Study title

Strategies for developing sustainable health research capacity in Low and Middle Income Countries; a prospective, qualitative, multi-site study investigating the barriers and enablers to locally-led clinical trial conduct in Ethiopia, Cameroon, and Sri Lanka

Study supporting material document: **Protocol**

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Start-up of investigator-initiated trials in resource-limited settings: understanding the barriers and identifying enabling strategies

Application for Ethical Review and Approval by the University of Sri Jayewardenepura Ethical Review Board

Principal Investigator: Samuel Franzen.

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Sponsor: University of Oxford

Ethics Approval and number: Oxford Tropical Research Ethics Committee, OXTREC Reference: 70-11

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1 Contents

1 Abbreviations

EDCTP – European and Developing Countries Clinical Trial Partnership
IIT – Investigator-initiated trial
NHS – National Health Service (U.K.)
PI – Principal Investigator
RLS – Resource-limited settings
WHO – World Health Organisation

2 Definitions

2.1 Investigator-initiated trials

For the purposes of this study, an investigator-initiated trial (IIT) means a clinical trial that is conceived and designed by an individual principal investigator or team of collaborating principal investigators and where the research is conducted in their home country i.e. Local research. Other individuals or organisations may have had input into the clinical trial planning and design, but the primary investigator(s) remain the custodian(s) of the trial protocol and primary author(s) on any subsequent publications. This separates IITs from international research where there is a local investigator.

2.2 Trial start-up

The period of trial conduct from concept development to intervention delivery.

3 Study Information

Study title	Start-up of investigator-initiated trials in resource-limited settings – understanding the barriers and identifying enabling strategies
Sponsor	Centre for Tropical Medicine, Nuffield Department of Medicine, University of Oxford, CCVTM, Churchill Hospital, Old Road, Oxford, OX3 7LJ, UK
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Estimated budget	Not applicable. Study conducted as part of Samuel Franzen's PhD thesis. Logistical costs will be covered through the Global Health Clinical Trials Programme research grant

4 Protocol Summary

4.1 Study title

Start-up of investigator-initiated trials in resource-limited settings – understanding the barriers and identifying enabling strategies

4.2 Rationale

Clinical trials in developing countries are important sources of evidence for public health policy. However, there are few clinical trials, important research topics remain unaddressed and there is a lack evidence to guide clinical decision making. Investigator-initiated trials may help address these problems but further work is needed to understand how their numbers can be increased.

4.3 Research question

What are the enablers and barriers to the successful start-up of investigator-initiated trials in resource limited-settings?

4.4 Goals, aims and objectives

The goal of this study is to produce evidence-based data and transferable recommendations that will help to increase the start-up of investigator-initiated trials in resource-limited settings.

The aim of the study is to understand the individual, operational, organisational and institutional factors that impact on the start-up of investigator-initiated trials in resource-limited settings and to identify enabling strategies. The following objectives are proposed:

Objective 1: To identify the operational processes involved in the start-up of investigator-initiated trials in resource-limited settings, identifying rate-limiting steps that can be optimised and best-practice that can be shared.

Objective 2: To explore individual perceptions of clinical trials and the organisational and institutional factors that impact on the successful start-up of investigator-initiated trials in resource-limited settings.

Objective 3: To use the findings from Objective 1 and 2 to hypothesise transferable recommendations for supporting investigator-initiated trial start-up, that could be readily implementable, without the requirement for new resources.

4.1 Study design

This will be an applied qualitative study that uses multiple methods to explore the issues surrounding the start-up of IITs. Research will be conducted at multiple research institutes, during 4 field visits. Each field visit will be conducted in 1 country located within each of the 4 study regions; Sub-Saharan Africa, South Asia, East Asia and Latin America.

Results from each field visit will be analysed individually, drawing out the barriers and enablers to IIT start-up in that specific setting. Data on the factors that impact on IIT start-up will be descriptively analysed using thematic content analysis, and the conceptual framework updated. The updated conceptual framework will be used to guide the next round of data collection, both in terms of data collection activities and in choice of future study sites. After all field visits are completed, data from all sites will be comparatively analysed, identifying common and divergent themes. Identified enablers and best practice will be reviewed and used to hypothesise recommendations for enabling strategies.

4.2 Study sites

The first field visit will be conducted in Cameroon at the University of Yaoundé and the University of Buea.

The second field visit will be based at the Institute of Research & Development (Battaramulla) and research will be conducted at other institutions within Sri Lanka.

Other field sites in East Asia and Latin America will be selected as the research progresses.

4.3 Target population

We will be recruiting four categories of participants:

1. IIT trial teams:
    a. Investigators and trial managers/coordinators who have started investigator-initiated trials within the last 5 years
    b. Trial staff who have worked on the investigator's investigator-initiated trials
2. Foreign-initiated trial teams:
    a. Investigators and trial managers/coordinators who have started foreign-initiated trials in the last 5 years
    b. Trial staff who have worked on the investigator's foreign-initiated trials
3. Clinicians, academic researchers and healthcare staff who are in a position where they could take on the role of a senior member of a clinical trial team in the future, but have no current experience of running clinical trials
4. Leaders of research groups and academic/clinical departments, local regulators, policy makers, representatives of healthcare and research funding bodies and any other stakeholders with influence over clinical trials

4.4 Methods

We will be conducting: process mapping exercises with participants in categories 1a/b and 2a/b, Focus group discussions with participants from categories 1a, 2a and 3, and interviews with participants in category 4.

4.5 Strategic implications and dissemination

We will produce publications that summarise the findings on common barriers and enablers and present an argument for why effort should be made to increase investigator-initiated trials in resource-limited settings. The purpose of this is to put information in the public domain so that it may influence future funding and capacity building agendas. A generic process map will be produced that gives practical guidance on how to start an investigator-initiated trial in most resource-limited settings. This will be made publicly available on the Global Health Trials website. Transferable recommendations will be made that suggests possible methods for implementing enabling strategies. All results will be used by the Global Health Clinical Trials Programme to help direct future activities. All findings will be discussed on the Global Health Trials website and made available to participants and their institutions. The data will also be used for the Principal Investigator's PhD thesis which will be made available in an open access archive.

4.1 Period and duration

The period of the entire study will be February 2012 to October 2014. Each field visit will last approximately 6-12 weeks.

The exact dates for the Cameroon and Sri Lankan field visits will depend on logistics, including when all approvals have been granted. The Cameroon field visit is expected to take place in March 2012 and the Sri Lankan field visit is expected to take place in July 2012.

4.2 Potential risks

This study is minimal risk and does not involve any clinical interventions. The study is limited to interviewing research staff and related medical professionals. Neither the wider public nor patients are involved.

4.3 Potential benefits

There will be no direct benefits from participating in this study. However, it will be an opportunity for participants to share their knowledge and experience and contribute to research that is relevant to them. The activities may also help participants to identify strategies that could improve the efficiency of their work and highlight areas that need improving. We hope that participating in this study will be an interesting experience for participants and may contribute to their learning and professional development.

5 Background

5.1 The importance of clinical trials in resource-limited settings

Proponents of the current evidence-based medicine movement argue that randomised control trials are essential for establishing the efficacy and safety of new interventions. Systematic reviews, primarily using clinical trial data, have become increasingly important for guiding clinical decision making around the world

[1]. Such data is argued to play a key role in promoting good clinical practice by transferring research findings into evidence informed public health policy [2-4].

Developing countries suffer the greatest burden of disease globally and more high quality evidence is required to guide public health policy [1, 5-7]. For clinical trial evidence to be useful for policymaking it is essential that interventions addressing developing country health concerns be tested on local populations and where the disease is most prevalent [4, 8, 9]. Therefore, it has been argued that more clinical trials must be conducted in developing countries [5, 8].

5.2 Making evidence useful

Even when high quality evidence is available it may not influence public health policy and clinical practice. Within developing countries there are many forces that prevent the incorporation of evidence-based data into good clinical practice [10]. One study found that just under half of healthcare providers and policy makers from low or middle income countries had little trust in systematic reviews [11].

One author [8] believes that trials in developing countries are more likely to produce reliable results and have a public health impact and institutional benefit if they address local priorities, recognise cultural and organisational challenges, study topics are kept very simple, credit is shared appropriately and there is a commitment to developing the intellectual and infrastructure capacity of the country. Other studies have found that local research and publications are more likely to change clinical practice compared to foreign research and publications, and that the availability of more locally applicable research would improve clinicians work [11, 12].

5.3 The current clinical trial situation

Despite the importance of local research and publications for influencing public health policy, most clinical trials in developing countries are conducted by foreign non-commercial organisations and the pharmaceutical industry. These trials may leave important local research gaps (e.g. disease management), either because they lack commercial interest or because research agendas are not fully aligned to local interests. Furthermore, they often do not leave sites with the skills capacity to conduct trials on their own [5, 13-16].

Regardless of the trial types conducted, most developing countries still have insufficient clinical trial capacity and suffer from a number of common problems [4, 5, 13, 15, 17, 18]. Sites that have the capacity and perform well are oversubscribed [19]. In response to this, strengthening Africa owned clinical trial capacity to allow countries to pursue their own R&D agenda has been identified as an international priority [20].

5.4 A role for investigator-initiated trials?

Investigator-initiated trials (IITs) may have an important role in helping to achieve the goal of strengthening local capacity as well as resolving the current evidence gap [5, 14-16, 21]. Because IITs are locally led, they may be more likely to influence policy and practice, thus making their data more practically useful [11, 12].

IITs typically address simple topics that are applicable to local populations and priorities e.g. disease management. They are usually more in tune with local needs and are more culturally sensitive [12, 15, 16].

IITs are not normally concerned with commercial interest so they can address topics that are ignored by industry [14, 22] and they may have lower overhead costs and be less biased than industry-led research [23].There is also a greater chance for more local researchers to be involved at all levels of trial development ,which the WHO, EDCTP and other groups believe will help to improve trial capacity [5, 8, 19, 20].

Indeed IITs fulfil all of Yusuf's requirements for a successful trial and he also argues that by increasing local involvement in clinical trials, more clinicians will become aware of evidence-based medicine and will be more likely to adopt its findings into their clinical practice. This attitude may eventually permeate the public health and educational system [8].

Unfortunately IITs are not without their problems and capacity to conduct independent trials is particularly limited [5]. IITs suffer similar problems to other trials in developing countries [15]. These problems are believed to responsible for the general paucity of trial research and may include: complicated and bureaucratic regulations, relatively poor and fragmented healthcare infrastructure, wide socio-economic divide, lack of sufficient numbers of trained investigators and research staff, limited material capacity, rudimentary regulatory systems and vulnerable populations [4, 5, 13, 15, 17, 18].

However, it is likely that IITs suffer additional unique challenges beyond those of other trial types. While there has been a general increase in the number of clinical trials conducted in developing countries [24], there has been a global decline in the number of IITs, partly due to the recent increase in regulatory requirements [14, 16, 21, 22, 25]. There is little literature on IIT operations in developing countries but they appear particularly vulnerable to funding hurdles and financial and administrative problems [15]. The more independent nature of IITs may also mean that they lack support and expertise to overcome problems when they occur. Devasenapathy [13] suggests that limited opportunities for careers in research and little recognition for research efforts reduces investigators participation in trials.

6 Rationale

Initiatives have been set up in developed nations to address problems with clinical trial conduct. The Clinical Trials Transformation Initiative in the U.S. and the MRC Clinical Trials Toolkit and Medicines for Children Research Network in the U.K are looking into methodological problems and ways to identify solutions. There are also initiatives dedicated to increasing the number of IITs [26-28]. Within developing countries there are organisations aiming to increase clinical trial capacity and health research output [29]. However, these are predominantly disease specific and concerned with international, multi-site, investigational medicinal product evaluation. No such initiatives exist for IIT research in developing countries so little is known about IIT trial processes and how they could be improved.

Academic discussion over the conduct of clinical trials in developing countries has mostly focused on ethical issues, regulatory boards and community engagement. While this is very important, there is minimal information on the factors that impact on IIT conduct in these settings. Given that IITs have the potential to improve good clinical practice in resource-limited settings, as well as increase local trial capacity; more research describing IIT processes and the unique difficulties they face is warranted.

Structured empirical research is required to help understand the barriers and enablers to these trials and to identify strategies to increase their output [15, 21]. Our pilot data indicates that most critical barriers to

IIT conduct occur in the start-up phase, so to properly target the problems, this research should focus on those issues. Because local investigators are responsible for the initiation of these trials, it is important that this research concentrates on their experiences. To be of maximum benefit to the global trials community it must investigate these issues in diverse geographical settings and produce transferable findings.

To address this important knowledge gap, we propose to conduct the following study presented in this protocol.

