Informed Consent Forms

TIMCI: Tools for the Integrated Management of Childhood Illness

Evaluation of pulse oximetry and clinical decision support algorithms in primary care

Pragmatic cluster randomised controlled trial, with embedded mixed methods, cost and cost-effectiveness studies in India and Tanzania

NCT: NCT04910750

Date: 4th February 2023

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For all other sub-studies, specific ICFs were developed, which all are in the same structure, only adapting wording in the “study procedures” section, to reflect the need for each of the sub-studies.

Tools for the Integrated Management of Childhood Illness

Information leaflet and consent form for caregivers of children under 5 years of age

Title	Tools for the Integrated Management of Childhood Illness: Effect of introducing devices to improve the quality of health care for young children
Principal Investigator	[Name] [Affiliation]
Collaborators	[Ministry of Health] PATH, an international public health organization (USA) Swiss Tropical and Public Health Institute, a research organization (Switzerland)
Funding agency	UNITAID

Introduction & purpose of the study

My name is […]. I am a research assistant working with [RESEARCH ORGANISATION]. I would like to tell you about a study taking place at this facility. The [MINISTRY OF HEALTH], along with [RESEARCH ORGANISATION], PATH and Swiss TPH are working together to try to improve the care of unwell children who attend [HEALTH FACILITIES] in [COUNTRY]. This involves using new devices such as tablet computers and medical equipment, to help healthcare providers better diagnose and treat sick children under 5 years of age. In order to understand if these devices really help, we are comparing information about unwell children who attend health facilities using the devices and others not using them. If we find that the care is better when the devices are used, we will provide this equipment to all facilities involved in the project.

Participant selection, voluntary participation and participant rights

We are inviting all caregivers of unwell children under 5 years of age at this facility to take part. You can choose to take part or not. The medical care of your child will be the same, whether or not you choose to take part. You can ask me any questions, or discuss your participation with other people or your family before deciding. If you take part now, you can change your mind and decide not to take part later, without needing to give any reason. Your legal rights will not be affected in any way, regardless of your decision about participation.

Study procedures

If you agree to take part, we will ask you some details about you and your child today, and record some basic information from their health records. We will also ask you for your contact details so that we can call you to find out how your child is doing in one week and one month from now. If your child returns to a health facility or has to go to hospital for any reason, we will also ask for some basic information about their care from you and their records. You can choose to participate and choose not to answer some of the questions if you wish. If you visit a facility involved in the study after one month, we may ask you to participate again. It should take no more than 10 – 15 minutes to answer the questions today and no more than 5 minutes for each of the phone calls.

Risks & benefits of participation

No compensation will be given for your participation. There are no anticipated risks or direct benefits for you or your child, but by taking part you will help us understand how to improve care for unwell children at health facilities. This may benefit your child and other children in the future.

Confidentiality & sharing of the results

Your privacy is very important to us and we will take strict measures to protect it. If you take part, information that could identify you or your child (such as your child's name, your name, your phone number) will not be shared with anyone outside the study team. It will be stored securely, and destroyed when the study is completed. If you take part in the study on more than one occasion, information about each occasion will be grouped together. We will make a summary report of the results available for you at the facility. Information will be shared with research collaborators abroad and kept for 10 years. Some information will be pooled together and made available publicly, so that others involved in the care of unwell children can learn from it. No information or results shared will contain your child's name, your name, or any other information that could identify you or your child.

Right to refuse / withdraw

If you decide not to take part anymore, please let the PI / alternate contact below, or me, know. Information collected on previous occasions will be kept for 10 years, but we will stop collecting information from you.

Study approval

This study has been approved by [ETHICS COMMITTEE]. They may review the information collected to ensure that the research has been conducted properly, but will not be able to identify you or your child.

Further information

If you have any queries about the study after you leave the facility today, please contact:

[PI / ALTERNATE CONTACT]:
[ADDRESS]
[PHONE]
[EMAIL]

[ETHICS COMMITTEE CONTACT]:
[ADDRESS]
[PHONE]
[EMAIL]

Certificate of consent

Name of child	Name of caregiver	Relationship of caregiver to child

Statement by the caregiver

- I have read the information above, or it has been read to me. I have had the opportunity to ask questions, which have been answered to my satisfaction. I consent voluntarily for my child to be enrolled in this study and to answer questions on their behalf.
- I understand that I will be contacted by phone by the research assistant in one (1) and four (4) weeks from now to ask how my child is doing.
- If I cannot provide a phone number or for any reason the research assistant cannot reach me by phone:

a.

b. I agree to be contacted through a community health worker (CHW) or a community leader. **YES / NO**

c. I agree to have a research assistant visit me at my household **YES / NO**

I agree to return to this health facility in one (1) week and in four (4) weeks. I will be reimbursed for the cost of transportation from my household to this health facility. **YES / NO**

- I understand that I am free to withdraw from the study at any time.

Name of caregiver (PRINT)	Signature of caregiver	Date (day, month, year)

If illiterate:

A literate witness must sign (if possible, the caregiver should choose this person, who should have no connection to the research team). Caregivers who are illiterate should include their thumb-print.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness	Signature of witness	AND	Caregiver thumbprint
Date (day, month year)			

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands the following:

1. Their information will be maintained anonymously and confidentially, and it will not be possible to identify them in any reports

2. The care of their child will not be affected in any way, whether they choose to take part or not

I confirm that the participant had an opportunity to ask questions about the study, and all the questions have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A signed copy of this ICF has been provided to the participant.

