

Informed consent form for the community component (group one)

Title of study: *Helicobacter pylori* and its association with gastrointestinal dysfunction in children in Kampala, Uganda

Makerere University Department of Paediatrics and Child Health - Mulago Hospital and Centre for International Health, University of Bergen, Norway are carrying out this study.

Information to the caretaker and the participant in group one

Introduction:

A well functioning gastrointestinal tract is essential for growth and health in children. In Uganda, unfortunately, many children suffer from repeated episodes of gut infections and therefore do not have a good functioning gastrointestinal tract. If the gut is not functioning normally, certain nutrients are not absorbed and the child will not grow well. In addition he/she may suffer from repeated episodes of abdominal pain.

Purpose: The purpose of this study is to find out how common one of the gut germs that infect the gut called *Helicobacter pylori* is. We also want to find out how well the gut of our Uganda children functions by carrying out some tests on stool and blood. This will help us improve on the way we care for children with infections of the gut.

Procedures: You will be asked questions about your family, income, the health of your child/children below 12 years of age, and their past medical care. You will be asked to collect about 20 gram of faeces from your child and put it in a container that we shall provide. The sample will be collected today or tomorrow. The faeces will be investigated for common germs and one specific one called *Helicobacter pylori*. A faecal test that will inform us about the gastrointestinal function will also be done. Since we know that HIV reduces someone's ability to fight infections, and that HIV infected people tend to get frequent gut infections, we shall also test your child for HIV if you accept. We shall collect a drop of blood using a finger prick. The test will be availed to you if you also wish to test yourself. You will sign a separate HIV counselling form following appropriate counselling by one of our team members.

Possible risks or sides effects:

There are no risks associated with collection of faeces. Counselling and testing for HIV may cause some psychological discomfort but this will be minimised by appropriate counselling and if your child or yourself is found to be HIV infected, you will be referred for appropriate care. The finger prick will cause some minimal pain which will disappear shortly.

Possible benefits:

Any gut infections detected during this study will be treated free of charge. If the child has another problem that requires medical attention, he/she will be referred to hospital. If the child or caretaker is found to be HIV infected, he/she will be referred to an appropriate HIV treatment centre.

Costs: There will be no extra cost by participating in this study.

Right to withdraw from the study: You have the right to withdraw your child from the study at any time, if you wish, without any explanation. This will not affect the care provided to your child at the local health facility or any other health facilities.

Confidentiality: All information collected about you and your child (including laboratory results) will be confidential. It will only be available to the principal investigator, co-investigator and the Institutional Review Boards. All information leading to the identification of an individual child will not be disclosed in the reports.

Question from the parents/caretaker:

You are free to ask any question regarding the study and child's rights now or at any time.

You are free to contact the Principal Investigator, Professor James Tumwine, Department of Paediatrics, Mulago Hospital, telephone +256-772494120. E-mail: jtumwine@imul.com

OR Dr. Grace Ndeezi phone +256-772453191 at Mulago Hospital,

E-mail: gracendeezi@yahoo.com

OR Dr. Elin Hestvik, phone + 47-55974692, E-mail: Elin.Hestvik@cih.uib.no,

Centre for International Health, University of Bergen, Armauer Hansen Bd, N-5021 Bergen

Authorisation statement:

I have read the information about the study (or translated information) and I clearly understand the possible benefits, discomforts, inconvenience and risks of this study. *(If there is any part of this consent you have not understood, please ask the investigator before signing)*

I,..... (name of parent/caretaker),

Related to this child as..... (relationship),

Agree to the participation of..... (name of the child)

in this research. I understand that I may refuse participation from the research at any time I wish.

Signed.....Date.....

The child is older than 8 years and has assented.

Yes:

No:

(If no, do not proceed with the interview)

Witness (not the person administrating the consent form):

Signature.....Date.....

Consent administrated by:

Signature.....Name.....

Title..... Date.....

Investigator's signature.....Date.....

Informed consent form for the hospital based component.

Title of study: *Helicobacter pylori* and its association with gastrointestinal dysfunction in children in Kampala, Uganda

Makerere University Department of Paediatrics and Child Health - Mulago Hospital and Centre for International Health, University of Bergen, Norway are carrying out this study.

Information to the caretaker and the participant in group two

Introduction:

A well functioning gastrointestinal tract is essential for growth and health in children. In Uganda, unfortunately, many children suffer from repeated episodes of gut infections and therefore do not have a good functioning gastrointestinal tract. If the gut is not functioning normally, certain nutrients are not absorbed and the child will not grow well. In addition he/she may suffer from repeated episodes of abdominal pain.

Purpose: The purpose of this study is to find out how common one of the gut germs that infect the gut called *Helicobacter pylori* is. We also want to find out how well the gut of our Uganda children functions by carrying out some tests on stool and blood. This will help us improve on the way we care for children with infections of the gut.

Procedures: You will be asked questions about your family, income, the health of your child/children below 12 years of age, and their past medical care. You will be asked to collect about 20 gram of faeces from your child and put it in a container that we shall provide. The sample will be collected today or tomorrow. The faeces will be investigated for common germs and one specific one called *Helicobacter pylori*. A faecal test that will inform us about the gastrointestinal function will also be done. We shall also take a teaspoon of blood and perform a similar test and in addition test for some of the nutrients that are lost in faeces when the gut is not functioning normally. The test on gut function and nutrients using blood will be carried out at the University of Bergen teaching hospital. You will therefore be requested to allow us store some of the blood (1ml of serum) and later send it to the University of Bergen for testing.

Possible risks or sides effects:

There are no risks associated with collection of faeces. However your child will be subject to a needle prick while collecting blood from the arm fold. This is a procedure that is acceptable in the medical field and the volume of blood taken is also acceptable. We shall try to minimise pain by using a gel (xylocane gel) that reduces pain at the time of blood collection.

Possible benefits:

Children infected by helicobacter pylori and having symptoms of disease will be treated free of charge. The other results will be availed to the attending paediatrician who will decide on further management.

Costs: There will be no extra cost by participating in this study.

Right to withdraw from the study: You have the right to withdraw your child from the study at any time, if you wish, without any explanation. This will not affect the care provided to your child while in hospital.

Confidentiality: All information collected about you and your child (including laboratory results) will be confidential. It will only be available to the principal investigator, co-investigator and the Institutional Review Boards. All information leading to the identification of an individual child will not be disclosed in the reports.

