Informed Consent Forms

TIMCI: Tools for the Integrated Management of Childhood Illness

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

Cross-country Quasi-experimental Pre-post Study, With Embedded Mixed Methods Studies, Cost and Modelled Cost-effectiveness in Kenya and Senegal

NCT: NCT05065320

Date: 5th April 2023

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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 before and after their introduction.

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 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. 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.

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 to participate in this study.

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
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)

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 before and after their introduction.

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 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. 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.

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 to participate in this study.

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
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)

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 before and after their introduction.

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 accompany you during your consultation and throughout the rest of your visit to the facility. S/he will measure the time and record how much time it takes to provide different types of services in this facility. The research assistant will not be evaluating you, your child or the healthcare provider.

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 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. Recording timings of your visit today will not require any additional time from you.

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. 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.

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 to participate in this study.

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). Participants 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, including on the time taken for their visit, and again via a phone call in 7 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)

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 before and after their introduction.

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 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.

After your consultation, another research assistant colleague may ask you if s/he can accompany you today when leaving the health facility and until you have reached your final destination. If you agree, my colleague would like to accompany you and have a conversation about your experiences of care and the decisions you make around care seeking. S/he would like to audio-record the conversation between you and take few notes to remember what you have said. The audio-recording will be switched off in case others are involved in the conversation. We would also like to track the journey by recording data of your journey with [a

device/mobile phone]. If you agree now, and my colleague approaches you, s/he will verbally check with you if you still willing to participate. You are free to change your mind and not participate in this part of the study at any point without needing to give a reason.

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. Your audio-recordings will be converted into text, then deleted. Any information that could identify you or your child will be removed from the text. We will make a summary report of the results available for you at the facility. 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.

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 to participate in this study.

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
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
4. Another research assistant may ask to accompany them on leaving the facility until they reach their final destination, including audio-recording their conversation, taking notes and tracking the journey

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]
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]. You recently agreed to participate in our study when visiting a health facility with your unwell child. At the time, we mentioned that 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]. As part of this, we are interested to understand more about the experiences of caregivers at the health facility, including on the use of devices within the consultation.

Participant selection, voluntary participation and participant rights

We are inviting a few caregivers who have taken part in the study at the facility to take part in a follow-up interview. 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 would like to interview you today, or at another convenient time of your choosing. The interview will be in a conversation style, to understand more about you and your child, particularly about your experience of care, what you think about the devices, and the decisions you make around seeking care. We would like to audio-record the interview and take few notes, simply because we cannot write as fast as you talk and we would like to remember what you said. You can choose to participate and choose not to answer some of the questions if you wish. The interview will take approximately 1 – 1.5 hours, either in your home or another location nearby that provides confidentiality.

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. Your audio-recordings will be converted into text, then deleted. Any information that could identify you or your child will be removed from the text. We will make a summary report of the results available for you at the facility. 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.

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

Statement by the participant

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 to participate in this study.

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

If illiterate:

A literate witness must sign (if possible, the participant should choose this person, who should have no connection to the research team). Participants 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 , or a time of their choosing in the next few days
2. Their information will be maintained anonymously and confidentially, and it will not be possible to identify them in any reports
3. Information collected now will be grouped together with the information they provide to our team on other occasions
4. 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]
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]. You recently agreed to participate in our study when visiting a health facility with your unwell child. At the time, we mentioned that 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]. As part of this, we are interested to understand more about the experiences of caregivers at the health facility, including on the use of devices within the consultation.

Participant selection, voluntary participation and participant rights

We are inviting a few caregivers who have taken part in the study at the facility to take part in a follow-up interview. 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 would like to interview you today, or at another convenient time of your choosing. The interview will be in a conversation style, to understand more about you and your child, particularly about your experience of care, what you think about the devices, and the decisions you make around seeking care. We would like to audio-record the interview and take few notes, simply because we cannot write as fast as you talk and we would like to remember what you said. You can choose to participate and choose not to answer some of the questions if you wish. The interview will take approximately 1 – 1.5 hours, either in your home or another location nearby that provides confidentiality.

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. Your audio-recordings will be converted into text, then deleted. Any information that could identify you or your child will be removed from the text. We will make a summary report of the results available for you at the facility. 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.

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

Statement by the participant

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 to participate in this study.

