the information we collect will be kept confidential.

CONSENT FORM 2

HEALTH CARE CHOICE AND DRUG USE FOR DIARRHOTA IN RURAL. BANGLADESH.

(This statement will be read to the <u>health care provider</u> before obtaining verbal consent)

We are from the International Centre for Diarrhoeal Disease Research, Bangladesh and we are studying the treatment given for diarrhoea by different types of health care providers. This study will give us information on the availability of correct treatment for diarrhoea in the villages and will help us designing interventions to improve management of diarrhoea in the community.

If you agree to participate in this study, we would like to ask you to give your recommendations for a child with diarrhoea. Only your qualification and answers to the questions will be recorded, your name or address will not be mentioned.

সন্মু ভিপত্ত – ১

গ্রাঘৰাংলায় ভাষারিয়ার স্থাক্ষ্য সেবা শছক এবং ঔষধের ব্যবহার।

(মৌখিক সন্তি নেয়ার আগে এই কথাপুলি মাকে গড়ে শোনানো হবে)

আপনার ৰাচ্চার এখন ডায়রিয়া চলছে অথবা গত সপুচেই ডায়রিয়া ছিল। আমরা জানি গ্রামে অনেকে চিকিৎসা দিয়ে খাকেন। তাদের সম্পর্কে আরো বিস্তারিত জানতে চাই – বিশেষ করে তাহারা কি ধরনের চিকিৎসা দিয়ে খাকে।

আপনি যদি অনুগ্রহ করে এই গবেষণায় অংশ গ্রহন করতে রাজী হন, তবে
আমরা আপনার ৰাচ্চা ভায়রিয়ায় যে পৰ চিকিংপা পেয়েছে সে সম্পর্কে কিছু
গ্রন্থ করতে চাই । তবে আপনি ইচ্ছা করলে অসন্যতি প্রকাশ করতে পারেন ।
আমরা যে পৰ তথা সংগ্রহ করবো তার গোপনীয়তা রকা করার অংগীকার
করছি ।

সন্তিপন্ত – ২

গ্রামনাংলার ডায়ুরিয়ায় স্থাশহা সেবা পছক এবং ঔষধের ক্রেবহার । ক্ষোখিক সন্মৃতি নেয়ার আগে স্থাশহা সেবা প্রদানকারীকে এই কথাগুলি পড়ে কোনানো হবে ১

আমরা আনুর্রাতিক উদরাময় গবেষণা কেন্দ্র থেকে এসেছি । আমরা বিতির বাজহা সেনা প্রদানকারীয় দেয়া ভায়রিয়া চিকিৎসার ধরন সম্পর্কে গবেষনায় নিয়োজিত । এই গবেষণা গ্রামে ভায়রিয়ার সঠিক চিকিৎসা সম্পর্কে আমাদেরকে ধারনা দেবে যাতে গ্রাম পর্যায়ে ভায়রিয়ার চিকিৎসার সাথে আমরা উপমূওক ব্যবজহা গ্রহমে সঠিক পরিকল্পমা নিতে পারি।

यिष जानिस अमुश्रह करत এই भरवस्ताग् जरनश्रहरम बाँखी हम छर जाग्नियाग् जावनम् निनुत्र अस्य र्य नावण्हामि मिर्म थारूम छा जामता आमरा छामरा गृथुमात जानमात्र र्याणाछा এवर विखित्र अस्त्रत अवाव निनिवन्ध क्रवरता । जामता जानमात्र साम बवर हिनोमा र्याणम बारस्य।