7 Conceptual Framework

7.1 Assumptions

An underlying assumption for this study is that evidence-based medicine is important for improving health outcomes. Since data derived from clinical trials is held as the gold standard of evidence-based information, we believe that clinical trials are important for improving health outcomes. We also believe that for clinical trial evidence to be most useful for developing countries, that it is important for clinical trials to be locally initiated and led. We therefore hypothesise that participants in developing countries will agree with this.

While we make these assumptions implicit within the study design, we will not be forcing them upon participants because questioning will allow for contradictory views. A key aspect of this study is to understand participants' perceptions of clinical trials and their importance. If participants do not agree with our assumptions and the hypothesis is therefore not valid, the data generated will still be of great use to the scientific community because it will demonstrate a primary barrier to the implementation of evidence-based medicine and clinical trials within these settings. It may also raise important points that could question our assumptions about the importance of evidence-based medicine and clinical trials for improving health outcomes in developing countries. Furthermore, because this study will include participant's already conducting clinical trials, as well as those who have no experience of clinical trials and may not believe they are important, we will still be able to collect important data on the barriers and enablers to their start-up and give an indication of how the situation could be improved if this outcome is desired.

7.2 Theoretical orientation

This research is formative, seeking to explore issues around the conduct of IITS in resource-limited settings. We have not adopted any specific theory prospectively into the research design. To try to embed exploratory data into existing theories at an early stage may restrict our interpretation of the data by trying to "fit" the data in these theories. Therefore our interpretations of the findings will be inductive; that is to say it will be more influenced by participants' experiences than by current theory.

To guide the study design and questions, we will be using existing literature, approaches taken from Organisational and Institutional Development and Quality Improvement, and our own pilot research. The information derived from Organisational and Institutional development and Quality Improvement led us to initially design a study that looks at the issues relating to the start-up of IITs at 3 levels; operational, organisational and institutional. We initially believed that the issues surrounding the start-up of IITs would fall discretely into one of these levels and would impact on each other in a hierarchical fashion.

However, after conducting pilot research in Sub-Saharan Africa, and relating this to current literature, we realised that an individual level should also be included. Furthermore, these 4 levels are not discretely separated and do not impact on each other in a hierarchical fashion. Instead, the issues relating to IIT start-up may overlap several levels and have reciprocal effects on one another, forming a system of interactions and relationships. We believe that only by looking at this "system" holistically, can the issues be fully appreciated and understood.

The existing literature on the problems relating to the start-up of IITs and running clinical trials in developing countries (summarised in the background) helped us to derive early study questions for piloting. The pilot data agreed with much of this information and it shall continue to influence our question topics. The pilot data also suggested that the investigation should only focus on the start-up phase of clinical trial conduct because the majority of critical challenges to clinical trials occurred in this phase. We also identified other important topics that we had previously not considered and these have subsequently been adopted into our preliminary conceptual framework. These topics include: The concept and influence of research culture, the role of initiative and entrepreneurship in trial initiation, the importance of previous trial experience in influencing confidence and motivation, the weighting of motivational factors involved in decisions to undertake IITs, the importance and value of research and whether training influences this, and the importance of academic/educational institution priorities.

8 Research Question

What are the enablers and barriers to the successful start-up of IITs in resource limited-settings?

9 Goals, aims and objectives

The goal of this study is to produce evidence-based data and transferable recommendations that will help to increase the start-up of IITs in resource-limited settings (RLS).

The aim of the study is to understand the individual, operational, organisational and institutional factors that impact on the start-up of IITs in RLS and to identify enabling strategies. The following objectives are proposed:

Objective 1: To identify the operational processes involved in the start-up of IITs in RLS, identifying rate-limiting steps that can be optimised and best-practice that can be shared.

Objective 2: To explore individual perceptions of clinical trials and the organisational and institutional factors that impact on the successful start-up of IITs in RLS.

Objective 3: To use the findings from Objective 1 and 2 to hypothesise transferable recommendations for supporting investigator-initiated trial start-up, that could be readily implementable, without the requirement for new resources.

10 Study design

This will be an applied qualitative study that uses multiple methods to explore the issues surrounding the start-up of IITs.

Qualitative methods have been chosen because they are well suited to developing and in depth understanding of the study issues from the perspective of the participants. Multiple methods will be used to help cross-examine the data. Collecting data using different methods will ensure that the findings reflect the actual experiences of participants.

Research will be conducted at multiple research institutes, during 4 field visits. Each field visit will be conducted in 1 country located within each of the 4 study regions; Sub-Saharan Africa, South Asia, East Asia and Latin America. Qualitative research is often criticised because findings are too context specific and difficult to generalise. By conducting research in diverse resource-limited settings located in different world regions we can get broad perspectives of the issues in different contexts. By doing this, the findings will be more robust and may be more representative of the general situation in resource-limited settings.

Results from each field visit will be analysed individually, drawing out the barriers and enablers to IIT start-up in that specific setting. Data on the factors that impact on IIT start-up will be descriptively analysed using thematic content analysis, and the conceptual framework updated. The updated conceptual framework will be used to guide the next round of data collection, both in terms of data collection activities and in choice of future study sites. After all field visits are completed, data from all sites will be comparatively analysed, identifying common and divergent themes. Commonality of these themes between sites may suggest that the findings will have transferability to other settings. Identified enablers and best practice will be reviewed and used to hypothesise recommendations for enabling strategies.

If this research proves successful in identify common barriers and enablers to IIT start up, we may conduct a follow up study that seeks to test if these common themes truly have transferability to other settings. Common barriers and enablers could be incorporated into a survey that asks investigators from all over the world to quantitatively rank how much the common barriers and enablers impact on IIT start up in their setting. Because the survey will be based on data derived from participant experiences in 4 diverse world regions, it is likely that at least some of the themes will be applicable to survey participants. This would identify which barriers and enablers have generic influence and what the most important issues are in different settings.

11 Study sites

Research activities will be conducted in one country within each of the study regions; Sub-Saharan Africa, South Asia, East Asia and Latin America. These will be the 4 field visits. During each field visit, research will be conducted at one or more institutions within the selected country. The number of institution visits will depend on the number of suitable institutions, participant availability and logistical considerations.

11.1 Site selection

The first field visit will be conducted in Cameroon which will represent the Sub-Saharan African sample. Two institution visits will be conducted, one at The University of Yaoundé and the other at the University of Buea. The Cameroonian Co-Principal Investigator is:

> Dr Julius Atashili, University of Buea, Faculty of Health Sciences, University of Buea, Cameroon. Email: atashili@yahoo.ie

The second field visit will be conducted in Sri Lanka which will represent the South Asia sample. The research will be based at The Institute of Research and Development (Battaramulla). Research will also be conducted at other institutions where there are suitable participants. The Sri Lankan Co-Principal Investigator is:

> Professor Sisira Hemananda Siribaddana, Institute of Research & Development, 393/3, Lilly Avenue, off Roabert Gunawardane Mawatha, Battaramulla. Email: nipuna@stmail.lk

Subsequent field sites will be selected as the research progresses, rather than finalising in advance. The conceptual framework will be updated and adapted after each field visit and this will be used to inform the choice of the next field visit. This will give the study flexibility which is very important when conducting formative research.

11.2 Organising institution visits

The institution visits will be organised with the help of the local Co-Principal Investigators (from herein referred to as local investigators). The local investigators will assist with the administrative and logistical organisation for the field visit and help identify and recruit potential participants. To increase the participatory nature of this study the local investigators will also be expected provide input on data collection, to review and comment on the findings and be involved in the preparation of papers. They will be acknowledged as authors on any subsequent papers produced as a result of the study.

11.3 Identifying local investigators

Local investigators will be identified by searching clinical trial registries and international and local journal publications for clinical trials that are situated in institutions that fit the criteria detailed below. Clinical trials that appear to have a significant level of local leadership will be followed up. Local leadership will be demonstrated by having at least one local PI. The local PIs of the study will be contacted via email, given further information on the study and asked if they would be interested in acting as the local investigator. Their suitability as a local investigator will be judged by the criteria listed below. The Global Health Trials network [30], informal networks of contacts and snowball sampling will also be utilised.

11.4 Eligibility criteria for institutions

Institutions must be based in a developing country within the specified regions; Sub-Saharan Africa, South Asia, East Asia and Latin America. The developing country must be representative of the region in terms of clinical trial numbers as registered on the WHO International Clinical Trial Registry Platform. Countries that have abnormally high or low trial output will not be included. The institution must be located in a resource-limited setting and not be significantly supported by a foreign funding body or sponsor e.g. MRC in Gambia or Wellcome Trust site in Malawi. The institution must also be host to potential participants who could take part in this study.

11.5 Eligibility criteria for local investigators

The local investigators must be based within an institution that fits the institution eligibility criteria, have experience of running clinical trials, be expertly informed in the local trial situation and be willing to take on the responsibilities required.

11.6 Permission for research activities

We will be seeking permission to carry out research activities from the institutions where research will take place and from the Ministry of Health, where required. This will be done in conjunction with applying for institutional ethics approval and national ethics approval, where required. The local investigators will help organise appropriate permissions and ethics approvals.

12 Participants

The following participants will be asked to take part in research methods. The following information applies to each field visit.

12.1 Selection criteria

We will be recruiting four categories of participants:

1. IIT trial teams:
    a. Investigators and trial managers/coordinators who have started investigator-initiated trials within the last 5 years
    b. Trial staff who have worked on the investigator's investigator-initiated trials
2. Foreign-initiated trial teams
    c. Investigators and trial managers/coordinators who have started foreign-initiated trials in the last 5 years
    d. Trial staff who have worked on the investigator's foreign-initiated trials
3. Clinicians, academic researchers and healthcare staff who are in a position where they could take on the role of a senior member of a clinical trial team in the future, but have no current experience of running clinical trials
4. Leaders of research groups and academic/clinical departments, local regulators, policy makers, representatives of healthcare and research funding bodies and any other stakeholders with influence over clinical trials

12.2 Eligibility criteria

To take part in the research activities, participants must fit into one of the participant categories listed above, must be legal adults and must be willing and able to give informed consent. Participants must also be proficient in the English language.

Not all research activities are open to all categories of participants. The research activities that are open to different participants will be given in the methods section.

12.3 Sample Selection

Participants based in the institutions of study will be purposively selected looking to achieve maximum variation across professional backgrounds.

The broad range of participant backgrounds will ensure a more rounded view of participant's perspectives on clinical trials. This will reduce bias associated with only talking to individuals who are currently within the clinical trial community. Foreign-initiated trial group members have been included as a comparison group to help understand how IITs differ from foreign-initiated trials in their challenges.

12.4 Participant identification and research invitation

Identification methods will involve searching clinical trial registries and international and local journal publications for clinical trials that are conducted within the chosen institutions. Any identified potential participants will be asked for contact details of any other individuals that they think would be suitable and interested in the research in a process known as snowball sampling. Local investigators will also help in the identification of participants by using their existing network of contacts and subsequent snowball sampling.

Given the small sample sizes required, it is expected that we will be able to recruit sufficient participants through this referral mechanism.

Once potential participants are identified, they will be given a Research Invitation that gives information on the study and asks them if they would be interested in taking part in the study. Research Invitations explicitly state that an expression of interest does not oblige participants to take part in the study. Research Invitations may be sent by email or given in person. If they are interested in taking part in the study, there will be an opportunity to ask further questions. If the participant is still interested we will organise for them to take part in research activities that are open to them. Participants will be asked for times and dates when they would be available to take part in research activities and for suggestions for meeting places that would be convenient and comfortable for them.

Before institution visits are finalised, Research Invitations will be used to assess if there are sufficient numbers of potential participants at the institution to meet recruitment goals.

A copy of the research invitation can be found in the appendix.

12.5 Organising the research methods

Research methods will be conducted in a place that is convenient for participants. This is likely to be a meeting room, or office in their institution or a comfortable space that can accommodate the required number of people. Participants will be asked if they have a preferred or suggested meeting place and if a more private place is required, we will accommodate participants' wishes.

12.6 Introduction to the research methods and consent process

In advance of the research method to be conducted, potential participants will be given an Information Sheet that explains the research and what participation will mean. They will be asked to carefully read the document and to say if they would still like to take part. On arrival, participants will be asked to re-read the Information Sheet and have the opportunity to ask further questions. Confidentiality and anonymity will be explained. We will emphasise that for process mapping and focus group discussions, that while we will ask everybody to keep what is said in the group confidential, we cannot prevent other participants from sharing what they have heard.