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

If illiterate:

A literate witness must sign (if possible, the participant should choose this person, who should have no connection to the research team). Participants 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 , or a time of their choosing in the next few days
2. Their information will be maintained anonymously and confidentially, and it will not be possible to identify them in any reports
3. Information collected now will be grouped together with the information they provide to our team on other occasions
4. 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]
Collaborators	[Ministry of Health] PATH [COUNTRY] and PATH Seattle, USA Swiss Tropical and Public Health Institute, Switzerland
Funding agency	UNITAID

Introduction & purpose of the study

My name is […]. I am a research assistant working with [RESEARCH ORGANISATION]. I am here with my colleague [….] who will support me today. You recently agreed to participate in our study when visiting a health facility with your unwell child. At the time, we mentioned that 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]. As part of this, we are interested to understand more about the experiences of caregivers.

Participant selection, voluntary participation and participant rights

We are inviting a few caregivers who have taken part in the study at the facility to take part in a follow-up group discussion. 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 would like to hold a group discussion with you and other caregivers. The discussion will be in a conversation style, to understand more about you and your child, particularly about your experience of care, what you think about the devices, and the decisions you make around seeking care. We would like to audio-record the group discussion and take few notes, simply because we cannot write as fast as you talk and we would like to remember what you said. You can choose to participate and choose not to answer some of the questions if you wish. The discussion will take approximately 1.5 – 2 hours.

Risks & benefits of participation

You will receive a small token of appreciation for your time, and reimbursement if you require transport to arrive. 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. Audio-recordings of the discussions will be converted into text, then deleted. Any information that could identify you or your child will be removed from the text. We will make a summary report of the results available for you at the facility. 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.

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

Statement by the participant

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 to participate in this study.

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

If illiterate:

A literate witness must sign (if possible, the participant should choose this person, who should have no connection to the research team). Participants 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 as part of a group discussion with other caregivers of children under 5 years of age.
2. Their information will be maintained anonymously and confidentially, and it will not be possible to identify them in any reports
3. Information collected now will be grouped together with the information they provide to our team on other occasions
4. 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]
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 am here with my colleague [….] who will support me today. You recently agreed to participate in our study when visiting a health facility with your unwell child. At the time, we mentioned that 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]. As part of this, we are interested to understand more about the experiences of caregivers.

Participant selection, voluntary participation and participant rights

We are inviting a few caregivers who have taken part in the study at the facility to take part in a follow-up group discussion. 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 would like to hold a creative group discussion with you and other caregivers. The discussion will involve acting out some scenarios about experiences in health facilities, to understand more about your experience of care. We would like to video-record (or audio-record) the group discussion and take some photos and a few notes, simply because we cannot write as fast as you talk and we would like to remember what you have done and said. You can choose to participate and choose not to answer some of the questions if you wish. The discussion will take approximately 3 hours.

Risks & benefits of participation

You will receive a small token of appreciation for your time, and reimbursement if you require transport to arrive. 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. Your audio-recordings will be converted into text, then deleted. Any information that could identify you or your child will be removed from the text. Videos and photos will be viewed and analysed only by qualified researchers in the project (in Tanzania and abroad) who have signed strict confidentiality agreements. We will make a summary report of the results available for you at the facility. 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.

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

Statement by the participant

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 to participate in this study.

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

If illiterate:

A literate witness must sign (if possible, the participant should choose this person, who should have no connection to the research team). Participants 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 as part of a group discussion with other caregivers of children under 5 years of age.
2. Their information will be maintained anonymously and confidentially, and it will not be possible to identify them in any reports
3. Information collected now will be grouped together with the information they provide to our team on other occasions
4. 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 healthcare providers

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]. Your facility has been selected to be part of a study on children under 5 years of age. 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 pulse oximetry and tablet computers with clinical guidelines, 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 before and after the introduction of the devices.

Alongside this, we would like to understand what contributes to whether or not the devices help. This includes the type of services available at the facility and the number, type, training and experience of staff providing care to children under 5 years of age.

Participant selection, voluntary participation and participant rights

We are inviting all healthcare providers involved in the care of unwell children at facilities involved in the study if they would like take part. You can choose to take part or not. Your decision will not affect your position in any way. No information on your decision to participate or not will be shared with your colleagues or supervisors. You can ask me any questions, or discuss your participation with other people 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.