Question from the parents/caretaker:

You are free to ask any question regarding the study and child's rights now or at any time.

You are free to contact the Principal Investigator, Professor James Tumwine, Department of Paediatrics, Mulago Hospital, telephone +256-772494120. E-mail: jtumwine@imul.com

OR Dr. Grace Ndeezi phone +256-772453191 at Mulago Hospital,

E-mail:gracendeezi@yahoo.com

OR Dr. Elin Hestvik, phone +256774803686, E-mail: Elin.Hestvik@cih.uib.no,

Centre for International Health, University of Bergen, Armauer Hansen Bd, N-5021 Bergen

Authorisation statement:

I have read the information about the study (or translated information) and I clearly understand the possible benefits, discomforts, inconvenience and risks of this study. *(If there is any part of this consent you have not understood, please ask the investigator before signing)*

I,..... (name of parent/caretaker),

Related to this child as..... (relationship),

Agree to the participation of..... (name of the child)

in this research. I understand that I may refuse participation from the research at any time I wish.

Signed.....Date.....

The child is older than 8 years and has assented.

Yes:

No:

(If no, do not proceed with the interview)

I also understand that some tests will be performed at the University of Bergen and I have accepted that some of the blood sample can be stored and transferred at a later date for testing.

SignedDate.....

Witness (not the person administrating the consent form):

Signature.....Date.....

Consent administrated by:

Signature.....Name.....

Title.....Date.....

Investigator's signature.....Date.....

Authorisation statement:

I have read the information about the study (or translated information) and I clearly understand the possible benefits, discomforts, inconvenience and risks of this study. *(If there is any part of this consent you have not understood, please ask the investigator before signing)*

I,..... (name of parent/caretaker),

Related to this child as..... (relationship),

Agree to the participation of..... (name of the child)

in this research. I understand that I may refuse participation from the research at any time I wish.

Signed.....Date.....

The child is older than 8 years and has assented.

Yes:

No:

(If no, do not proceed with the interview)

I also understand that some tests will be performed at the University of Bergen and I have accepted that some of the blood sample can be stored and transferred at a later date for testing.

SignedDate.....

Witness (not the person administrating the consent form):

Signature.....Date.....

Consent administrated by:

Signature.....Name.....

Title.....Date.....

Investigator's signature.....Date.....

Appendix III: Questionnaire for the apparently healthy children

Questionnaire to caretaker of healthy children

"Helicobacter pylori and its association with gastrointestinal dysfunction
in children in Kampala, Uganda"

Study participant identification

- studid1 Consent form is obtained? 0=no 1=yes
- studid2
- studid3 Study participant number: (5 digits, 1 letter)
- studid4 Place of living LC1 (text)
- studid5 Phone number of the care taker
If not available, write N/A
- studid6 Date of interview (dd/mm/yyyy)
(example 02.10.2007)
- studid7a Child's name, First name (text)
- studid7b Second name (text)
- studid8 Is the child a boy or a girl? 1=girl 2=boy
- studid9a Child's age (years)
- studid9b (months)
- studid10 Child's date of birth (dd/mm/yyyy)
(example 09.05.2004)
- studid11 Childs age in months, to be calculated (0-144 months)
(age in years multiple 12, plus age in months)
- studid12 Who is giving the information? 1=Mother
2=Father
3=Stepmother
4=Stepfather
(only one answer)

5=Grandmother
 6=Grandfather
 7=Aunt
 8=Uncle
 9=Siblings
 10=Gardian
 11=Not applicable

studid13 Age of the informant (in years)

studid14 Is the mother alive? 0=no 1=yes
 (If the mother is the informant, don't ask, just write 1)

studid15 If yes how old is the mother (years)

studid16 Is the father alive? 0=no 1=yes
 (If the father is the informant, don't ask, just write 1)

studid17 If yes how old is the father (years)

Socio-demographic characteristics:

sodech1 Size of the family living together /sharing kitchen
 for the last 3 months:

sodech1a Children less than 5 years (number)

sodech1b Children older than 5 years (number)

sodech1c Adults (18 years and above) (number)

sodech2 With who is the child living at the moment? (Answer all questions!)

sodech2a Mother 0=no 1=yes

sodech2b Father 0=no 1=yes

sodech2c Stepmother 0=no 1=yes

sodech2d Stepfather 0=no 1=yes

sodech2e Grandmother 0=no 1=yes

sodech2f Grandfather 0=no 1=yes

sodech2g Aunt 0=no 1=yes

sodech2h Uncle 0=no 1=yes

sodech2i Adopted 0=no 1=yes

sodech2j Not applicable 0=no 1=yes

For question sodech3a, sodech4a and sodech5a use these codes:

1=No education

2=Completed Primary school

3=Completed Secondary School

4=Completed Collage/University

sodech3a Education of mother/ female caretaker?

sodech3b How many years has the mother /female
 caretaker been in school? (number)

sodech4a Education of father /male caretaker?

sodech4b How many years has the father /male caretaker been in school? (number)

sodech5a Education of index child?

sodech5b How many years has the index child been in school? (number)

For question sodech6a and sodech7a use these codes:

- 1= Taking care of house / children
- 2= Working at the fields
- 3= Part time job outside the house (less than 30h/week)
- 4= Full time job outside the house (more than 30h/week)
- 5= No occupation
- 6= Disabled

sodech6a Mother/ female caretaker mainly daily occupation

sodech6b Mother/ female caretaker occupation/profession

sodech7a Father/ male caretaker mainly daily occupation

sodech7b Father/ male caretaker occupation/profession

Assets in the house:

assets1 How many of the following items do you have in your household?

assets1a Chairs/stools (number)

assets1b Foam mattresses (number)

assets1c Lanterns (number)

assets2 Does your household have a working (Answer all questions!)

assets2a Cupboard 0=no 1=yes

assets2b Radio 0=no 1=yes

assets2c Mobile phone 0=no 1=yes

assets2d TV 0=no 1=yes

assets2e Fan 0=no 1=yes

assets2f Refrigerator 0=no 1=yes

assets2g Bicycle 0=no 1=yes

assets2h Motorcycle/scooter 0=no 1=yes

assets2i Car/truck 0=no 1=yes

Sources of power

soupow1 What is the main type of fuel used for lightening in the house? 1=Open fire
2=Paraffin/ Kerosene