Each participant will be asked if s/he consents to be take part in the research, for the research to be recorded using a digital tape recorder, and for quotes of their words to be used in reports. They will then be asked to sign 2 copies of the consent form. The participant will be given one copy and the facilitator will keep the other copy for study documentation. Participants who refuse to allow the quotations to be used in reports will still be able to take part in all research methods because it is not essential that we include quotations in reports. Participants who refuse to allow their contributions to be recorded will not be allowed to take part in process mapping or focus group discussions, but the can still take part in interviews. This is because it would be too difficult to accurately record group discussions using only notes. However, in one-to-one interviews the use of notes alone may be sufficient, although not desirable.

It will also be emphasised that there will be no incentives given for taking part in the research and that the participant has the right to withdraw and have their data destroyed at any time.

A copy of the Information Sheet and Consent Form can be found in the appendix.

13 Methods

The following methods will apply to every institution visit at all field visits. These methods have been evaluated in the pilot research and were found to be effective at generating useful data that can answer the study question.

All methods will be conducted in the English language.

13.1 Process mapping

Process mapping has been used extensively as an organisational development and quality improvement tool. It identifies operational processes, bottlenecks and facilitative strategies that can help the operations to run more effectively. This can be a very helpful learning experience for participants and identifies targets for optimisation. The method used here is drawn from the NHS Institution for Innovation and Improvement.

13.1.1 Participants

Participants in categories 1a/b and 2a/b will be eligible to take part in this exercise. The process mapping will only take place if senior members of the trial group are present and agree for the research to take place.

Process mapping is a group exercise. Process mapping sessions will be stratified by trial group so that participants will complete this exercise only with other members of their trial group. The process mapping is only conducted with one group at a time so that the findings can be attributed to specific events and circumstances. There is no ideal group size for the process mapping exercise but it would be desirable for the group to be larger than 5 but no greater than 15.

13.1.2 Sample size

Only 1 process mapping exercise will be conducted per trial group. We are aiming for 1-2 mapping exercises to be conducted with IIT trial groups and 1-2 with foreign-initiated trial groups.

13.1.3 Method

A facilitator will explain the objectives of the process mapping exercise, confidentiality and anonymity will be assured and everyone will be asked to agree to certain “ground rules”. The ground rules include: not sharing what has been said with others who did not participant in the exercise, only one person speaking at a time and respecting others views and opinions. A process mapping exercise works much like a focus group discussion but the focus is on producing a sequential map of the operational processes required to start a clinical trial. A facilitator will ask participants to draw the process map themselves by giving them paper and pens and sticky notes. They will be asked to assign time metrics to process steps and to identify which processes are particularly difficult or easy.

The process mapping exercise will take approximately 2 hours depending on how much participants want to discuss.

Before the exercise begins, the facilitator will collect signed consent forms and ask participants to fill in a demographic information form that records basic personal details, contact information and career information. The form will be filled in privately and only the facilitator and note-taker will have access to the form during the method. After the exercise has been completed, this information will be kept confidential by the processes outlined in the data collection section.

An example of the demographic information form can be found in the appendix.

13.1.4 Topic guide

The topic guide for this method only covers the introduction to the activity, information on the clinical trial that is being process mapped and prompts that could be used to encourage discussion. A detailed topic guide is not required because the discussion will follow the topics that participants bring up as they draw the process map. Prompts may include asking if participants found anything particularly difficult or easy, operations that they may have forgotten, strategies that helped them and ways they could have done things better.

An example of the process mapping topic guide can be found in the appendix

13.1.5 Data collection and recording

A note taking form will be used and will be completed by a note taker or the facilitator. The facilitator may also make notes on the topic guide. In addition, an audio recording will be made of the discussion. Each participant will be given an ID number, and the note taker or facilitator who will draw a map of participants and record which participant made which contributions, to match up with the transcript of the discussion. However, given the large number of participants and the rapid nature of discussion, it may not always be possible to record which participant made which contribution. This is not a major problem because the main goal of the exercise is to understand the experiences of the research group, rather than the individual.

The completed process map will be collected by the facilitator.

An example of the note-taking form can be found in the appendix.

13.2 Focus group discussions

While the process mapping focused on operational issues, the focus group discussions will allow the operational issues to be situated with the broader context. We hope that this will generate a deep understanding of what participants perceive as the drivers of operational issues and will identify other important factors. The group dynamic fostered within focus group discussions will bring a breadth of opinions and ideas and may help the refinement and elaboration of individual ideas. It is also beneficial because it can generate a wide variety of perspectives in a short amount of time.

13.2.1 Participants

Participants in categories 1a, 2a and 3 will be eligible to take part in this exercise.

Focus groups will be stratified by experience of running clinical trials. Participants in categories 1a and 2a who have experience of running clinical trials will form one target group and participants in category 3 who have no experience of running clinical trials will form another target group. We will aim for an equal number of participants from category 1a and 2a in the experienced target group. There will be 4-8 participants per focus group discussion.

The experienced and inexperienced groups have been separated because it is likely that each group will have very different experiences. Grouping participants by experience will be helpful in encourage an effective group dynamic and will also allow clearer identification of findings.

13.2.2 Sample size

One to two focus group discussions will be conducted with participants who have experience of running clinical trials and 1-2 focus group discussions will be conducted with participants who have no experience of running clinical trials.

13.2.3 Method

A facilitator will explain the objectives of the focus group discussion, confidentiality and anonymity will be assured and everyone will be asked to agree to certain “ground rules”. The ground rules include: not sharing what has been said with others who did not participant in the focus group, only one person speaking at a time and respecting others views and opinions. The facilitator will then pose topics and questions for discussion.

Focus group discussions will take approximately 2 hours depending on how much participants want to discuss.

Before the discussion begins, the facilitator will collect signed consent forms and ask participants to fill in a demographic information form that records basic personal details, contact information and career information. The form will be filled in privately and only the facilitator and note-taker will have access to the form during the method.

13.2.4 Topic guide

The discussions will be led by a facilitator who will follow a topic guide. The topic guide will begin with introductory questions on the research needs of the country and the general clinical trial situation. It will then focus on perceptions of different clinical trial types, operations and running clinical trials, the influence of research culture and motivation and organisational and institutional factors that impact on clinical trial

start-up. The questions will close by asking participants if they have any suggestions for important research topics that we should address in the future, and the opportunity for final suggestions, comments and questions.

An example of the topic guide can be found in the appendix.

The topic guide may be adapted and updated as the data collection progresses and the conceptual framework is updated. This will allow the study to focus on important emerging issues that were not originally anticipated.

13.2.5 Data collection and recording

A note taking form will be used for all focus group discussions and will be completed by a note taker or the facilitator. The facilitator may also make notes on the topic guide In addition, an audio recording will be made of the discussion. Each participant will be given an ID by the note taker or facilitator, who will draw a map of participants and record which participant made which contributions, to match up with the transcript of the focus group afterwards.

13.3 Interviews

The purpose of the interviews is to concentrate on important topics that emerged during the process mapping and focus group discussions. By interviewing participants that have an influence over these issues it may be possible to get a better understanding of the issue and explain how the present situation has formed and what keeps it in place. The topics of discussion may be sensitive because the participants will hold governing or influential positions. This makes the private nature of an interview the most suitable method.

13.3.1 Participants

Participants in category 4 will be eligible to take part in this exercise. These participants may include: Leaders of research groups and academic/clinical departments, local regulators, policy makers, representatives of healthcare and research funding bodies and any other stakeholders with influence over clinical trials

13.3.2 Sample size

An approximate target of 5-8 interviews has been set. However the exact number depends on the issues that emerge and the availability of the participants.

13.3.3 Method

The interviewer will explain the objectives for the interview. Interviews will start with the opportunity for the respondent to give an uninterrupted narrative of their experiences with clinical trials. Subsequent questions will follow a topic guide, which is based on the conceptual framework that was developed from the previous research activities. Open questions will be used throughout the interviews in order for participants to describe their experiences and opinions in their own words.

Interviews will take approximately 1.5 hours depending on how much participants want to share.

Before the interview begins, the facilitator will collect the signed consent form and ask the participant to fill in a demographic information form that records basic personal details, contact information and career information.

13.3.4 Topic guide

The interviews will be guided by a series of broad topic areas. Important themes that emerged in the previous research activities will be discussed. The focus of the interview will be adapted to take account of the participant's experience e.g. An interview with a member of an ethics board will focus on regulatory issues or an interview with a head of an institution will involve discussions on institution priorities.

The interview will open with an opportunity for the participant to discuss their current and previous work roles. It will then ask questions on the health needs and clinical trial environment of the country. There will then be questions on perceptions of different clinical trial types. This will be followed by the experience specific questions. After this, there will be questions on organisational and institutional factors that influence IIT start up. The interview will close by asking the participant to identify any future research areas that this study should investigate and there will be an opportunity to add further comments, suggestions or ask questions.

A topic guide that gives a general structure for the interviews can be found in the appendix.

The topic guide will be adapted and updated as the data collection progresses and the conceptual framework is updated. This will allow the study to focus on emerging pertinent issues that were not originally anticipated.

13.3.5 Data collection and recording

The interview will be recorded with the participant's permission and the interviewer will make additional brief notes on the topic guide form. If the participant declines to have the interview recorded, the interviewer will make more in depth notes.

13.4 Data collection review

After each research method is completed a contact summary form will be completed by the facilitator/interviewer and note taker, if present. This will facilitate reflection on the research activities by summarising key findings, the important themes that have emerged and looking at how the methods could be improved. Important topics that need to be discussed further will be incorporated into the conceptual framework and added to topic guides. This will also be an opportunity to consider if data saturation has been reached or whether further research activities are required.

An example of the contact summary form can be found in the appendix.

14 Total recruitment and research method goals

The total recruitment goals are considerably variable depending on the number of methods completed and the number of participants that take part in each method. This is because the number of methods to be conducted is flexible within certain limits, as is the number of participants that can take part in group exercises. It is highly unlikely that we will only conduct the minimum number of methods and recruit the minimum number of participants in all field visits. It is equally unlikely that that will conduct the maximum number of methods and recruit the maximum number of participants. We expect that the actual number of

methods and participants will be somewhere between these figures. This recruitment matrix is therefore included as a summary to clarify the recruitment and research method possibilities. It is important to note that each focus group discussion and process mapping exercise will be one unit of analysis. Therefore the results will represent the group rather than individuals. Only the interviews will be analysed by individual participant.

14.1 Recruitment matrix

		Per field visit				Total for all 4 field visits (each with identical methods and recruitment goals)	
Method	Participants	Number Methods	Participants /method	Total Participants Min	Total Participants Max	Total Participants Min	Total Participants Max
Process mapping	Categories 1a/b & 2a/b	2-4	5-15	10	60	40	240
Focus groups	Categories 1a, 2a &3	2-4	4-8	8	32	32	128
Interviews	Category 4	5-8	1	5	8	20	32
Total participants for all methods				23	100	92	400

15 Data handling

15.1 File Names

Each research method completed will be assigned a unique identifying number. This will be written on data collection forms, in notes taken and will be used to name audio files and transcript documents.

Participants will be assigned a unique ID number to provide anonymity and facilitate identification of contributions when transcribing and referencing quotations. The ID number will be used on data collection forms and also the demographic information form, so that the participant's demographic information can be linked to their ID.

15.2 Confidentiality in the field

The demographic information form will be the only form that records personally identifiable information (except the consent form which contains only the participants name). The ID number of the participant will be recorded on this form. All other data collection forms will only refer to the participant by the unique participant ID number. Therefore it will only be possible to connect the participant with their contributions by having access to both forms.

First names may be verbally used when directing questions during group discussions but all notes will only refer to the participant using the ID number. First names will not be used during interviews as they will not be required.

All notes and audio files will be kept on the person of the facilitator at all times or in a locked vehicle or room. Participants and non-participants will not be allowed to view the notes at any time and content of discussions and interviews will not be revealed to anyone else.

Demographic information forms and data collection forms will be kept in separate folders.

15.3 Confidentiality after the field

All data and forms will be taken directly to a secure room and inserted into separate folders for each form type. The demographic information form will be kept in a separate location to other data collection forms.

16 Data entry

16.1 Entering and filing data

An Excel spread sheet will be created for demographic details and recording of the participant ID number. This file will be password protected using a different password to any other password protection used.

Another Excel spread sheet will be created for recording research methods that have taken place and the participants (ID only) and research documents that are associated with them e.g. audio recordings, transcriptions, notes, contact summary forms. It will also record the location of these documents e.g. folder number or computer file name. None of this information will contain personally identifiable information. Participants will only be referred to by ID number.

Digital data such as audio files and transcriptions will be imported to a computer and given a file name that corresponds to the data type and research activity ID number.

All this data will be stored on securely encrypted password protected devices.