Study procedures

If you agree to take part, we will ask you some details about the types of services you provide, the training you have received, and your experience delivering services for children under 5 years of age. We would also like to observe around 5 – 10 consultations you conduct with children under 5 years of age over the next few days. This is to understand how services are provided in this facility, and will not be evaluating you as an individual, the child, or their caregiver. We will record some information about the consultation on a tablet, provided that the caregiver of the child in the consultation has also given consent. We will not interrupt the consultation, but may ask brief questions after you have finished the consultation for clarification purposes if necessary. It should take no more than 10 – 20 minutes to answer the questions today, and around 1 -2 minutes at the end of each observed consultation should there be a need for any clarifications.

We will be conducting these questionnaires on a total of 5 occasions at each facility. Each visit will be about 3 months apart. We may therefore ask you to participate again, but we will check with you verbally each time if you are still willing to participate. If you agree at subsequent visits, we would ask you some details on any changes to training, service delivery and experience since the previous visit, and ask to observe another 5 – 10 consultations in the same way. You can take part today and decide to take part in all, some or none of the following visits, without needing to give any reason.

Risks & benefits of participation

No compensation will be given for your participation. There are no anticipated risks or direct benefits for you or the children you consult with, but by taking part you will help us understand how to improve care for unwell children at health facilities and improve the quality of training and support provided to healthcare providers. This may benefit children attending your facility 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 (such as your name) will not be shared with anyone outside the study team. It will be securely stored, 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. 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 name, or any other information that could identify 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

Statement by the participant

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 to participate in this study.

Name of participant	Signature of participant	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 their training and experience, and observation of some of their consultations with children under 5 years of age
2. Their information will be maintained anonymously and confidentially, and it will not be possible to identify them in any reports, nor will any information be shared with their colleagues or supervisors

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 healthcare providers

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]. Your facility has been selected to be part of a study on children under 5 years of age. 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 pulse oximetry and tablet computers with clinical guidelines, 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 before and after the introduction of the devices.

Alongside this, we would like to understand what contributes to whether or not the devices help. An important part of this is understanding the experiences and perspectives of healthcare providers delivery care and using the devices. Insights from healthcare providers on using these devices will be critical to guide future approaches to implementation.

Participant selection, voluntary participation and participant rights

We are inviting healthcare providers involved in the care of unwell children at facilities involved in the study if they would like take part. You can choose to take part or not. Your decision will not affect your position in any way. No information on your decision to participate or not will be shared with your colleagues or supervisors. You can ask me any questions, or discuss your participation with other people 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.

Study procedures

If you agree to take part, we will ask you some details about you and your experience delivering services for children under 5 years of age. We are particularly interested in your experience of the devices and of delivery care. We would like to audio-record the interview and take few notes, simply because we cannot write as fast as you talk and we would like to remember what you said. The interview should take approximately 1 hour. You can take part and decide not to answer some of the questions if you like.

Risks & benefits of participation

No compensation will be given for your participation. There are no anticipated risks or direct benefits for you or the children you consult with, but by taking part you will help us understand how to improve care for

unwell children at health facilities and improve the quality of training and support provided to healthcare providers. This may benefit children attending your facility 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 (such as your name) 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. Your audio-recordings will be converted into text, then deleted. Any information that could identify you will be removed from the text. We will make a summary report of the results available for you at the facility. 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 name, or any other information that could identify 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

Statement by the participant

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 to participate in this study.

Name of participant	Signature of participant	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 their experience delivering care for children under 5 years of age, including the use of devices
2. Their information will be maintained anonymously and confidentially, and it will not be possible to identify them in any reports, nor will any information be shared with their colleagues or supervisors

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 healthcare providers

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]. Your facility has been selected to be part of a study on children under 5 years of age. 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 pulse oximetry and tablet computers with clinical guidelines, to help healthcare providers better diagnose and treat sick children under 5 years of age. An important part of this is understanding the experiences and insights of healthcare providers delivering care before the devices are introduced. These insights will be used to guide the implementation of interventions for children under 5 years of age at national and international levels.

Participant selection, voluntary participation and participant rights

We are inviting healthcare providers involved in the care of unwell children at facilities involved in the study if they would like take part. You can choose to take part or not. Your decision will not affect your position in any way. No information on your decision to participate or not will be shared with your colleagues or supervisors. You can ask me any questions, or discuss your participation with other people 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.

Study procedures

If you agree to take part, we will ask you some details about you and your experience delivering services for children under 5 years of age. We are particularly interested in your experience delivering care to children under 5 years of age. We would like to audio-record the interview and take few notes, simply because we cannot write as fast as you talk and we would like to remember what you said. The interview should take approximately 1 hour. You can take part and decide not to answer some of the questions if you like.