- 3=Candle
- 4=Gas
- 5=Electricity
- 6=Not applicable

soupow2 What is the main fuel used for cooking in your household? 1=Wood
 2=Charcoal
 3=Paraffin/ Kerosene
 4=Gas
 5=Electricity
 6=Not applicable

Sources of water

souwat1 What is the main source of drinking water in your household? 1=Pond, river or stream
 2=Unprotected natural spring
 3=Rainwater
 4=Open or unprotected well
 5=Covered well
 6=Borehole
 7=Public tap
 8=Piped into plot/house
 9=Bottled water
 10=Not applicable

souwat2 Is it tapped water in the house? 0=no 1=yes

souwat3 Is it tapped water in the yard? 0=no 1=yes
 Economic activities / likelihood

econom1 Do you own or rent the house you live in? 1=Own
 2=Rent

econom1a 3=Other, specify _____

econom2 Is the family cultivating land? 0=no 1=yes

econom3 If yes, what are you growing? (Answer all questions!)

econom3a Crops 0=no 1=yes

econom3b Maize 0=no 1=yes

econom3c Rice 0=no 1=yes

econom3d Sorghum/millet 0=no 1=yes

econom3e Fruits 0=no 1=yes

econom3f Legumes 0=no 1=yes

econom3g Root/vegetable 0=no 1=yes

econom3h Cotton 0=no 1=yes

econom3i Tea 0=no 1=yes

econom3j Coffee 0=no 1=yes

econom3k Tobacco 0=no 1=yes
econom3l Other, specify _____

econom4 Is there someone in the family ? 0=no 1=yes
owning land

econom5 If yes, how much? (acre= area of a football field)
econom5b If don't know 1=Not enough for the need of the family
 2=Enough for the extended family
 3=Enough to sell to other people
 4=Enough to sell weekly at the marked
 5=Enough to sell daily at the marked

econom6 Do you own domestic animals or birds? 0=no 1=yes

econom7 Do you have the animals in the same 0=no 1=yes
compound as living?

econom8 How many animals do you have of the following?

econom8a Cows (number)
econom8b Oxen/bulls (number)
econom8c Pigs (number)
econom8d Goat (number)
econom8e Sheep (number)
econom8f Horses/donkey/mules (number)
econom8g Other, specify _____

econom9 Approximately how many fowl do you have? (number)

econom10 Who is head of the household? 1=A man
2=A woman
3=Not applicable

econom11a Who is the main provider of income Mother 0=no 1=yes
econom11b in the household? Father 0=no 1=yes
econom11c Stepmother 0=no 1=yes
econom11d Stepfather 0=no 1=yes
econom11e Grandmother 0=no 1=yes
econom11f Grandfather 0=no 1=yes
econom11g Aunt 0=no 1=yes
econom11h Uncle 0=no 1=yes
econom11k Siblings 0=no 1=yes

econom12 Is the "main provider of income" 0=no 1=yes
currently employed?

econom13 What are the main sources of income 1=Regular employment
"the main provider" has? 2=Irregular employment
3=Home employment
4=Contribution from others
5=Retirement pension/grant
6=Relief program
7=Don't know
8=No response
9=Not applicable

econom14 How much money do the family earn per month
-includes all income even handouts in USH
Medical history of the index child

Disease prevention and caretaking

dispre1 Who is usually looking after the 1=Mother
child during the day? 2=Father
3=Stepmother
4=Stepfather
5=Grandmother
6=Grandfather
7=Aunt
8=Uncle
9=Older siblings
10=Neighbour
11=Housemaid
12= Not applicable

dispre2 Is the child using a bed net regularly? 0=no 1=yes

dispre3 Where do you dispose the children`s faeces? 1= In the toilet
2= In the garden/compound
3= Together with water
by washing clothes
4= Other

dispre3a 4=Other, specify

dispre4 How would you describe the health status 1= very good
of your child? 2= good

3=poor

4=Very poor

Ask question dispre5-8 only if child younger than 5 years!!!

dispre5 Was/is the child breast feed? 0=no 1=yes 2= Don't know

dispre6 If the child was breast feed, how old was she/he (weeks)
when she/he stopped breastfeeding?

dispre7 At what age was she/he when you started to give (weeks)
complementary feeds (e.g. porridge, milk, mashed
food, water etc?)

dispre8 Did the child receive prelactate feeding 0=no 1=yes
for instance for 1-3 days just after birth?

Medical history

For question medhis 1-13 please use these codes

0=no

1=yes

2= Don't know

medhis1 Has the child been ill with a fever at any time in the last 2 weeks?

medhis2 Has the child had any illness with cough at any time in the
last 2 weeks?

medhis3 Has the child had diarrhoea at any time in the last 2 weeks?

medhis4 Has the child been given medicine from a health facility
against worms in the last 6 months?

medhis5 If the child is younger than 5 years, has the child been given
vitamin A (drops from the capsule) in the last 6 months?

medhis6 Is the child taking multivitamins/getting vitamin supplies daily?

medhis7 Is the child chronically ill?

medhis7a If yes, describe

medhis8 Has the child been taking medication for more than 2 weeks now?

medhis9 Is the child taking daily medication?

medhis9a If yes, describe which with name

medhis10 Have the child taken any medication last 3 months? 0=no 1=yes

medhis10a If yes, was this antibiotics 0=no 1=yes

medhis10b antimalaria 0=no 1=yes

medhis10c vitamins 0=no 1=yes

medhis10d deworming medicine 0=no 1=yes

medhis10e other

medhis11 Has the child been in a clinic/visited a health facility
for the last 3 months?

medhis11aif yes, for what reason

medhis12 Has the child been admitted to a hospital the last 3 months?

medhis12a If yes, for what reason

medhis13 Have the child had any nose bleeding in the last two weeks?