16.2 Transcription

Audio files will be transcribed into Word by the transcriber, fully verbatim, recording hesitations, pauses, utterances, incomplete sentences and interruptions as appropriate. Individual participants will be identified, where possible, by their unique identification number, as detailed above. Where identification is difficult, the transcriber will attribute the comments to „[Unknown]". The transcription will be proof-read against the audio file to check for accuracy and any missing or additional information will be added.

17 Data analysis

Each individual field visit will be analysed separately and have its own distinct set of findings but the findings will also be compared to previous field visits and be used to further develop the conceptual framework. Early data analysis will begin in the field, while data collection for the field visit is still continuing. This will help identify emerging topics that should be investigated further and will also show if data saturation has

been achieved. After all data has been collected for a field visit, it will then be analysed again more thoroughly.

17.1 Analysis of discussions during process mapping, focus groups and interviews

Thematic content analysis will be used to analyse this data. This method is commonly used in healthcare research and in particular, exploratory research. Data from multiple participants is looked at collectively and common ideas or "themes" are identified inductively. Themes are formed by grouping common ideas together into codes in a process known as coding. Analysis will be characterised by frequently going back to the original transcripts to ensure text is coded within context. Coding will be facilitated by using Nvivo 9 software.

The Principal Investigator and another member of the study team who is experienced in thematic content analysis will independently code the first 2 transcripts from each method. This coding will be guided by the original coding template developed during pilot research. They will then compare coding templates, looking for commonalities and deviances and then agree on a final coding template. This will help to increase the validity of the interpretations. As more data is reviewed and coded, the template will be further refined to reflect any new emerging ideas or themes. To further increase validity, the Local Investigators will review the findings from each institution visit to check that they are a credible representation of the clinical trial situation within their institution.

While being descriptive, thematic analysis can produce a "rich" account of events by looking at the diversity of themes that focus on a common topic. Several themes that relate to a particular topic may be interpreted as a concept. Given the exploratory and practical aims and scope of this study, we will not be using more advanced theory generating techniques. However, we will be linking the data to existing theories in an attempt to give it more in-depth explanatory value.

This analytical method was used during the pilot research and was very effective at generating a credible description of the trial issues.

17.2 Analysis of process maps

The process map data analysis is more illustrative. Participants' drawings and discussion notes will be combined to produce a "tidied" version of the processes involved in IIT start-up. Barriers, enablers, time metrics and actions to be done with hindsight will be colour coded. These will be interactively linked to notes with further information on discussion points. Microsoft Visio software allows this to be completed very effectively. Discussions during process mapping will also be transcribed and will be analysed by thematic content analysis.

17.3 Development of themes and concepts and contribution to theory

The main research question of this study is to identify the enablers and barriers to the successful start-up of IITs in resource limited-settings. To answer this question we will be representing participants' experiences and perspectives in the form of common themes. Common themes that relate to similar topics and that interact with each other at different levels will be developed into concepts. These concepts will then be incorporated into a holistic conceptual framework that represents the current "system" influencing IIT start-up. The themes and concepts will reflect how participants' understand the issues and what the issues mean to them. The interpretation of themes and concepts will be both descriptive and analytical, in

the sense that it “tells the story” from the participants perspective, as well as attempting to look at the bigger picture of collective experience to identify underlying patterns that give meaning to what is going on.

We will look for differences and similarities in themes and concepts between different groups of participants, and between institutions (if more than one institution has been studies per field visit). After each individual field visit has been analysed, we will comparatively analyse the four field visits, looking for differences and similarities in themes and concepts between the field sites and groups of participants. Similarities in findings would suggest that these themes and concepts may have transferability to other settings and that the findings would be useful outside the context in which they were generated. We will relate the findings to the original research question and objectives with particular emphasis on summarising the barriers and enablers to the start-up of IITS and making recommendations.

Our interpretation of themes and concepts will be influenced by the theoretical orientation and assumptions mentioned previously and will be framed within the study questions and conceptual framework. However, we will be reflexive during this process, by keeping in mind our guiding assumptions and attempting to remain open to new ideas and ways of thinking. During analysis we will attempt to set aside these assumptions and challenge them so that we can adapt and develop the conceptual framework to incorporate new ideas that have emerged during data collection. We will also be relating our findings to existing theories. Agreement with existing theory will give the findings greater generalisability and robustness, while contradictory theory will cause us to reconsider and challenge our interpretations. Because the analysis is an iterative on-going process, the consulting of current theory will also shape the way we interpret our data. This process will embed our research within wider academic thinking and give it transparency by allowing readers to interpret and critique the findings.

18 Team roles

Principal investigator: Samuel Franzen

Research Coordinator for Global Health Trials, Institute of Research & Development, 393/3, Lilly Avenue, off Roabert Gunawardane Mawatha, Battaramulla. Tel: 94115662895. Email: sam@globalhealthtrials.org

Role: Designing and running the study, administration and operations, identifying and recruiting participants and investigators, facilitating research activities, data collection, data entry, analysis and write up.

Local Co-Principal Investigators:

Cameroon

Dr Julius Atashili, University of Buea, Faculty of Health Sciences, University of Buea, Cameroon. Email: atashili@yahoo.ie

Sri Lanka

Professor Sisira Hemananda Siribaddana, Institute of Research & Development, 393/3, Lilly Avenue, off Roabert Gunawardane Mawatha, Battaramulla. Email: nipuna@stmail.lk

Role: Local administration and operations, identifying and recruiting participants, advice and input on data collection, analysis and write up.

Co-investigators:

Dr Trudie Lang, Global Health Clinical Trials Programme, Division of Tropical Medicine, Nuffield Department of Medicine, University of Oxford, U.K. Email: trudie.lang@ndm.ox.ac.uk

Dr Clare Chandler, Department of Global Health and Development, London School of Hygiene and Tropical Medicine, U.K. Email: clare.chandler@lshtm.ac.uk

Role: Assistance with the designing the study, analysis approach and interpretation of findings. Providing guidance and support to the Principal Investigator.

Investigators' curriculum vitaes can be found in the appendix.

Temporary team members

Note-taker: Taking notes during process mapping and focus group discussions

Transcriber: Conducting transcription of all relevant field documents.

19 Time lines

We aim to begin the first field visit to Cameroon in March 2012 and the Sri Lankan field visit around July 2012. However, the exact dates and order of field visits will depend on logistics, including when approvals are given. Each field visit will last approximately 6-12 weeks. Between each field visit there will be a period of 3 months for organising the next visit and analysing the data. We aim to complete all field visits and analysis by July 2013. After this, further work may be conducted but the write up of the findings will be completed by May 2014.

20 Ethical considerations

This study has been ethically approved by the Oxford Tropical Research Ethics Committee (OXTREC Reference: 70-11). We will be applying for local ethics approval from the local IRBs where the field research will take place. National ethics approval within the field research countries will be sought where necessary. We will consult with the local investigators to identify the most appropriate review boards from which to seek local ethics approval.

A copy of the OXTREC approval letter can be found in the appendix.

We consider this study to qualify as a minimal risk investigation. This study investigates operational processes and factors that impact on the conduct of clinical trials. Research emphasis is on organisations and institutions, not individual responsibility. There is no intervention and no deception.

20.1.1 Participants

The study participants are experienced researchers, healthcare staff and regulatory officials that fully understand the concept of research, their rights and what will be involved. They will be aware of how the findings will be used and the consequences of their participation. Participants will have the right to withdraw any information shared.

20.1.2 Sensitive information

Some information may be professionally sensitive or could be covered by confidentiality agreements. We will emphasise that participants may share as much or as little information as they like and that they may choose not to answer questions. If participants are restricted in the details that they can provide, they are still welcome to take part in the study by contributing their personal opinions on matters without referring to specific circumstances.

20.1.3 Confidentiality

All data will be kept confidential using the measures mentioned previously. However, for process mapping and focus group discussions we cannot guarantee that participants will not share what they have heard. Therefore, this risk will be highlighted to potential participants at the recruitment and consent stage, before asking if they agree to participate in the study. All participants in the group exercises will be requested to agree to a code of confidentiality and there will be an opportunity to discuss this at the beginning of the session.

20.1.4 Maintaining anonymity

In the data analysis phase, participants will be identified only through their participant numbers. In the write up, verbatim quotes will only be used with the consent of the participant. When quotes are used and individual participant experiences and background are described, participants will be given pseudonyms and care will be taken to ensure that any details that could identify them or the projects that they work on are made generic and non-identifiable. The local investigators will help to decide on the level of descriptive detail that is appropriate and that does not compromise the anonymity of the participants. When we are unsure, we will contact the participant for confirmation. The participant's wishes will always be respected and adhered to.

20.1.5 Risks

This study is minimal risk and does not involve any clinical interventions. The study is limited to interviewing research staff and related medical professionals. Neither the wider public nor patients are involved.

20.1.6 Benefits

There will be no direct benefits from participating in this study. However, it will be an opportunity for participants to share their knowledge and experience and contribute to research that is relevant to them. The activities may also help participants to identify strategies that could improve the efficiency of their work and highlight areas that need improving. We hope that participating in this study will be an interesting experience for participants and may contribute to their learning and professional development.

21 Data usage and dissemination of results

The goal of this study is to produce evidence-based data and transferable recommendations that will help to increase the start-up of IITs in resource-limited settings. The evidence based-data will focus on demonstrating the barriers and enablers to trial start-up as well as contributing to current literature on the potential for IITs to fill the current evidence gap and improve capacity of research sites in resource-limited settings.

We hope to publish journal articles that summarise the findings on common barriers and enablers and present an argument for why effort should be made to increase IITs in resource-limited settings. Conceptual models will be used to help demonstrate the findings, their relationships and describe what drives specific issues. The main aim is to put this information in the public domain so that it may influence future funding and capacity building agendas.

We will produce a generic process map that will be made publicly available on the Global Health Trials website. This will act as a resource that guides researchers on how to start an IIT in most resource-limited settings. There will be particular emphasis on best practice for a successful trial and how to avoid problems. It will have an interactive format that allows viewers to select different processes to find more guidance information. Guidance information will be derived from this research, current literature and other users' comments (using participatory Web 2.0 programming).

Transferable recommendations will be made that suggest possible strategies for implementing enablers. The enablers and implementation strategies could be mapped onto conceptual models of the current situation to demonstrate their potential effects.

All finalised reports will be made available to participants and to the institutions where the research was conducted.

All published information will be discussed on the Global Health Trials website to encourage input from researchers around the world. This may lead to the refinement of ideas, suggestions for how to practically implement the recommendations, and collaboration with sites that are willing to attempt these strategies.

This research will also be used for the Principal Investigator's PhD thesis.

22 Signature of Principal Investigator

Principal Investigator: Samuel Franzen

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23 References

1. Garner, P., et al., *Getting research findings into practice - Implementing research findings in developing countries.* British Medical Journal, 1998. **317**(7157): p. 531-535.
2. Isaakidis, P., et al., *Relation between burden of disease and randomised evidence in sub-Saharan Africa: survey of research.* BMJ, 2002. **324**(7339): p. 702.
3. Machin. D and Fayers. F, *Randomized Clinical Trials: Design, Practice and Reporting*. 2010, Chichester: Wiley-Blackwell.
4. Lexchin, J., *One step forward, one step sideways? Expanding research capacity for neglected diseases.* BMC Int Health Hum Rights, 2010. **10**: p. 20.
5. Lang, T.A., et al., *Clinical Research in Resource-Limited Settings: Enhancing Research Capacity and Working Together to Make Trials Less Complicated.* PLoS Negl Trop Dis, 2010. **4**(6): p. e619.
6. Xavier, D., et al., *Treatment and outcomes of acute coronary syndromes in India (CREATE): a prospective analysis of registry data.* Lancet, 2008. **371**(9622): p. 1435-42.
7. Jaffar, S., et al., *Health services strengthening in Africa--research is a key component.* Trop Med Int Health, 2010. **15**(11): p. 1270-3.
8. Yusuf, S., *Clinical research and trials in developing countries.* Stat Med, 2002. **21**(19): p. 2859-67.
9. Garner, P., T.T. Torres, and P. Alonso, *Trial design in developing countries.* BMJ, 1994. **309**(6958): p. 825-6.
10. Halpern, S.D., J.H.T. Karlawish, and J.A. Berlin, *The Continuing Unethical Conduct of Underpowered Clinical Trials.* JAMA, 2002. **288**(3): p. 358-362.
11. Guindon, G.E., et al., *Bridging the gaps between research, policy and practice in low- and middle-income countries: a survey of health care providers.* CMAJ, 2010. **182**(9): p. E362-72.
12. Page, J., et al., *Attitudes of developing world physicians to where medical research is performed and reported.* BMC Public Health, 2003. **3**: p. 6.
13. Devasenapathy, N., K. Singh, and D. Prabhakaran, *Conduct of clinical trials in developing countries: a perspective.* Current Opinion in Cardiology, 2009. **24**(4): p. 295-300.
14. Traversa, G., et al., *The need to promote independent research on drugs.* Ann Oncol, 2010. **21**(11): p. 2295.
15. Mbuagbaw, L., et al., *The challenges and opportunities of conducting a clinical trial in a low resource setting: the case of the Cameroon mobile phone SMS (CAMPS) trial, an investigator initiated trial.* Trials, 2011. **12**: p. 145.
16. Tyndall, A., *Why do we need noncommercial, investigator-initiated clinical trials?* Nat Clin Pract Rheum, 2008. **4**(7): p. 354-355.
17. Dreifuss, R. and R.A. Mashelkar, *Public health innovation and intellectual property rights*, Commission on Intellectual Property Rights Innovation and Public Health, Editor. 2006, World Health Organization Geneva.
18. Mwaba, P., et al., *Research capacity strengthening in African countries.* Lancet, 2010. **375**(9729): p. 1874.
19. Barbour, V., B. Cohen, and G. Yamey, *A new vision for clinical trials in Africa.* PLoS Med, 2004. **1**(3): p. e71.
20. Matsoso. P, et al., *How does the regulatory framework affect incentives for research and development? A proposal for a regulatory framework to improve regulatory capacity and introduce incentives for research and development in areas of public health importance*, Commission on intellectual property rights innovation and public health, Editor. 2005: Geneva.
21. Shafiq, N., P. Pandhi, and S. Malhotra, *Investigator-initiated pragmatic trials in developing countries--much needed but much ignored.* Br J Clin Pharmacol, 2009. **67**(1): p. 141-2.
22. Bergmann, L., et al., *Investigator-initiated trials of targeted oncology agents: why independent research is at risk?* Annals of Oncology, 2010. **21**(8): p. 1573-1578.