Risks & benefits of participation

No compensation will be given for your participation. There are no anticipated risks or direct benefits for you or the children you consult with, but by taking part you will help us understand how to improve care for unwell children at health facilities and improve the quality of training and support provided to healthcare providers. This may benefit children attending your facility 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 (such as your name) 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. Your audio-recordings will be converted into text, then deleted. Any information that could identify you will be removed from the text. We will make a summary report of the results available for you at the facility. 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 name, or any other information that could identify 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]
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[ETHICS COMMITTEE CONTACT]:
[ADDRESS]
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[EMAIL]

Certificate of consent

Statement by the participant

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 to participate in this study.

Name of participant	Signature of participant	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 their experience delivering care for children under 5 years of age
2. Their information will be maintained anonymously and confidentially, and it will not be possible to identify them in any reports, nor will any information be shared with their colleagues or supervisors

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 healthcare providers

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]. Your facility has been selected to be part of a study on children under 5 years of age. 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 pulse oximetry and tablet computers with clinical guidelines, 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 before and after their introduction.

Alongside this, we would like to understand what contributes to whether or not the devices help. An important part of this is understanding the perspectives and experiences of staff using the devices. Insights from staff using the devices and delivering care are critical to guide the future implementation of these interventions and national and international levels.

Participant selection, voluntary participation and participant rights

We are inviting healthcare providers involved in the care of unwell children at facilities involved in the study if they would like take part. You can choose to take part or not. Your decision will not affect your position in any way. No information on your decision to participate or not will be shared with your colleagues or supervisors. You can ask me any questions, or discuss your participation with other people 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.

Study procedures

If you agree to take part, we will ask you to take part in a group discussion along with other healthcare providers and your work. We are particularly interested in your experience with the devices, and in delivering services for children under 5 years of age. We would like to audio-record the interview and take few notes, simply because we cannot write as fast as you talk and we would like to remember what you said. The interview should take approximately 2.5 hours. You can take part and decide not to answer some of the questions if you like.

Risks & benefits of participation

No compensation will be given for your participation. There are no anticipated risks or direct benefits for you or the children you consult with, but by taking part you will help us understand how to improve care for

unwell children at health facilities and improve the quality of training and support provided to healthcare providers. This may benefit children attending your facility 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 (such as your name) 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. Audio-recordings of the discussions will be converted into text, then deleted. Any information that could identify you will be removed from the text. We will make a summary report of the results available for you at the facility. 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 name, or any other information that could identify 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]
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[EMAIL]

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

Certificate of consent

Statement by the participant

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 to participate in this study.

Name of participant	Signature of participant	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 their experience delivering care for children under 5 years of age, including the use of devices
2. Their information will be maintained anonymously and confidentially, and it will not be possible to identify them in any reports, nor will any information be shared with their colleagues or supervisors

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 key stakeholdres

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]. Your facility has been selected to be part of a study on children under 5 years of age. 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 pulse oximetry and tablet computers with clinical guidelines, to help doctors and nurses 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 before and after their introduction.

Alongside this, we would like to understand what contributes to whether or not the devices help. An important part of this is understanding the insights of key stakeholders to guide future approaches to policy and implementation of these devices.

Participant selection, voluntary participation and participant rights

We are inviting stakeholders at global, national and subnational levels to take part in in-person or online interviews. You can choose to take part or not. Your decision will not affect your position in any way. No information on your decision to participate or not will be shared with your colleagues or supervisors. You can ask me any questions, or discuss your participation with other people 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.

Study procedures

If you agree to take part, we will ask you some details about you and your work in relation to pulse oximetry and clinical decision support algorithms for children under 5 years of age. We are particularly interested in your experience of policy or implementation in relation to these devices. We would like to audio-record the interview and take few notes, simply because we cannot write as fast as you talk and we would like to remember what you said. The interview should take approximately 1 hour. You can take part and decide not to answer some of the questions if you like.

Risks & benefits of participation

No compensation will be given for your participation. There are no anticipated risks or direct benefits for you as an individual, but by taking part you will help us understand how to improve care for unwell children at health facilities and inform future policy and guidelines on implementation of these devices.