Name of researcher	Signature of researcher	Date (day, month, year)

Tools for the Integrated Management of Childhood Illness

Information leaflet and consent form for caregivers of children under 5 years of age

Title	Tools for the Integrated Management of Childhood Illness: Effect of introducing devices to improve the quality of health care for young children
Principal Investigator	[Name] [Affiliation] [Contact details]
Collaborators	[Ministry of Health] PATH, an international public health organization (USA) Swiss Tropical and Public Health Institute, a research organization (Switzerland)
Funding agency	UNITAID

Introduction & purpose of the study

My name is […]. I am a research assistant working with [RESEARCH ORGANISATION]. I would like to tell you about a study taking place at this facility. The [MINISTRY OF HEALTH], along with [RESEARCH ORGANISATION], PATH and Swiss TPH are working together to try to improve the care of unwell children who attend [HEALTH FACILITIES] in [COUNTRY]. This involves using new devices such as tablet computers and medical equipment, to help healthcare providers better diagnose and treat sick children under 5 years of age. In order to understand if these devices really help, we are comparing information about unwell children who attend health facilities using the devices and others not using them. If we find that the care is better when the devices are used, we will provide this equipment to all facilities involved in the project.

Participant selection, voluntary participation and participant rights

We are inviting all caregivers of unwell children under 5 years of age at this facility to take part. You can choose to take part or not. The medical care of your child will be the same, whether or not you choose to take part. You can ask me any questions, or discuss your participation with other people or your family before deciding. If you take part now, you can change your mind and decide not to take part later, without needing to give any reason. Your legal rights will not be affected in any way, regardless of your decision about participation.

Study procedures

If you agree to take part, we will ask you some details about you and your child today, and record some basic information from their health records. Another research assistant would like to be present to observe your consultation and take some notes. This is to understand how services are provided in this facility, and the research assistant will not be evaluating you, your child or the healthcare provider. The research assistant will not interrupt your consultation or provide any advice about the care of your child. After your consultation, we would like to ask you some questions about your experience here today.

We will also ask you for your contact details so that we can call you to find out how your child is doing in one week and one month from now. If your child returns to a health facility or has to go to hospital for any reason, we will also ask for some basic information about their care from you and their records. You can choose to participate and choose not to answer some of the questions if you wish. If you visit a facility involved in the study after one month, we may ask you to participate again.

It should take no more than 20 – 30 minutes to answer the questions today and no more than 5 minutes for each of the phone calls.

Risks & benefits of participation

No compensation will be given for your participation. There are no anticipated risks or direct benefits for you or your child, but by taking part you will help us understand how to improve care for unwell children at health facilities. This may benefit your child and other children in the future.

Confidentiality & sharing of the results

Your privacy is very important to us and we will take strict measures to protect it. If you take part, information that could identify you or your child (such as your child's name, your name, your phone number) will not be shared with anyone outside the study team. It will be securely stored, and destroyed when the study is completed. Information collected now will be grouped together with the information you may provide to our team on other occasions. We will make a summary report of the results available for you at the facility. Information will be shared with research collaborators abroad and kept for 10 years. Some information will be pooled together and made available publicly, so that others involved in the care of unwell children can learn from it. No information or results shared will contain your child's name, your name, or any other information that could identify you or your child.

Right to refuse / withdraw

If you decide not to take part anymore, please let the PI / alternate contact below, or me, know. Information collected on previous occasions will be kept, but we will stop collecting information from you.

Study approval

The study has been approved by [ETHICS COMMITTEE]. They may review the information collected to ensure that the research has been conducted properly, but will not be able to identify you or your child.

Further information

If you have any queries about the study after you leave the facility today, please contact:

[PI / ALTERNATE CONTACT]:
[ADDRESS]
[PHONE]
[EMAIL]

[ETHICS COMMITTEE CONTACT]:
[ADDRESS]
[PHONE]
[EMAIL]

Certificate of consent

Name of child	Name of caregiver	Relationship of caregiver to child

Statement by the caregiver

I have read the information above, or it has been read to me. I have had the opportunity to ask questions, which have been answered to my satisfaction. I consent voluntarily for my child to be enrolled in this study, including to provide some basic information about myself, my child, and their health status today and in one week and one month's time.

	Please circle	Please initial
I also consent to a research assistant observing the consultation today	Yes / No	☐
I also consent to answer some questions about my experience today	Yes / No	☐

Name of caregiver (PRINT)	Signature of caregiver	Date (day, month, year)

If illiterate:

A literate witness must sign (if possible, the caregiver should choose this person, who should have no connection to the research team). Caregivers who are illiterate should include their thumb-print.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness	Signature of witness	AND	Caregiver thumbprint
Date (day, month year)			

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands the following:

1. Taking part in the study involves the collection of information about them and their child today and again via a phone call in 7 days time and 28 days time
2. Their information will be maintained anonymously and confidentially, and it will not be possible to identify them in any reports
3. The care of their child will not be affected in any way, whether they choose to take part or not

I confirm that the participant had an opportunity to ask questions about the study, and all the questions have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A signed copy of this ICF has been provided to the participant.

Name of researcher	Signature of researcher	Date (day, month, year)