23. Johnston, B.C. and S. Vohra, *Investigator-initiated trials are more impartial.* Nature, 2006. **443**(7108): p. 144-144.
24. Petryna, A., *Clinical Trials Offshored: On Private Sector Science and Public Health.* Biosocieties, 2007. **2**: p. 19.
25. Morice, A.H., *The death of academic clinical trials.* Lancet, 2003. **361**(9368): p. 1568.
26. European League Against Rheumatism. [cited 2011 10/10/2011]; Available from: http://www.eular.org/.
27. Italian Medicines Agency. [cited 2011 10/10/2011]; Available from: http://www.agenziafarmaco.gov.it/en.
28. European Group for Blood and Marrow Transplantation. [cited 2011 10/10/2011]; Available from: http://www.ebmt.org/Contents/Pages/Default.aspx.
29. Kilama, W.L., *The 10/90 gap in sub-Saharan Africa: resolving inequities in health research.* Acta Trop, 2009. **112 Suppl 1**: p. S8-S15.
30. Global Health Trials. [cited 2011 19/10/11]; Available from: www.globalhealthtrials.org.

24 Appendices

24.1 Study Instruments

- 24.1.1Demographic Information Form
- 24.1.2 Process Mapping Topic Guide
- 24.1.3 Note-taking form
- 24.1.4 Focus Group Discussion Topic Guide
- 24.1.5 Interview Topic Guide
- 24.1.6 Contact Summary Form

24.2 Participant Information Sheet and Consent Form

24.3 Advertisement - Research Invitation

24.4 Oxford Tropical Research Ethics Committee – Approval document and number

24.5 Investigators' Curriculum Vitaes

24.1 Study Instruments

Documents only provided in English. We will only be recruiting English speaking participants.

24.1.1 Demographic information form

Participant Demographic Information Form

For study team use only

Participant IDNO _____/_____/_____(_____) [institution/method/methodNO(participantNO)]

Consent form signed and collected (tick) ☐

Ensure Participant IDNO matches contribution seating plan in Note taking Form

To be completed by participants

Personal details – please use block capitals

Name	
Title	
Gender	
Age	
Email	

Career information – please briefly describe your past and present career details

Qualifications	
Job title(s) *Please include all currently held positions e.g. PI and ethics board member*	
Work place (s)	

Roles and responsibilities	
Previous relevant work experience *Please include any experiences that you have had with research and number of years experience*	

24.1.2 Process mapping topic guide

Process Mapping Topic Guide

PM IDNO _____/__PM__/_____ Participant sub-group: IIT / FIT

Facilitator Initials |_|_|_| Note-taker Initials |_|_|_|

Recording NO _____|_____

Date: |_|_/_|_/_|_| (DMY)

Introduction:

- ✓ Purpose of study
- ✓ Aim of process mapping exercise and duration
- ✓ Who is involved and other participants
- ✓ Why participants cooperation and input is important
- ✓ What will happen with the data and how participants will benefit
- ✓ Ground rules: -allow participants to make their own (draw on whiteboard/flipchart)
    - Only one person speak at a time – also for benefit of recording and analysis
    - Important to hear everyone's opinions. No right or wrong answers to questions – want opinions and ideas. All opinions and ideas are valuable.
    - Interested in hearing all sides of issues –positive and negative
    - Confidentiality – what is said in the room should not be shared with others
- ✓ Questions? Chance for further questions and discussion with facilitator at the end
- ✓ Receive PIS
- ✓ Consent
- ✓ Participants complete demographic information form
- ✓ Assign participants ID number
- ✓ Prepare note taking form and draw seating diagram to assign contributions to participants (use participant ID)
- ✓ Check audio device

The space provided is for brief notes to be filled in by the facilitator. For full note-taker notes, please use the note-taking form

Before the process mapping starts:

1. Can you tell me about your most recent clinical trial?
    - *Intervention/phase/sponsor/funder/design/participants?*

2. Can you tell me about any previous clinical trials that this group has conducted?
    - *Intervention/phase/sponsor/funder/design/participants?*

Begin process mapping exercise using suitable prompts: try to include all the information on the process map rather than using additional notes.

If participants have difficulty doing the exercise, encourage them to start from the beginning and work forward towards intervention delivery.

Prompts to be used, only if the participants do not answer the questions themselves

- *Are there any other processes that you think you may have missed out? Use the Global Health Trials process map as a memory aid, but do not show it to participants because it may affect the way they draw the map.*
- *How long did each process take?*
- *Are there any processes that were particularly difficult? If so, why?*
- *Are there any processes that were particularly easy, or went well, if so, why?*
- *Are there any strategies or techniques that helped you?*
- *Is there anything that you would have done differently with hindsight?*
- *Is there anything you think needs adding to the process map before we finish? It may help to go through the map one last time, from start to finish.*
- *Do you think the process map is an accurate representation of what you did to start the trial?*

3. How did you find this exercise? Was it easy or hard? How could it be improved? Do you think it was a useful learning exercise?

24.1.3 Note taking form (for process mapping and focus group discussions)

Process mapping and Focus Group Discussion Note taker Form

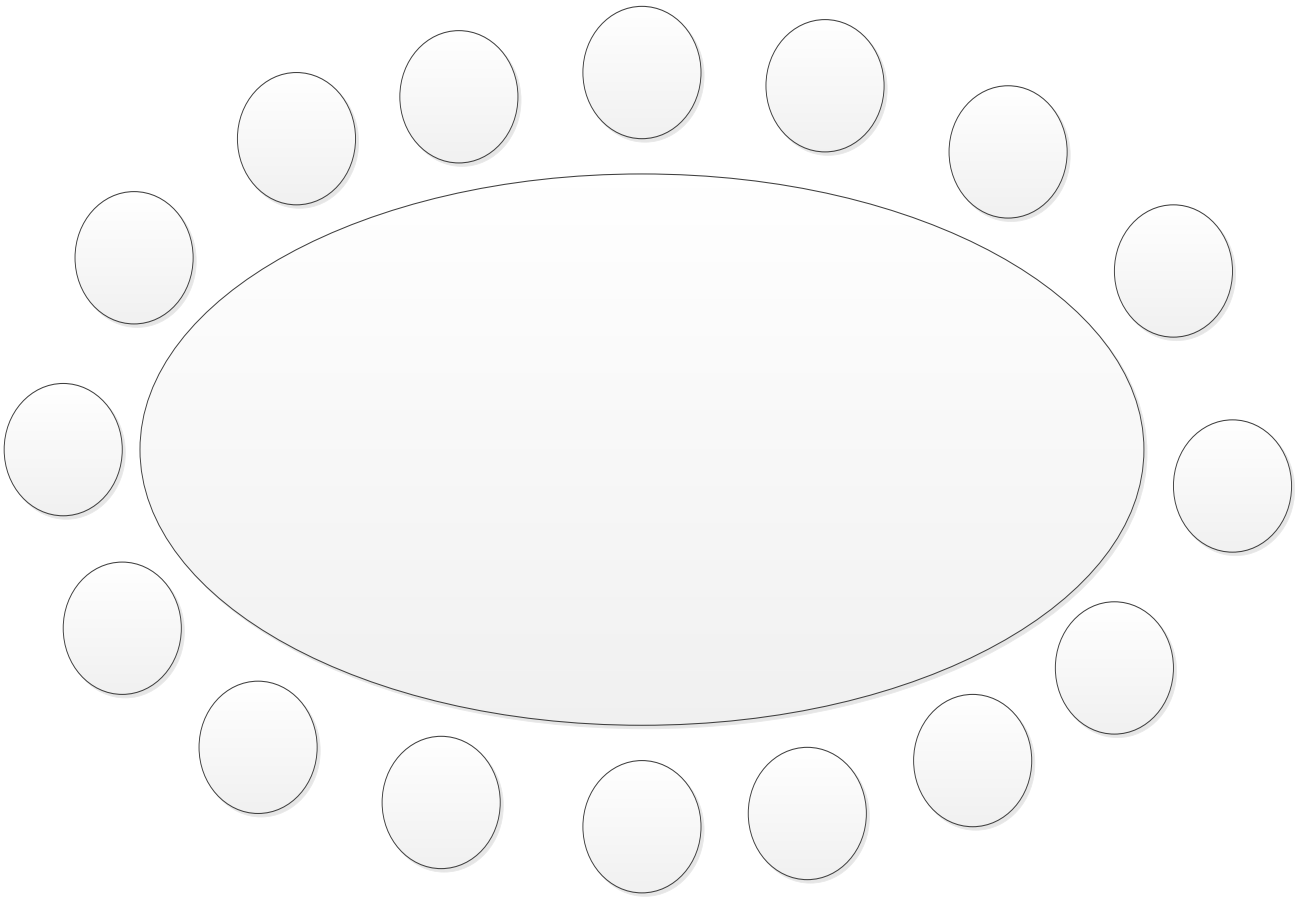
Method IDNO _____/_____/_____ (institution-method-method number)

Participant sub-group: IIT / NC-FIT / Experienced / Inexperienced

Facilitator Initials |_|_|_| Note-taker Initials |_|_|_| Recording NO _____|_____

Date: |_|_/_|_/_|_| (DMY) Time start _____:_____ end _____:_____

Seating diagram: Enter participant numbers e.g.1-8. These will form the participant ID e.g. Participant 4, taking part in the 2nd focus group at the University of x = is UoX-FGD-02/(***04)***



Check – have you matched the participant IDs to the demographic information form? Check when the participant introduces their first name

Additional seating notes to help identification:

Meeting place description: *detail and description, e.g. size and accessibility, and how this could affect the discussion; interruptions during the discussion*

Group dynamics: *general description – level of participation, dominant and passive participants, interest level, boredom, anxiety – and how these relate to the different topics discussed*

Impressions and observations:

Running notes (detailed notes following the discussion, as near verbatim as possible, including identification of all contributors):

*Continues as required…**make sure you write the method ID and page number on the top of every sheet.***

24.1.4 Focus Group Discussion topic guide

Focus Group Discussion Topic Guide

FGD IDNO _____/__FGD__/_____ Participant sub-group: Experienced / Inexperienced

Facilitator Initials |_|_|_| Note-taker Initials |_|_|_|

Recording NO _____|_____

Date: |_|_/_|_/_|_| (DMY)

Introduction:

- ✓ Purpose of study
- ✓ Aim of FGD and duration
- ✓ Who is involved and other participants
- ✓ Why participants cooperation and input is important
- ✓ What will happen with the data and how participants will benefit
- ✓ Ground rules: -allow participants to make their own (draw on whiteboard/flipchart)
  - Only one person speak at a time – also for benefit of recording and analysis
  - Important to hear everyone's opinions. No right or wrong answers to questions – want opinions and ideas. All opinions and ideas are valuable.
  - Interested in hearing all sides of issues –positive and negative
  - Confidentiality – what is said in the room should not be shared with others
- ✓ Questions? Chance for further questions and discussion with facilitator at the end
- ✓ Receive PIS
- ✓ Consent
- ✓ Participants complete demographic information form
- ✓ Assign participants ID number
- ✓ Prepare note taking form and draw seating diagram to assign contributions to participants (use participant ID)
- ✓ Check audio device

The spaces provided are for brief notes to be filled in by the facilitator. For full note-taker notes, please use the note-taking form

Warm up

0. Can we go around the room and introduce ourselves by our first names, and say why you were interested in taking part in this research and what you hope to take away from this session.