medhis14 How often is the child having 1=more than 4 times/day
stool/bowel movement? 2=3-4 times/day
3=1-2times/day
4=every 2nd-3thay
5=more seldom

medhis15 How is the consistency of the stool? 1=normal formed
2=taking form of a containe
3=watery
4=hard

medhis16 Is the child having diarrhoea now? 0=no 1=yes

medhis17 Have you observed blood in the stool? 0=no 1=yes

medhis18 If yes, for how long ago? 1=This week
2=This month
3=Last month

4=Longer time ago

medhis19 Have you observed mucus/slime in the stool? 0=no 1=yes

medhis20 If yes, for how long time ago? 1=This week
2=This month
3=Last month
4=Longer time og

medhis21 Have you observed any other irregularities in the stool? 0=no 1=yes

medhis21a If yes, describe _____

If the child is a girl older than 10 years:

medhis22 Has she started having her menstrual period? 0=no 1=yes 2= Don`t know

medhis23 If yes, when was the last period? 1=Now
2=1-3 days ago
3=more than 4 days ago

medhis24 Do any member of the household have diarrhoea? 0=no 1=yes 2= Don`t know

nutrit Nutrition

nutrit1 How many times per week is the child eating meat? (number, 0=never)

nutrit2 How many times per week is the child eating fish? (number, 0=never)

nutrit3 How many times per week is the child eating egg? (number, 0=never)

nutrit4 How many times per week is the child drinking milk? (number, 0=never)

Ask to be able to see the child's immunization card / child health card!

immuni2 Please record the immunization given

immuni2a	At birth	BCG	<input type="checkbox"/>	0=no	1=yes
immuni2b		Polio 0	<input type="checkbox"/>	0=no	1=yes
immuni2c	At 6 weeks	Polio 1	<input type="checkbox"/>	0=no	1=yes
immuni2ad		DPT+HebB+Hib1	<input type="checkbox"/>	0=no	1=yes
immuni2e	At 10 weeks	Polio 2	<input type="checkbox"/>	0=no	1=yes
immuni2f		DPT+HebB+Hib2	<input type="checkbox"/>	0=no	1=yes
immuni2ag	At 14 weeks	Polio 3	<input type="checkbox"/>	0=no	1=yes
immuni2h		DPT+HebB+Hib3	<input type="checkbox"/>	0=no	1=yes
immuni2ai	Between 6-9 months	Measles	<input type="checkbox"/>	0=no	1=yes

Please record the weight of the child at birth?

grodew1a Weight (kilo)

Observations

obsele1 Is it electricity in the house? 0=no 1=yes

obstoi2 Is there a toilet in the house/yard? 0=no 1=yes

obstoi2a If yes, is the family sharing this toilet 0=no 1=yes
with anyone in the neighbourhood?

obstoi3 If yes, is the toilet a 1=Open pit
2=Pit latrine
3=VIP latrine
4=Flush toilet

obstoi3a Other, specify

obscom4 Status of compound 1= Littered
2= Not littered
3= Animal faeces on the ground
4= Human faeces on the ground

obshus5 Main material of the floor 1= Earth/dung
2= Cement
3= Tiles
4= Rudimentary wooden
5= Finished wooden
6= Carpet/vinyl

7= Not applicable

obshus6 Main materiel of the roof

- 1= Thatch grass
- 2= Iron sheet
- 3= Tiles
- 4= Concrete
- 5= Wood
- 6=Not applicable

obshus7 Main material of the walls

- 1= Mud and pole
- 2= Wood
- 3= Tin
- 4= Bricks without mortar
- 5= Burnt bricks with mortar
- 6= Plastered walls
- 7= Not applicable

obshus8 Main material of windows

- 1= No Material
- 2= Wood
- 3= Nett
- 4= Glass
- 5= Not applicable

obshus9 Main material of doors

- 1= No door
- 2= Only outer door
- 3= Outer and inner door
- 4= Not applicable

obshus10 In what type of house is the child living

- 1= Shack
- 2= Traditional hut
- 3= Semi-permanent house
- 4= Permanent house
- 5= Not applicable

obshus11 How many rooms are there in the house?

(number)

Anthropometric measurements

To be filled by the nurse/investigator

antrop1 Height/ Length

(cm)

antrop2 Weight

(kg)

antrop3 Head circumference

(cm)

antrop4 Mid upper arm circumference

(cm)

Control questions

contro2 Stool collection container is marked with date, name, 0=no 1=yes
date of birth or age and study ID number

contro3 Stool collection container is given to the care taker? 0=no 1=yes

contro4 Caretaker is explained how to fill the stool container
and when it will be collected! 0=no 1=yes

contro5 Stool collected on day of visit 0=no 1=yes

contro5b If no, date of call back is clarified (dd/mm/yyyy) _____

contro6 I have checked the questionnaire and all
questions are answered! 0=no 1=yes

contro7 My initials are _____ (4 letters)

contro8 My colleague's initials are _____ (4 letters)

Appendix IV: Questionnaire for the HIV-infected children

Questionnaire to caretaker of HIV+ children

"Helicobacter pylori and its association with gastrointestinal dysfunction
in children in Kampala, Uganda"

Study participant identification

studid1

studid2 Study participant number (4 digits, 1 letter)

studiid3 Consent form is obtained? 0=no 1=yes

studid4 Hospital number (if available) (number)

studid4a Ward nr

studid4b Bed nr

studid5a Place of living LC1 (text)

studid5b LC2 (text)

studid5c LC3 (text)

studid5d LC4 (text)

studid6 Phone number of the care taker

If not available, write N/A

studid7 Date of interview (dd/mm/yyyy)
(example 02.10.2007)

studid8a Child's name, First (christian name) (text)

studid8b Second name (text)

studid9 Is the child a boy or a girl? 1=girl 2=boy

studid10a Child's age (years)

studid10b (months)

studid10c Child's date of birth if known (dd/mm/yyyy)
(example 09.05.2004)

studid11 Childs age in months, to be calculated (0-144 months)
(age in years times 12 plus age in months)

studid13 Who is giving the information? (only one answer) 1=Mother/adoption mother
 2=Father/adoption father
 3=Stepmother
 4=Stepfather
 5=Grandmother
 6=Grandfather
 7=Aunt
 8=Uncle
 9=Siblings
 10=Guardian
 11=Not applicable

studid14 Age of the informant (in years)

studid15 Is the mother alive? 0=no 1=yes
 (If the mother is the informant, don't ask, just write 1)

studid16 If yes how old is the mother (years)

studid17 Is the father alive? 0=no 1=yes
 (If the father is the informant, don't ask, just write 1)

studid18 If yes how old is the father (years)

Socio-demographic characteristics:

sodech1 Size of the family living together /sharing kitchen
 for the last 3 months:

sodech1a Children less than 5 years (number)

sodech1b Children older than 5 years (number)

sodech1c Adults (above 18 years) (number)

sodech2 With who is the child living at the moment? (Answer all questions!)

sodech2a Mother 0=no 1=yes

sodech2b Father 0=no 1=yes

sodech2c Stepmother 0=no 1=yes

sodech2d Stepfather 0=no 1=yes

sodech2e Grandmother 0=no 1=yes

sodech2f Grandfather 0=no 1=yes

sodech2g Aunt 0=no 1=yes

sodech2h Uncle 0=no 1=yes

sodech2i Adopted 0=no 1=yes

sodech2j Not applicable 0=no 1=yes

For question sodech3b, sodech4b and sodech5b use these codes:

0=No education/not enrolled at school.