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 (such as your name) will not be shared with anyone outside the study team. It will be securely stored, 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. Audio-recordings of the discussions will be converted into text, then deleted. Any information that could identify you will be removed from the text. We will make a summary report of the results available for you at the facility. 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 name, or any other information that could identify 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

Statement by the participant

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 to participate in this study.

Name of participant	Signature of participant	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 their background and experience in relation to pulse oximetry, clinical decision support algorithms and services for children under 5 years of age
2. Their information will be maintained anonymously and confidentially, and it will not be possible to identify them in any reports, nor will any information be shared with their colleagues or supervisors

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 key stakeholders

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]. Your facility has been selected to be part of a study on children under 5 years of age. 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 pulse oximetry and tablet computers with clinical guidelines, to help doctors and nurses 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 before and after their introduction.

Alongside this, we would like to understand what contributes to whether or not the devices help. An important part of this is understanding the insights of key stakeholders to guide future approaches to policy and implementation of these devices.

Participant selection, voluntary participation and participant rights

We are inviting stakeholders at global, national and subnational levels to complete a quarterly survey. You can choose to take part or not. Your decision will not affect your position in any way. No information on your decision to participate or not will be shared with your colleagues or supervisors. You can ask me any questions, or discuss your participation with other people 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.

Study procedures

If you agree to take part, we will ask you some details about you and your work in relation to pulse oximetry and clinical decision support algorithms for children under 5 years of age. We would like to you to fill it out on a total of 5 occasions, each 3 months apart. You can take part and decide not to answer some of the questions if you like. We will only ask for your written consent on this first occasion, but you can decide not to participate in some or all of the future surveys without needing to give any reason.

Risks & benefits of participation

No compensation will be given for your participation. There are no anticipated risks or direct benefits for you as an individual, but by taking part you will help us understand how to improve care for unwell children at health facilities and inform future policy and guidelines on implementation of these devices.

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 (such as your name) will not be shared with anyone outside the study team. It will be securely stored, 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. 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 name, or any other information that could identify 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

Statement by the participant

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 to participate in this study.

Name of participant	Signature of participant	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 completing a survey, with some information collected about their background and experience in relation to pulse oximetry, clinical decision support algorithms and services for children under 5 years of age
2. Their information will be maintained anonymously and confidentially, and it will not be possible to identify them in any reports, nor will any information be shared with their colleagues or supervisors

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 healthcare providers

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) University of Waterloo, a research organization (Canada))
Funding agency	UNITAID

Introduction & purpose of the study

My name is […]. I am a research assistant working with [RESEARCH ORGANISATION]. Your facility has been selected to be part of a study on children under 5 years of age. 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 pulse oximetry and tablet computers with clinical guidelines, 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 before and after the introduction of the devices.

Alongside this, we would like to understand how much it costs to introduce and use these devices and how those costs compare to normal care when these devices are not used.

Participant selection, voluntary participation and participant rights

We are inviting healthcare providers involved in the care of unwell children at facilities involved in the study if they would like take part. You can choose to take part or not. Your decision will not affect your position in any way. No information on your decision to participate or not will be shared with your colleagues or supervisors. You can ask me any questions, or discuss your participation with other people 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.

Study procedures

If you agree to take part, we will ask you some details about the costs associated with providing services at this health facility. We will also review financial records and invoices related to providing the pulse oximeters and decision tools at this health facility, including staff positions or grades. It should take no more than 10 – 20 minutes to answer the questions today, and around 1 -2 minutes at the end of each observed consultation should there be a need for any clarifications.

Risks & benefits of participation

No compensation will be given for your participation. There are no anticipated risks or direct benefits for you or the children you consult with. By taking part you will help us understand the costs associated with these interventions to inform national and international policy. This may benefit children attending your facility 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 (such as your name) will not be shared with anyone outside the study team. It will be securely stored, and destroyed when the study is completed. Information on job titles and position grades will be kept securely and only accessed by the study team. If you take part in the study on more than one occasion, information about each occasion may be grouped together. We will make a summary report of the results available for you at the facility. 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 name, or any other information that could identify 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

Statement by the participant

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 to participate in this study.

Name of participant	Signature of participant	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 costs associated with providing services for children under 5 years of age at this health facility.
2. It includes reviewing financial records and invoices related to providing the pulse oximeters and decision tools at this health facility, including staff positions or grades
3. Their information will be maintained anonymously and confidentially, and it will not be possible to identify them in any reports, nor will any information be shared with their colleagues or supervisors

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)