Introductory questions: Research context:

1. What do you feel are the health topics that most needing research in [Country]?
   - *Disease areas*
   - *Information types – drug comparison/health services/ IMPs/disease management/guidelines*

- *Are these topics currently receiving attention*

2. Can you tell me about the clinical trials that are conducted in [Country]?

   - *IITs/FITs*
   - *Disease areas / Intervention types /Classification /Phase*
   - *Common/Not common – why?*
   - *What institutions and organisations conduct these trials?*
   - *Who are the most common funders and sponsor of research in [Country]? Local / Foreign*

Core topic: Trial and research perceptions

3. In your opinion, what is the importance of clinical trials?
   - *Why / Purpose/ What advantages / Disadvantages/ Alternatives to trials?*

4. What do you understand by the term IIT?
   - *Make sure everyone has common understanding, and explain how you will be using the term*

5. In your opinion, what is the value of IITs?
   - *Why / Purpose/ What advantages / Disadvantages/*

6. How are IITs different from industry or foreign sponsored trials
    - *Investigative areas / Purpose / Types of intervention / Study design*
    - *Advantages/disadvantages*

7. In your opinion, what do you think would be the most difficult and easy aspects of conducting a clinical trial?
    - *Planning / Regulatory / Operational / Resources / Knowledge / Support – funding/sponsorship*
    - *Can you be specific about that? Can you give an example?*
    - *Can you think of any solutions to the problems?*

8. Are there any types of research that you think would be particularly hard/easy to conduct?
    - *Which – Study population / Intervention type / Study location / Urban-Rural*
    - *Why*

9. Would these factors be different depending on if the trial was an FIT or an IIT?

10. How do you think the situation could be improved to make it easier to conduct an IIT?

Core topic: Individual

11. Do you think that there is a strong research culture in [Country]?
    - *Is research important for people or institutions or are there other competing priorities?*
    - *How is research valued and what types of research are most valued?*

12. What motivates people to conduct IITs and what might discourage people from conducting an IIT?

13. How do you think you could encourage and support more people to initiate their own trials?

Core topic: organisational/institutional issues

14. What do you think are the main factors that limit the number of IITS in [Country]?
    - *Resources (money/human/technical), trained personnel or bodies, opportunities, careers, infrastructure*
    - *Can you explain that in more detail*

15. Can you tell me about any support given to local researchers, how could this be improved?
    - *Capacity building / Training / Careers*
    - *Do you feel that there is a difference between the quality of support for independent local research compared to commercial or foreign research?*

Closing questions

16. We are coming to the end of our discussion. It has been very helpful and has generated some great ideas. I would like to ask for your input on the future direction of this research. What do you consider to be the priority areas that this research should address?

17. Do you have any suggestions, comments or questions that you would like to add?

24.1.5 Interview topic guide

Interview Topic Guide

Interview IDNO _____/__INT__/_____ Participant specialism _____

Facilitator Initials |_|_|_| Recording NO _____|_____ Date: |_|_/_|_/_|_| (DMY)

Participant IDNO _____/_INT_/_____ (01) (institution/method/method no. /participant no.)

Introduction:

- ✓ Purpose of study
- ✓ Aim of interview and duration
- ✓ Why participants cooperation and input is important
- ✓ What will happen with the data and how participants will benefit
- ✓ Questions? Chance for further questions and discussion with facilitator at the end
- ✓ Receive PIS
- ✓ Consent
- ✓ Participants complete demographic information form
- ✓ Assign participants ID number
- ✓ Check audio device
- ✓ <every time a participant mentions a problem –ask what the impact is

The spaces provided are for brief notes to be filled in by the facilitator when audio recording is used. When audio recording is not permitted please make extended notes on separate pieces of paper, making sure to reference the question and adding in the method IDNO and page number on each sheet of paper used.

Warm Up

1. Could you describe how you came to work in your current role?
    - Education, previous roles, previous institutions, interest and decision making (why choose this path)

Introduction

2. What do you feel are the health topics that most needing research in [Country]?
    - *Disease areas*
    - *Information types – drug comparison/health services/ IMPs/disease management/guidelines*
    - *Are these topics currently receiving attention*

3. Could you explain how the clinical trial environment has changed in [Country] over the past (10)* years? *adapt for experience
    - Numbers of trials, disease areas, funders/sponsors, local/foreign
    - Why has this occurred – external (policy/capacity building/world institutional factors) or internal influencing factors (politics/economic growth/education)

Core topic: Trial and research perceptions

4. In your opinion, what is the value of clinical trials?
    - *Why / Purpose/ What advantages / Disadvantages/ Alternatives to trials?*

5. What do you understand by the term IIT?
    - *Make sure you have a common understanding, and explain how you will be using the term*

6. In your opinion, what is the value of IITs?
    - *Why / Purpose/ What advantages / Disadvantages/*

7. How are IITs different from industry or foreign sponsored trials
    - *Investigative areas / Purpose / Types of intervention / Study design*
    - *Advantages/disadvantages*

Insert experience specific questions here. E.g. For a regulatory official, " How do you think the regulatory environment impacts on the conduct of IIT in [Country], could this be improved and if so how?

Continue questions as necessary but keep in mind that the interview should not last more than 1.5 hours

Core topic: Institutional and organisational factors

8. What do you think are the main factors that limit local research and the number of IITS in [Country]?
    - *Resources (money/human/technical), trained personnel or bodies, opportunities, careers, infrastructure*
    - *Can you explain that in more detail*

9. Can you think of any ways to better support independent research and increase the number of IITS in [Country]?

Close

10. We are coming to the end of our discussion. It has been very helpful and has generated some great ideas.
    I would like to ask for your input on the future direction of this research. What do you consider to be the priority areas that this research should address?

11. Do you have any suggestions, comments or questions that you would like to add?

24.1.6 Contact Summary Form

Contact summary form for all methods

Method IDNO _____/_____/_____ (institution-method-method number)

Participant sub-group: IIT / NC-FIT / Experienced / Inexperienced/Other

_____

Facilitator Initials |_|_|_| Note-taker Initials |_|_|_| Recording NO _____|_____

Date: |_|_/_|_/_|_| (DMY) Time start _____:_____ end _____:_____

1. What were the main issues or themes that struck you during this method?

2. What new information did you gain through this method?

3. What new questions or inconsistencies emerged for you as a result of this method?

4. Was there anything that struck you as salient, interesting, illuminating or important in this method?

5. How would you describe the general atmosphere and engagement of the method?

6. How would you describe the group dynamics? For example, were there dominant individuals (what was the result and what were their IDNOs)? Did all participants contribute? Did you feel there was pressure to adhere to dominant viewpoints (what topics)? *[Group exercises only]*

7. What else was important about this method?

8. Were there any problems with the topic guide (e.g. wording, order of topics, missing topics) you experienced in this method?

9. Description of meeting place –could this have affected the discussion? Interruptions?

24.2 Participant information sheet and consent form

Documents only provided in English. We will only be recruiting English speaking participants.

Participant Information Sheet

Study title: Start up of investigator-initiated trials in resource-limited settings: understanding the barriers and identifying enabling strategies

Who are we?

Global Health Clinical Trials is an open collaborative programme with the goal of promoting and facilitating the conduct of non-commercial clinical trials across all diseases in the field of Global Health. This research is being conducted by Samuel Franzen, Research Coordinator for Global Health Clinical Trials, at the Institute of Research and Development, Battaramulla, Sri Lanka.

Invitation for participation

We would like to invite you to take part in a study to understand what helps and hinders the start-up of trials that are initiated by local investigators in resource-limited settings. You have been sent this invitation because we are keen to hear about your experiences and perspectives on this topic. This study has been approved by the Oxford Tropical Research Ethics Committee and The University of Sri Jayewardenepura Ethical Review Board [Ethics approval pending].

Background

Clinical trials in developing countries are important sources of evidence for public health policy. However, few trials are conducted, evidence does not always influence clinical practice and important research topics remain unaddressed. Local investigator-initiated trials (IITs) may help to address these problems but further work is needed to understand how their number can be increased. The goal of this study is to produce evidence about how to increase the start-up of IITs in resource-limited settings.

Research aim and objectives

The aim of the study is to understand the operational, organisational and institutional factors that impact on the start-up of investigator initiated trials in resource-limited settings and to identify strategies that will increase the operational effectiveness and number of investigator-initiated trials conducted.

Who can be involved?

Anyone with the following career backgrounds is welcome to be involved:

1. A) Investigators and trial coordinators, who have worked on an investigator-initiated trial in the last 5 years
   B) Trial staff who have worked on an investigator-initiated trial in the last 5 years

2. A) Investigators and trial coordinators, who have worked on a foreign-initiated trial in the last 5 years
   B) Trial staff who have worked on a foreign-initiated trial within the last 5 years

3. Clinicians, academic researchers and healthcare staff who could take on the role of a senior member of a clinical trial team in the future, but have no current experience of running clinical trials

4. Leaders of research groups and academic/clinical departments, local regulators, policy makers, representatives of healthcare and research funding bodies and any other stakeholders with influence over clinical trials

What will I be expected to do?

Depending on your background, you may be asked to take part in one or more research activities. These will include process mapping, focus group discussions and interviews.

Process mapping: People in categories 1A&B and 2A&B will be asked to take part in this exercise. ***Please note that this exercise can only be completed if several key members of your trial group also agree to take part.*** You will be asked to draw a flow diagram with your colleagues, which we call a 'process map.' This process map should represent the steps that you go through when you start a clinical trial. You will only be asked to do this with your clinical trial group; no other participants will be present. A facilitator will guide you and your colleagues through this. They will demonstrate how to do the exercise and will ask you further questions relating to this topic. This may take up to 2 hours.

Focus group discussions: People in categories 1, 2 and 3 will be asked to take part in this activity. This will involve a discussion with up to 10 people who have a similar background as you. You may or may not know these people. A facilitator will pose questions and topics for the group to discuss. This may take up to 2 hours depending on how much participants want to discuss. You may choose not to answer any questions that you are uncomfortable with. Only the people involved in the discussion, the person asking the questions, and a note-taker will be present.

Interviews: People in category 4 and anyone else with expert experience of clinical trials will be asked to take part in this exercise. Interview questions will allow you to explain your experience and opinions on clinical trials and will then follow up on specific topics. The interview may take up to 2 hours depending on how much information you would like to share. You may choose not to answer any questions that you are uncomfortable with. The interview may be conducted in person or via a conference call. Only the interviewer will be present.

Please not that all activities will be audio recorded and notes will be taken. Transcriptions will be made from the audio recording. We would also like to quotes some of your words in reports and publications. If you do not wish for your contributions to be audio recorded, or direct quotations used in reports, it may still be possible for you to participate in the study. Please discus this further with Samuel Franzen.

What are the benefits of participating?

There will be no direct benefits from participating. However, this will be an opportunity for you to share your knowledge and experience and contribute to research that is relevant to you. The activities may help you to identify strategies that could improve the efficiency of your work and highlight areas that need improving. We hope that this will be an interesting experience for you and may contribute to your learning and development.

What are the risks or disadvantages of me taking part?

We do not envisage any harm from this study. However, it is likely that engaging in this research may encourage you to consider your circumstances in detail. We hope that this will be a positive experience but we cannot rule out any negative feelings that may occur. All your contributions will be kept confidential, in procedures outlined below. For group discussions it is important to remember that other participants will be present. We will ask everybody to keep what is said in the group confidential but we cannot prevent other participants from sharing what they have heard.

What will happen to the information I give and how will the results be disseminated?

All information will be kept confidential and will only be accessible to the study team. The data you give will be assigned a pseudonym and no personally identifiable information will be included in reports. Your pseudonym and personal information will be kept separately and can only be linked through a secure coding sheet. All data will be securely stored. All recordings will be destroyed when this research is completed. You may ask for your contributions to be removed and destroyed at any point. You will be sent reports of the findings when they are completed.

Reports and Publications will discuss the importance of investigator-initiated trials, the barriers and enablers to their conduct, and recommendations for implementing enabling strategies. Useful tools and resources will be made freely available on the Global Health Trials website. This research will also be used for a PhD thesis that will be stored in print within the Oxford University Archives and will be open access through the Oxford University online archive.