- 1=Not completed primary school.
- 2=Completed Primary school
- 3=Completed Secondary School
- 4=Completed Collage/University
- 9=Died/absent

sodech3a Education of mother/ female caretaker?

sodech3b How many years has the mother /female caretaker been in school? (number)

sodech4a Education of father /male caretaker?

sodech4b How many years has the father /male caretaker been in school? (number)

sodech5a Education of index child?

sodech5b How many years has the index child been in school? (number)

For question sodech6a and sodech7a use these codes:

- 1= Taking care of house / children
- 2= Working at the fields
- 3= Part time job outside the house (less than 30h/week)
- 4= Full time job outside the house (more than 30h/week)
- 5= No occupation
- 6= Disabled
- 7= Died
- 9= Not applicable

sodech6a Mother/ female caretaker mainly daily occupation

sodech6b Mother/ female caretaker occupation/profession _____(text)

sodech7a Father/ male caretaker mainly daily occupation

sodech7b Father/ male caretaker occupation/profession _____(text)

Assets in the house:

assets1 How many rooms are there in the house? (number)

assets2 How many of the following items do you have in your household?

assets2a Chairs/stools (number)

assets2b Foam mattresses (number)

assets2c Lanterns (number)

assets3 Does your household have a working (Answer all questions!)

assets3a Cupboard 0=no 1=yes

assets3b Radio 0=no 1=yes

assets3c Mobile phone 0=no 1=yes

assets3d TV 0=no 1=yes

assets3e Fan 0=no 1=yes

assets3f Refrigerator 0=no 1=yes

assets3g Bicycle 0=no 1=yes

assets3h Motorcycle/scooter 0=no 1=yes

assets3i Car/truck 0=no 1=yes

Sources of power

soupow1 Is it electricity in the house? 0=no 1=yes

soupow2 What is the main type of fuel used for
lightening in the house? 1=Fire
2=Paraffin/ Kerosene
3=Candle
4=Gas
5=Electricity
6=Not applicable

soupow3 What is the main fuel used for cooking
in your household? 1=Wood
2=Charcoal
3=Paraffin/ Kerosene
4=Gas
5=Electricity
6=Not applicable

Sources of water

souwat1 Is it tapped water in the house? 0=no 1=yes

souwat2 Is it tapped water in the yard? 0=no 1=yes

souwat3 What is the main source of drinking
water in your household? 1=Pond, river or stream
2=Unprotected natural spring
3=Rainwater
4=Open or unprotected well
5=Covered well

- 6=Borehole
- 7=Public tap
- 8=Piped into plot/house
- 9=Bottled water
- 10=Not applicable

Economic activities / likelihood

econom1 Do you own or rent the house you live in? 1=Own
 2=Rent

econom1a 3=Other, specify _____

econom2 Is the family cultivating land? 0=no 1=yes

econom3 If yes, what are you growing? (Answer all questis!)

econom3a Crops 0=no 1=yes

econom3b Maize 0=no 1=yes

econom3c Rice 0=no 1=yes

econom3d Sorghum/millet 0=no 1=yes

econom3e Fruits 0=no 1=yes

econom3f Legumes 0=no 1=yes

econom3g Root/vegetable 0=no 1=yes

econom3h Tobacco 0=no 1=yes

econom3i Tea/coffe 0=no 1=yes

econom3j Potatoes 0=no 1=yes

econom3k Cassava 0=no 1=yes

econom3l Other, specify _____

econom4 Is there someone in the family owning land? 0=no 1=yes

econom5 If yes, how much? _____ (acre= area of a football field)

econom5b If don't know 1=Not enough for the need of the family
 2=Enough for the extended family
 3=Enough to sell to other people
 4=Enough to sell weekly at the marked
 5=Enough to sell daily at the marked

econom6 Do you own domestic animals or birds? 0=no 1=yes

econom7 Do you have the animals/birds in the same compound as living? 0=no 1=yes

econom8 How many animals do you have of the following?

econom8a Cows _____ (number)

econom8b Oxen/bulls _____ (number)

econom8c Pigs _____ (number)

econom8d Goat (number)
 econom8e Sheep (number)
 econom8f Horses/donkey/mules (number)
 econom8g Birds (number)
 econom8f1 Other, specify _____

econom9 Who is head of the household? 1=A man
 2=A woman
 3=Not applicable

econom10a Who is the main provider of income	Mother	<input type="checkbox"/>	0=no	1=yes
econom10b in the household?	Father	<input type="checkbox"/>	0=no	1=yes
econom10c	Stepmother	<input type="checkbox"/>	0=no	1=yes
econom10d	Stepfather	<input type="checkbox"/>	0=no	1=yes
econom10e	Grandmother	<input type="checkbox"/>	0=no	1=yes
econom10f	Grandfather	<input type="checkbox"/>	0=no	1=yes
econom10g	Aunt	<input type="checkbox"/>	0=no	1=yes
econom10h	Uncle	<input type="checkbox"/>	0=no	1=yes
econom10k	Siblings	<input type="checkbox"/>	0=no	1=yes

econom11 Is the "main provider of income" 0=no 1=yes
 currently employed?

econom12 What are the main sources of income 1=Regular employment
 "the main provider" has? 2=Irregular employment
 3=Home employment
 4=Contribution from others
 5=Retirement pension/grant
 6=Relief program
 7=Don't know
 9=Not applicable/No response

econom13 How much money do the family earn per month _____
 -includes all income even handouts in USH

Housing/shelter

hushus What is the main material of the 1= Earth/dung
 floor of the house the child lives in 2= Cement
 3= Tiles
 4= Rudimentary wooden
 5= Finished wooden