Do I have to take part in this research?

All participation in research is voluntary. You are free to decide if you want to take part or not. If you do agree, you can change your mind at any time without any consequences.

Further information

You are free to ask any questions about this research. Please contact Samuel Franzen for further information.
Samuel Franzen (Principal Investigator) – Institute of Research & Development, 393/3, Lilly Avenue, off Roabert Gunawardane Mawatha, Battaramulla. Tel: 94115662895. Email: sam@globalhealthtrials.org

What if there is a problem?

If you have a concern about any aspect of this project, please speak to Samuel Franzen who will do his best to answer your query. If you remain unhappy and wish to make a formal complaint, please contact:

University of Sri Jayewardenepura Ethical Review Board, Department of Community Medicine, Faulty of Medical Sciences, University of Sri Jayewardenepura, Phone : +94112758588/+94(0)773075088, Email : fms.erc.usjp@gmail.com

Or The Research Ethics Committee at the University of Oxford (ethics@medsci.ox.ac.uk; Medical Sciences Inter-Divisional Research Ethics Committee, Medical Sciences Divisional Office, Level 3 John Radcliffe Hospital, Oxford, OX3 9DU, UK).

CONSENT FORM

Study title: Start up of investigator-initiated trials in resource-limited settings: understanding the barriers and identifying enabling strategies

Principal Investigator: Samuel Franzen – Institute of Research & Development, 393/3, Lilly Avenue, off Roabert Gunawardane Mawatha, Battaramulla. Tel: 94115662895. Email: sam@globalhealthtrials.org

Declarations:

- I have had the study explained to me. I have read and understood all the information and had my questions answered satisfactorily.
- I understand that my participation is voluntary.
- I understand that I can withdraw from this study at any time and it will not affect me in any way.
- I understand that this study has approved by the Oxford University Tropical Research Ethics Committee and The University of Sri Jayewardenepura Ethical Review Board [Ethics approval pending].
- I understand that the information I give will be used for research purposes, who will have access to my information and how the findings will be published and stored.
- I understand how to raise concerns and who to contact if I have a complaint.

To be completed by the participant:

Please confirm which study methods you consent to be involved in:

Yes, I agree to take part in a process mapping exercise (please initial) ☐

Yes, I agree to take part in a focus group discussion (please initial) ☐

Yes, I agree to be interviewed (please initial) ☐

Please confirm that you agree to have your contributions recorded and that quotations may be used:

Yes, I agree for my contributions to be audio recorded (please initial) ☐

Yes, I agree for my words to be used as quotes in publications (please initial) ☐

Signature: _____ Date: _____

Participant Name: _____ Time: _____

(please print name)

To be completed by the person taking consent:

I certify that the participant apparently understands the nature and the purpose of the study and has agreed to participate. The participant has been given opportunity to ask questions which have been answered satisfactorily.

Signature: _____ Date: _____

Designee/investigator's name _____ Time: _____

24.3 Advertisement - Research Invitation

Documents only provided in English. We will only be recruiting English speaking participants.

Invitation to take part in future research activities

Study title: Start up of investigator-initiated trials in resource-limited settings: understanding the barriers and identifying enabling strategies

Who are we?

Global Health Clinical Trials is an open collaborative programme with the goal of promoting and facilitating the conduct of non-commercial clinical trials across all diseases in the field of Global Health. The core activities of the programme include the Global Health Trials website (www.globalhealthtrials.org) and research into factors that affect the conduct of clinical trials in resource-limited settings

Invitation for participation

We would like to invite you to take part in a study to understand what helps and hinders the start-up of trials that are initiated by local investigators in resource-limited settings. You have been sent this invitation because we are keen to hear about your experiences and perspectives on this topic.

This research is being conducted by Samuel Franzen, Research Coordinator for Global Health Clinical Trials, at the Institute of Research and Development, Battaramulla, Sri Lanka. This study has been approved by the Oxford Tropical Research Ethics Committee and The University of Sri Jayewardenepura Ethical Review Board [Ethics approval pending].

The study logistics and administration for the research activities in your area are may not be finalised. By expressing interest in this study you are under no obligation to take part. The purpose of this invitation is to register interest in the study so that we may send you further information once the research activities in your area are organised.

Background

Clinical trials in developing countries are important sources of evidence for public health policy. However, few trials are conducted, evidence does not always influence clinical practice and important research topics remain unaddressed. Local investigator-initiated trials (IITs) may help to address these problems but further work is needed to understand how their number can be increased. The goal of this study is to produce evidence about how to increase the start-up of IITs in resource-limited settings.

Research aim and objectives

The aim of the study is to understand the operational, organisational and institutional factors that impact on the start-up of investigator initiated trials in resource-limited settings and to identify strategies that will increase the operational effectiveness and number of investigator-initiated trials conducted.

Who can be involved?

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B) Trial staff who have worked on an investigator-initiated trial in the last 5 years

2. A) Investigators and trial coordinators, who have worked on a foreign-initiated trial in the last 5 years
   B) Trial staff who have worked on a foreign-initiated trial within the last 5 years

3. Clinicians, academic researchers and healthcare staff who could take on the role of a senior member of a clinical trial team in the future, but have no current experience of running clinical trials

4. Leaders of research groups and academic/clinical departments, local regulators, policy makers, representatives of healthcare and research funding bodies and any other stakeholders with influence over clinical trials

What will I be expected to do?

Depending on your background, you may be asked to take part in one or more research activities. These will include process mapping, focus group discussions and interviews.

Process mapping: People in categories 1A&B and 2A&B will be asked to take part in this exercise. ***Please note that this exercise can only be completed if several key members of your trial group also agree to take part.*** You will be asked to draw a flow diagram with your colleagues, which we call a 'process map.' This process map should represent the steps that you go through when you start a clinical trial. You will only be asked to do this with your clinical trial group; no other participants will be present. A facilitator will guide you and your colleagues through this. They will demonstrate how to do the exercise and will ask you further questions relating to this topic. This may take up to 2 hours.

Focus group discussions: People in categories 1A, 2A and 3 will be asked to take part in this activity. This will involve a discussion with up to 10 people who have a similar background as you. You may or may not know these people. A facilitator will pose questions and topics for the group to discuss. This may take up to 2 hours depending on how much participants want to discuss. You may choose not to answer any questions that you are uncomfortable with. Only the people involved in the discussion, the person asking the questions, and a note-taker will be present.

Interviews: People in category 4 and anyone else with expert experience of clinical trials will be asked to take part in this exercise. Interview questions will allow you to explain your experience and opinions on clinical trials and will then follow up on specific topics. The interview may take up to 2 hours depending on how much information you would like to share. You may choose not to answer any questions that you are uncomfortable with. The interview may be conducted in person or via a conference call. Only the interviewer will be present.

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What are the benefits of participating?

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What are the risks or disadvantages of me taking part?

We do not envisage any harm from this study. However, it is likely that engaging in this research may encourage you to consider your circumstances in detail. We hope that this will be a positive experience but we cannot rule out any negative feelings that may occur. All your contributions will be kept confidential, in procedures outlined below. For group discussions it is important to remember that other participants will be present. We will ask everybody to keep what is said in the group confidential but we cannot prevent other participants from sharing what they have heard.

What will happen to the information I give and how will the results be disseminated?

All information will be kept confidential and will only be accessible to the study team. The data you give will be assigned a pseudonym and no personally identifiable information will be included in reports. Your pseudonym and personal information will be kept separately and can only be linked through a secure coding sheet. All data will be securely stored. All recordings will be destroyed when this research is completed. You may ask for your contributions to be removed and destroyed at any point. You will be sent reports of the findings when they are completed.

Reports and Publications will discuss the importance of investigator-initiated trials, the barriers and enablers to their conduct, and recommendations for implementing enabling strategies. Useful tools and resources will be made freely available on the Global Health Trials website. This research will also be used for a PhD thesis that will be stored in print within the Oxford University Archives and will be open access through the Oxford University online archive.

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Further information

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Or The Research Ethics Committee at the University of Oxford (ethics@medsci.ox.ac.uk; Medical Sciences Inter-Divisional Research Ethics Committee, Medical Sciences Divisional Office, Level 3 John Radcliffe Hospital, Oxford, OX3 9DU, UK).

24.4 Oxford Tropical Research Ethics Committee – Approval document and number

[Please see attached separate document for PDF version]

Dr S Franzen
Global Health Clinical Trials Programme
CCVTM
Nuffield Department of Medicine
University of Oxford
OX3 7LJ

1st December 2011

Dear Dr Franzen

Full Title of Study: Start up of investigator-initiated trials in resource-limited settings: Understanding the barriers and identifying enabling strategies

OXTREC Reference: 70-11

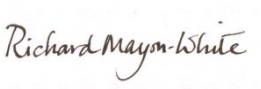
In addition to your application, the documents reviewed were:

Documentation:	**Version:**	**Date:**
Protocol & Appendices	V1.3	

Thank you your email 29th November 2011 in which you have attached the final copy of protocol v1.3 and revised appendices.

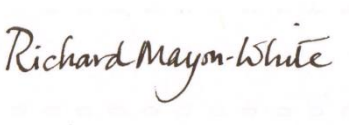
As Chairman for OXTREC I am happy to grant final approval for this study and look forward to receiving the LEC approval letter in due course.

Yours sincerely



Richard Mayon-White

OXTREC Chair



24.5 Investigators Curriculum Vitaes

24.5.1 Samuel Franzen

Samuel Franzen

Institute of Research & Development, 393/3, Lilly Avenue, off Roabert Gunawardane Mawatha, Battaramulla. Tel: 94115662895. Email: sam@globalhealthtrials.org

EDUCATION

2010-2014 **PhD Candidate, Clinical Medicine** University of Oxford

My research focuses on identifying the enablers and barriers to the successful start-up of investigator-initiated trials in resource-limited settings. I aim to identify examples of enabling strategies and to develop recommendations that will facilitate the start-up of these local trials. I will be using mixed methods to produce applied outputs in collaboration with local researchers in Sub-Saharan Africa, South Asia, East Asia and Latin America.

2002-2005 **BSc (Hons) Biology - 1st class** University of Nottingham

RESEARCH EXPERIENCE

10.10-10.14 **Research Coordinator** Global Health Trials, University of Oxford

- Coordinate and conduct research on the conduct of clinical trials in resource-limited settings. Research activities focus on process and quality improvement, methodological optimisation, operational improvement and institutional and organisational development.
- Advisory capacity to the Clinical Trial Transformation Initiative that seeks to facilitate the conduct of clinical trials in the United States
- Develop online tools and resources, data capture platforms and website functionality that aims to facilitate the conduct of clinical trials in resource-limited settings
- Contribute to content and design of the Global Health Trials website

03.10-09-.10 **Intern** Rwanda Zambia HIV Research Group, Kigali, Rwanda

- My main responsibility involved co-coordinating the training for the government clinic Data Managers in preparation for the nationwide rollout of Couples' Voluntary Counseling and Testing (CVCT). This included writing the CVCT Data Managers training course, overseeing training and assisting the Ministry of Health with the design of data collection tools and reporting structures.
- I was also responsible for scheduling the training for all government CVCT implementers to ensure that we complied with our CDC training grant. The implementers include: couples testing and family planning counsellors, data managers, laboratory technicians and health promoters. This involved liaising with both government and non-governmental partners over issues of cost sharing and logistics. I also attended weekly management meetings on the routine running of the group's

projects and attended World Bank debates on HIV related topics.

09.08–03.10 **Research Technician and Site Coordinator** Immunology department, Imperial College London

E*valuating the efficacy of hydroxychloroquine in decreasing immune activation in asymptomatic HIV-infected patients:* Phase II multi-centre double blind placebo controlled MRC CTU clinical trial.

Data Collection

- Separating and archiving blood products in accordance with category 2 and 3 laboratory practice.
- Analysis of extracellular markers of immune activation, T-cell memory subsets and intracellular markers of cellular proliferation, inflammation and apoptosis using 6-colour flow cytometry.
- Validating new methods and procedures.

Administration

- Booking and receiving samples from thirteen trial sites, checking and filing Case Report Forms.
- Designing and maintaining trial databases and archives for flow cytometry data and patient recruitment.
- Maintaining and updating trial central laboratory file, ensuring all required documentation is in place and following MHRA recommendations.
- Writing and updating Standard Operating Procedures.

***The CD4 Initiative validation trial:* Developing a novel, inexpensive, point of care test for measuring CD4 counts in resource poor settings.**

- Running three prototype index tests and a reference standard test (NHS lymphocyte subset counts).
- Data entry and analysis for sensitivity, specificity and predictive values.
- Meticulous record keeping of all activities to allow for examination of data trends and product failures.
- Providing post evaluation feedback and troubleshooting with manufacturers.