- 6= Carpet/vinyl
- 7= Not applicable

husrof What is the main material of the 1= Thatch grass
roof of the house the child lives in 2= Iron sheet
3= Tiles
4= Concrete
5= Wood
6=Not applicable

huswal What is the main material of the 1= Mud and pole
walls of the house the child lives in 2= Wood
3= Tin
4= Bricks without mortar
5= Burnt bricks with mortar
6= Plastered walls
7= Not applicable

huswind What is the main material of the 1= No Material
windows of the house the child 2= Wood
lives in 3= Netting
4= Glass
5= Not applicable

husdoor Does the house the child lives 1= No door
in have doors? 2= Only outer door
3= Outer and inner door
4= Not applicable

hushus2 In what type of house is the 1= Shack
child living 2= Traditional hut
3= Semi-permanent house
4= Permanent house
5= Not applicable

Medical history of the index child
Disease prevention and caretaking

dispre1 Who is usually looking after the 1=Mother
child during the day? 2=Father
3=Stepmother
4=Stepfather
5=Grandmother
6=Grandfather

- 7=Aunt
- 8=Uncle
- 9=Older siblings
- 10=Neighbour
- 11=Housemaid
- 12= Not applicable

dispre2 Is the child using a bed net regularly? 0=no 1=yes

dispre3 Where do you dispose the children`s faeces? 1= In the toilet
 2= In the garden/compound
 3= Together with water
 by washing clothes
 4= Other

dispre3a 4=Other, specify _____

dispre4 How would you describe the health status 1= very good
 of your child? 2= good
 3=Poor
 4=Very poor

Ask question dispre5-8 only if child younger than 5 years!!!

Use 999 if the child is still breast feed.

dispre5 Was/is the child breast feed? 0=no 1=yes 2= Don't know

dispre6 If the child was breast feed, how old was she/he (weeks)
 when she/he stopped breastfeeding?

dispre7 At what age was she/he when you started to give (weeks)
 complementary feeds (e.g. porridge, milk, mashed
 food, water etc?)

dispre8 Did the child receive prelactate feeding 0=no 1=yes
 for instance for 1-3 days just after birth?

dispre9 Is it a toilet in the house/yard? 0=no 1=yes

dispre10 If yes, is the family sharing this toilet 0=no 1=yes
 with anyone in the neighbourhood?

dispre11 Is the toilet a 1=Open pit
 2=Pit latrine
 3=VIP latrine
 4=Flush toilet

Medical history

For question medhis 1-13 please use these codes

0=no

1=yes

9= Don't know

medhis1 Has the child been ill with a fever at any time in the last 2 weeks?

medhis1b Is the child having fever today?

medhis2 Has the child had any illness with cough at any time in the last 2 weeks?

medhis3 Has the child had diarrhoea at any time in the last 2 weeks?

medhis3b Has the child had malaria within the last 2 weeks?

medhis4 Has the child been given medicine from a health facility against worms in the last 6 months?

medhis5 If the child is younger than 5 years, has the child been given vitamin A (drops from the capsule) in the last 6 months?

medhis6 Is the child taking multivitamins/getting vitamin supplies daily?

medhis7 Have the child taken any medication the last 2 weeks? 0=no 1=yes

medhis7a If yes, was this antibiotics 0=no 1=yes

medhis7b antimalaria 0=no 1=yes

medhis7c vitamins 0=no 1=yes

medhis7d deworming medicine 0=no 1=yes

medhis7e other

medhis8 Is the child on any medication now? 0=no 1=yes

medhis8a If yes, was this antibiotics 0=no 1=yes

medhis8b antimalaria 0=no 1=yes

medhis8c vitamins 0=no 1=yes

medhis8d deworming medicine 0=no 1=yes

medhis8e other

medhis9 Is the child chronically ill except from being HIV positive?

medhis9a If yes, describe

medhis10 Has the child been taking medication for more than 2 weeks now?

medhis11 Is the child taking daily medication?

medhis11a If yes, describe which with name

medhis12 Have the child taken any medication last 3 months? 0=no 1=yes

medhis12a If yes, was this antibiotics 0=no 1=yes

medhis12b antimalaria 0=no 1=yes

medhis12c vitamins 0=no 1=yes

medhis12d deworming medicine 0=no 1=yes

medhis12e other

medhis13 Has the child been in a clinic/visited a health facility
for the last 3 months except from this time?

medhis13aif yes, for what reason

medhis14 Has the child been admitted to a hospital the last 3 months,
except from this time?

medhis14a If yes, for what reason

medhis15 Have the child had any nose bleeding in the last two weeks?

medhis16 How often is the child having 1=more than 4 times/day
stool/bowel movement? 2=3-4 times/day
3=1-2times/day
4=every 2nd-3rd day
5=more seldom

medhis17 How is the consistency of the stool? 1=normal formed
2=taking form of a container
3=watery
4=hard

medhis18 Is the child having diarrhoea now? 0=no 1=yes

medhis19 Have you observed blood in the stool? 0=no 1=yes

medhis19a If yes, for how long ago? 1=This week

2=This month
3=Last month
4=Longer time ago

medhis20 Have you observed mucus/slime in the stool? 0=no 1=yes

medhis20a If yes, for how long time ago? 1=This week
2=This month
3=Last month
4=Longer time ago

medhis21 Have you observed any other irregularities 0=no 1=yes
in the stool?

medhis21a If yes, describe _____

medhis22 Is the child complaining about abdominal pain? 0=no 1=yes

medhis22a If yes, how often? 1=daily
2=4-6 times/week
3=2-3 times/week
4=1 time or less/week

medhis23 Do any member of the household 0=no 1=yes 2= Don't know
have diarrhoea?

If the child is a girl older than 10 years:

medhis24 Has she started having her menstrual period? 0=no 1=yes 2= Don't know

medhis25 If yes, when was the last period? 1=Now
2=1-3 days ago
3=more than 4 days ago

nutrit Nutrition (if still breast feeding use 99)

nutrit1 How many times per week is the child eating meat? (number, 0=never)

nutrit2 How many times per week is the child eating fish? (number, 0=never)

nutrit3 How many times per week is the child eating egg? (number, 0=never)

nutrit4 How many times per week is the child drinking milk? (number, 0=never)

Immunization / Growth and development

Ask to be able to see the child's immunization card / child health card!

immun1 Immunization card available/seen 0=no 1=yes

immuni2 Please record the immunization given if card available

immuni2a	At birth	BCG	<input type="checkbox"/>	0=no	1=yes
immuni2b		Polio 0	<input type="checkbox"/>	0=no	1=yes
immuni2c	At 6 weeks	Polio 1	<input type="checkbox"/>	0=no	1=yes
immuni2ad		DPT+HebB+Hib1	<input type="checkbox"/>	0=no	1=yes
immuni2e	At 10 weeks	Polio 2	<input type="checkbox"/>	0=no	1=yes
immuni2f		DPT+HebB+Hib2	<input type="checkbox"/>	0=no	1=yes
immuni2ag	At 14 weeks	Polio 3	<input type="checkbox"/>	0=no	1=yes
immuni2h		DPT+HebB+Hib3	<input type="checkbox"/>	0=no	1=yes
immuni2aiat	9 months	Measles	<input type="checkbox"/>	0=no	1=yes

grodew1 Please record the weight of the child at birth?

grodew1a Weight (kilo)

Anthropometric measurements

antrop1	Height/ Length	<input type="text"/>	(cm)
antrop2	Weight	<input type="text"/>	(kg)
antrop3	Head circumference	<input type="text"/>	(cm)
antrop4	Mid upper arm circumference	<input type="text"/>	(cm)

Physical examination

genexa1	Axillary temp	<input type="text"/>	(grade Celsius)
genexa2	Pallor:	<input type="checkbox"/>	0= Absent 1= Present
genexa3	Jaundice:	<input type="checkbox"/>	0= Absent 1= Present
genexa4	Degree of dehydration	<input type="checkbox"/>	0=No 1=Some 2=Severe
genexa5	Oral thrash	<input type="checkbox"/>	0= Absent 1= Present
genexa6	Pedal edema	<input type="checkbox"/>	0= Absent 1= Present
genexa7	Perineal excoriation	<input type="checkbox"/>	0= Absent 1= Present 2=not present

Abdominal examination:

abdexa1	Distension	<input type="checkbox"/>	0= Absent 1= Present
abdexa2	Hepatomegally	<input type="checkbox"/>	0= Absent 1= Present
abdexa3	Splenomegally	<input type="checkbox"/>	0= Absent 1= Present
abdexa4	Ascites	<input type="checkbox"/>	0= Absent 1= Present

Cardiovascular system:

carexa1 Pulse rate beats/min
carexa2 Puls is 1= Normal
2= Bradycardia
3= tachycardia
carexa3 Heart sounds 1=Normal 2= Abnormal
carexa2b If abnormal specify
carexa4 Heart failure 1=Yes 2= No

Respiratory system

respex1 Respiratory rate (breaths/min)
respex2 Chest in drawing 1=Yes 2=No
respex3 Percussion note 1=Normal 2=Abnormal

CNS

cnsexal Level of consciousness 1=Normal 2=Abnormal
cnsexal2 Localizing signs 1=Yes 2=No

Clinical diagnosis (As indicated in patients' file/medical notes)

clidia1
clidia2
clidia3
clidia4

hivsta Which stage of HIV using WHO classification
is the child in on enrolment (1-4)?

Control questions

contro2 Stool collection container is marked with date of 0=no 1=yes
collection, name, date of birth or age, sex
and study id number
contro3 Stool collection container is given to the care taker? 0=no 1=yes
contro4 Caretaker is explained how to fill the stool container
and when it will be collected! 0=no 1=yes

contro5 I have controlled the questionnaire and all questions are answered! 0=no 1=yes

contro6 My initials are (4 letters)

Helicobacter pylori (Hp)rapid test

hptest1 Hp test 0=negative
1=positive
2=weakly positive
3=not performed

Microbiology findings

microsc1 Parasites seen 0=no 1=yes

microsc1a If yes, what is seen: Ring worm 0=no 1=yes

microsc1b Hook worms 0=no 1=yes

microsc1c Giardia lamblia 0=no 1=yes

microsc1d Entamoeba histolytica 0=no 1=yes

microsc1e Cystis isospora belli 0=no 1=yes

microsc1f Hymenolepsis nana ova 0=no 1=yes

microsc1f1 Others

microsc1g

culture1 Growth of bacteria 0=no 1=yes

culture1a If yes, what is growing Salmonella 0=no 1=yes

culture1b Yersinia enterocolitica 0=no 1=yes

culture1c Shigella 0=no 1=yes

culture1d E.Coli 0=no 1=yes

culture1e If E.coli which subtype EPEC 0=no 1=yes

culture1f EHEC 0=no 1=yes

culture1g EIEC 0=no 1=yes

culture1h ETEC 0=no 1=yes

culture1i EaggEC 0=no 1=yes

culture1j Others

microsp Microsporidia is found 0=no 1=yes

cryptos Cryptosporidia is found 0=no 1=yes

rotavir Rotavirus is found 0=no 1=yes

adenovi Adenovirus is found 0=no 1=yes

Faecal calprotectin (FC)

fclev11

fclev12

fclev13 Middle of 1 and 2

Feacel elastase

fecela1

fecela2

fecela3 Middle of 1 and 2

Haematologi

hb Hb on day of enrolment g/dl

wbc WBC on day of enrolment m/mm3

lym Lymphocytes on day of enrolment %
 absolute

mon Monocytes on day of enrolment %
 absolute

gran Granulocytes on day of enrolment %
 absolute

cd4 CD4 count absolute /mm3

cd5 CD4 count percentage %

albumin Albumin level

amylase Amylase level

vita Vitamin A level

vitb Vitamin D level

vitb1 Vitamin E level

zink Zink level

sercal Level of serum calprotectin



Professor Thorkild Tylleskär
Senter for internasjonal helse, UiB
Armauer Hansens hus
5021 BERGEN

Deres ref	Vår ref	Dato
	2007/13898-ANØL	05.12.2007

Ad. prosjekt: Fekale markører i vurderingen av gastrointestinal dysfunksjon hos barn Uganda.
(217.07)

Det vises til din søknad om godkjenning av forskningsprosjekt, datert 25.09.07 og søknad om opprettelse av forskningsbiobank, også datert 25.09.07. Prosjektet ble første gang behandlet i møte 25.10.07. Saken ble der utsatt og prosjektleder ble invitert til å møte komiteen for spørsmål ved ny behandling.

Komiteen behandlet søknaden på ny i møte den 22.11.07.

De regionale komiteene for medisinsk og helsefaglig forskningsetikk foretar sin forskningsetiske vurdering med hjemmel i Forskningsetikklovens § 4. Saker vedrørende forskningsbiobanker behandles i samsvar med Biobankloven. Saksbehandlingen følger Forvaltningsloven.

Komiteen ser fortsatt på den mangelfulle oppfølgingen av positive *Helicobacter pylori* funn som vanskelig. Komiteen ser de praktiske vanskelighetene prosjektleder oppgir som begrunnelse men anbefaler likevel at en ser nærmere på mulighetene for tettere oppfølging. I valg av behandlingsform kan bruk av vismut være et forenklet og et godt alternativ til den planlagte trippelbehandlingen. Komiteen har merket seg at Ugandiske myndigheter har godkjent studien og komiteen stiller seg bak deres merknader til informasjonsskrivet.

Vedtak:

Prosjektet godkjennes på vilkår av at ovennevnte merknader tas til følge. REK Vest forutsetter at søknad om opprettelse av forskningsbiobank godkjennes av Sosial- og helsedirektoratet.

REK Vest tilrår at den søkte forskningsbiobanken blir opprettet.

Komiteenes vedtak etter Forskningsetikklovens § 4 kan påklages (jfr. forvaltningsloven § 28) til Den nasjonale forskningsetiske komité for medisin og helsefag. Klagen skal sendes REK-Vest (jfr. forvaltningsloven § 32). Klagefristen er tre uker fra den dagen du mottar dette brevet (jfr. forvaltningsloven § 29).

Postadresse
Postboks 7804
5020 Bergen

rek-vest@uib.no
www.etikkom.no/REK
Org no. 874 789 542

Regional komité for medisinsk
og helsefaglig forskningsetikk,
Vest-Norge
Telefon 55 97 84 97 / 98 / 99

Besøksadresse
Haukeland Universitetssykehus

Komiteens vurdering av søknad om opprettelse av forskningsbiobank videresendes Sosial- og helsedirektoratet for endelig vedtak der.

Komiteen ber om å få tilsendt sluttrapport evt. trykt publikasjon for studien når dette foreligger.

Vennlig hilsen


Jon Løkven
leder


Anne Berit Ølshheim
sekretær

Kopi:
-SHDir

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**FACULTY OF MEDICINE
OFFICE OF THE DEAN**

Thursday, October 04, 2007

Prof. James Tumwine
Dept. of Paediatrics

Dear Prof. Tumwine

Re: **Approval of Proposal**

Your proposal entitled “**Helicobacter pylori and its association with gastrointestinal dysfunction in children in Kampala, Uganda.**” was considered and reviewed by the research and ethics committee. The proposal was found to be good but some amendments were suggested for incorporation in order to improve on the science of the study. I am happy the suggested changes have been incorporated.

On behalf of the committee, I am glad to inform you that the proposal has been approved. You may now proceed with the process of data collection.

Yours truly,

A handwritten signature in black ink, appearing to read "Katabira Elly".

Prof. Katabira Elly

Chair Research & Ethics Committee

ANNEX C: WHO CLINICAL STAGING OF HIV FOR INFANTS AND CHILDREN WITH ESTABLISHED HIV INFECTION

All clinical events or conditions referred to are described in Annex D

Clinical stage 1

Asymptomatic
Persistent generalized lymphadenopathy

Clinical stage 2

Unexplained persistent hepatosplenomegaly
Papular pruritic eruptions
Extensive wart virus infection
Extensive molluscum contagiosum
Recurrent oral ulcerations
Unexplained persistent parotid enlargement
Lineal gingival erythema
Herpes zoster
Recurrent or chronic upper respiratory tract infections (otitis media, otorrhoea, sinusitis, tonsillitis)
Fungal nail infections

Clinical stage 3

Unexplained moderate malnutrition not adequately responding to standard therapy
Unexplained persistent diarrhoea (14 days or more)
Unexplained persistent fever (above 37.5 °C, intermittent or constant, for longer than one month)
Persistent oral Candidiasis (after first 6 weeks of life)
Oral hairy leukoplakia
Acute necrotizing ulcerative gingivitis/periodontitis
Lymph node TB
Pulmonary TB
Severe recurrent bacterial pneumonia
Symptomatic lymphoid interstitial pneumonitis
Chronic HIV-associated lung disease including bronchiectasis
Unexplained anaemia (<8.0 g/dl), neutropenia (<0.5x10⁹/L³) or chronic thrombocytopenia (<50 x 10⁹/L³)

Clinical stage 4^a

Unexplained severe wasting, stunting or severe malnutrition not responding to standard therapy
Pneumocystis pneumonia
Recurrent severe bacterial infections (e.g. empyema, pyomyositis, bone or joint infection, meningitis, but excluding pneumonia)
Chronic herpes simplex infection; (orolabial or cutaneous of more than one month's duration, or visceral at any site)
Extrapulmonary TB
Kaposi sarcoma
Oesophageal candidiasis (or candidiasis of trachea, bronchi or lungs)
Central nervous system toxoplasmosis (after the neonatal period)
HIV encephalopathy
Cytomegalovirus (CMV) infection; retinitis or CMV infection affecting another organ, with onset at age more than 1 month
Extrapulmonary cryptococcosis including meningitis
Disseminated endemic mycosis (extrapulmonary histoplasmosis, coccidioidomycosis, penicilliosis)
Chronic cryptosporidiosis (with diarrhoea)
Chronic isosporiasis
Disseminated non-tuberculous mycobacterial infection
Cerebral or B cell non-Hodgkin lymphoma
Progressive multifocal leukoencephalopathy
HIV-associated cardiomyopathy or nephropathy

^a Some additional specific conditions can be included in regional classifications (e.g. penicilliosis in Asia, HIV-associated rectovaginal fistula in Southern Africa, reactivation of trypanosomiasis in Latin America).

Ref: <http://www.who.int/hiv/pub/guidelines/HIVstaging150307.pdf>

Copied from : Antiretroviral therapy for HIV infection in infants and children: Towards universal access. Recommendations for a public health approach: 2010 revision.