07.08–09.08 **Voluntary Medical Technical Officer** Toxicology department, Norfolk and Norwich Hospital

06.07-10.07 **Project Officer and Researcher** Deep Griha Society (DGS), Pune, India

Deep Griha's Integrated Service for HIV and AIDS: Designed a nutrition and self-reported health questionnaire (involved literature reviews and key informant interviews) and trained staff on its implementation (produced training material and ran a staff training session). I also assisted in HIV awareness events and conducted workshops on the utilisation of volunteers.

Project proposal for a community youth center: Compiled community surveys, conducted interviews with community heads and sourced potential sites considering issues such as community support and service duplication. Wrote progress reports and a project proposal that obtained long-term funding. The Youth Centre (DIYA) was opened in July 2008: http://deepgriha.org/index.php/programmes/youth-empowerment/diya-centre.

Injecting drug user drop in center offering substitution therapy and nutritional support: Researched best practice guidelines, observed current practice and produced reports making recommendations. I also produced awareness material on harm reduction and safer drug taking.

08.06–03.07 **Researcher** Shellfish Aquaculture and Research Lab, Cheju National University, S. Korea

I histologically identified mussels' reproductive stages to assess seasonal fecundity and proof read Professors' papers and presentations before their submission to English language journals and conventions.

07.04-04.05 **Researcher** Nottingham and Suez Canal Universities: Sinai desert, Egypt

Involved one month's fieldwork (capturing mice, producing faecal/blood smears and dissection), lab-work (examining gastrointestinal tract samples), statistical analysis and writing a project report.

TRAINING COURSES AND CONFERENCES

2011	**Managing Research**	Medical Sciences, University of Oxford
2011	**Public Policy in Practice**	Green College, University of Oxford
2011	**Qualitative Research methods**	Centre for Evidence-Based Medicine, University of Oxford
2010	**Research in Progress Meeting**	Royal Society of Tropical Medicine and Hygiene
2010	**Qualitative Research Methods**	Development studies, University of Oxford
2010	**Quantitative Research Methods**	Development studies, University of Oxford
2009	**Design and Analysis of Clinical Trials**	Imperial College 2-day course
2009	**Good Clinical Practice (GCP) Online**	EPIGEUM, Imperial College London
2009	**Research Governance Workshop Series**	Clinical Research Governance Office, Imperial College
2009	**Phlebotomy**	Chelsea and Westminster Hospital Trust
2009	**Protection of children and vulnerable adults**	British Red Cross
2007	**HIV and Disability and Sex and Sexuality**	Deep Griha Society, Pune, India

24.5.2 Dr Trudie Lang

Curriculum Vitae
Trudie Lang PhD, FICR
2011

I have worked in the field of drug/vaccine development and clinical trials for 17 years, with the last 12 specialising in tropical medicine. Working for a major pharmaceutical company helped me understand the product development research process and experience the related management, political and commercial factors. I have been fortunate to work within the varied settings of public private partnerships, the World Health Organisation, NGO's and presently in the University of Oxford. My PhD used quantitative and qualitative social science methods to examine the development of several anti-malarial drugs to conclude how an optimal product should be developed specifically for community based public health use in Africa. I am currently enjoying a post that allows me to use my background to research trial management, training, conduct and design in developing countries. In Kilifi I reorganised the trial activities into a centralised clinical trial facility that has a primary focus of establishing a cadre of international standard 'trialists'. I now coordinate the Global Health Trials Programme and The Global Health Network.

Employment History

2008 – Current **Head of Clinical Trials, Oxford University Centre for Tropical Medicine and Kemri-Wellcome Programme, Kilifi Kenya.**

- PI, Global Health Clinical Trials Research Programme.
- Co-investigator in Kilifi for the phase III RTSS malaria vaccine trial
- Co-PI for LD- Methotrexate Product Development plan
- Co applicant on FEAST trial in Kenya, Uganda and Tanzania
-

2006 – 2008 **Head of Clinical Trials, Kemri-Wellcome Programme, Kilifi Kenya.**

- University of Oxford post responsible for the scientific direction, management and governance of all clinical trials conducted in the Kilifi KEMRI / Wellcome programme.
- Drive trial design and clinical research strategy to ensure the trials contribute to the ethos and scientific aims of the Unit
- Objective to establish a international regulatory standard dedicated trials facility in order to raise the standard of research and develop cadre of highly skills African clinical trialists
- Source funding for core activities, new projects and increase profile of clinical trials capability in Africa through networking with international donor and research groups, publications and meetings.
- Maintain my own research and academic interests through designing new trials and supervising students

2004 – 2006 **University of Oxford, Project Manager, Malaria and TB vaccines**

- Plan and design and manage clinical trials in UK and Overseas for malaria and TB vaccines
- Write and maintain a product development plan for the vaccines and track against milestones.
- Coordinate GMP vaccine manufacture, delivery and in-house stocks
- Develop and oversee regulatory strategies and activities for both malaria and TB vaccines
- Develop links with key Government department to generate funding leads, support and recognition for groups work in the UK
- Developing and maintaining relationships with pharmaceutical companies and funding agencies
- Contribute to the establishment of public-private partnerships for both malaria and TB vaccines

2002-2004 World Health Organisation, Project Manager, Malaria Phase IV Programme
Programme: *Secondment from GSK*

- Develop and manage phase IV programme for new anti-malarials within WHO TDR (£1.5M Gates Funded)
- Gather external expertise in order to generate optimal protocols and publish output.
- Conclude a system of studies to evaluate safety, effectiveness, IEC and pharmacovigilance in order to establish whether any new antimalarial has true potential for public health benefit.

1998-2004 GSK Tropical Medicines, Clinical Trials Manager, Tropical Medicine

- Lead clinical trial programmes for tropical medicine department within GSK
- Production of clinical sections of regulatory file for MHRA submission
- Represent clinical trial activities on product development teams with development partners

Higher Education

Date	**Institution**	**Qualifications**
1988 - 1991	Kingston University	Bsc (hons) Bioanalytical Science
1998 - 2002	London School of Hygiene And Tropical Medicine	PhD (Public Health)

Advisory Group Memberships, Committee Posts, Collaborations and Fellowships

1. Meetings Secretary – Royal Society for Hygiene and Tropical Medicine. 2006 - 2010
2. Fellow of the Institute of Clinical Research – Awarded by the board in 2006 - current
3. Research Fellow, Green College, Oxford. 2007 - current
4. International Advisory Board Member – Institute of Clinical Research 2007 – current
5. The Oxford Tropical Research Ethics Committee member 2008 – current
6. Strategic Management Committee – Fosphomycin Malaria Partnership
7. Clinical Technical Advisory Group Member – WWARN 2009 – current

Teaching roles & experience

- Supervisor, DPhil (Oxford),
- Supervisor 14 master students
- Taught sessions – Oxford MSc Global Health programme
- Developed and manage 15 e-learning modules with Oxford Centre for Continued Education
- Developing diploma and masters course for Global Health Clinical Trials Research Programme

Selected Publications

1. Lang T, Can Digital Technology and Data Sharing Improve Global Health Research. Science, In Press
2. Lang T, PhaikYeong C, White N, Time for Sensible Guidelines for Clinical Trials. The Lancet, In Press.
3. Lang T, Diverse ethics of translational research in the developing world. Invited commentary. The American Journal of Bioethics, 10: 8, 41 — 42, First published on: 05 August 2010 (iFirst)
4. Lang TA, White NJ, Hien TT, Farrar JJ, Day NPJ, et al. 2010 Clinical Research in Resource-Limited Settings: Enhancing Research Capacity and Working Together to Make Trials Less Complicated. PLoS Negl Trop Dis 4(6): e619. doi:10.1371/journal.pntd.0000619
5. O'Meara WP, Lang T. Malaria vaccine trial endpoints - bridging the gaps between trial design, public health and the next generation of vaccines. Parasite Immunol. 2009(9):574-81

6. Lang TA, Kokwaro GO. Malaria drug and vaccine trials in Africa: obstacles and opportunities. Trans R Soc Trop Med Hyg2008 Jan;102(1):7-10.
7. Lang T, Chilengi R, Noor RA, Ogutu B, Todd JE, Kilama WL, Targett GA. Data safety and monitoring boards for African clinical trials. Trans R Soc Trop Med Hyg2008 Dec;102(12):1189-94.
8. Lang T, Hughes D, Kanyok T, Kengeya-Kayondo J, Marsh V, Haaland A, Pirmohamed M, Winstanley P. Beyond registration--measuring the public-health potential of new treatments for malaria in Africa. Lancet Infect Dis2006 Jan;6(1):46-52.
9. Lang T, Hill AV, McShane H, Shah R, Towse A, Pritchard C, Garau M. New TB vaccine granted orphan drug status. BMJ2005 Dec 17;331(7530):1476.
10. Lang T, Greenwood B. The development of Lapdap, an affordable new treatment for malaria. Lancet Infect Dis2003 Mar;3(3):162-8.

24.5.3 Dr Clare Chandler

Clare I R Chandler

Lecturer in Social Science
Department of Global Health & Development, Faculty of Public Health & Policy
London School of Hygiene & Tropical Medicine

Education

Institution	Degree	Date	Subject
University of Durham	BA 1st	2003	Anthropology
London School of Hygiene & Tropical Medicine	MSc	2005	Epidemiology
London School of Hygiene & Tropical Medicine	PhD	2008	Anthropology and public Health
London School of Hygiene & Tropical Medicine	PGCILT	2010	Introductory Certificate in Learning & Teaching

Work history

2008- **Lecturer.** Core social scientist for ACT Consortium: 25 different projects related to access, targeting, safety and quality of antimalarial drugs in 9 countries.
Role: Working with projects on study and tool design, data analysis, supervising staff and contributing to overall ACT Consortium strategy and communication with policy makers.
Funder: Bill & Melinda Gates Foundation.

2005-2008 **PhD Student.** PhD study of malaria overdiagnosis in district hospitals in northeast Tanzania.
Methods: Ethnography, in-depth interviews, focus group discussion, quantitative observation of clinical encounters, questionnaire survey, psychometric survey
Role: Conception, design, implementation, analysis, interpretation, dissemination
Funder: MRC/ESRC and Sir Halley Stewart Trust

2007-2008 **Consultant: anthropology.** Study of pharmacovigilance of antimalarial drugs in Uganda.
Methods: Focus group discussions, policy analysis
Role: Qualitative analysis and interpretation, dissemination
Funder: Uganda Malaria Surveillance Programme

2006-2007 **Research Assistant: epidemiology.** Randomised controlled trial of anaemia diagnostic tools for primary health facilities in Tanzania.
Methods: 3-armed RCT, rolling cross-sectional study, semi-structured questionnaires
Role: Fieldwork manager (supervision, budgets, running research site, local liaison), evaluation design
Funder: European Commission

2004-2008 **Consultant: anthropology.** Series of studies to design and evaluate interventions to improve quality of care in Tanzanian district hospitals.
Methods: Interviews, focus group discussions, participatory research workshops, questionnaires
Role: Study design, fieldwork and supervision, analysis and interpretation, dissemination
Funder: European Commission

Current research grants

Principal Investigator

2010-11: $41,400 from Bill & Melinda Gates Foundation via ACT Consortium for a qualitative study to understand perceptions of malaria and antimalarials amongst HIV positive individuals enrolled in an antimalarial drug trial in Tanzania. (co-PI: Lasse Vestergaard, University of Copenhagen)

Co-investigator
2011-12: ~$10,000 from Medicines for Malaria Venture for protocol of a qualitative study to investigate user perspectives of malaria medicine for childrens in Nigeria and Ghana. (PI: Ane Haaland, University of Oslo)

2010-11: $111,086 from Clinton Foundation for a mixed method study to investigate the quality and use of RDTs and corresponding use of ACTs and artemisinin monotherapies in the private sector in Cambodia. (PI: Shunmay Yeung, LSHTM)

2008-12: $ 3,916,476 from Bill & Melinda Gates Foundation via ACT Consortium for a cluster randomized trial to compare home-based management of fever/malaria with enhanced health facility based care in Tororo, Uganda (PI: Sarah Staedke, LSHTM)

2010-12: $94,224 from Bill & Melinda Gates Foundation via ACT Consortium for evaluating the process, context and impact of interventions to enhance health facilities and community-based care in Tororo, Uganda (PI: Sarah Staedke, LSHTM)

2008-12: $ 1,658,018 from Bill & Melinda Gates Foundation via ACT Consortium for a cluster randomized trial of health worker and community interventions to improve adherence to national guidelines for the use of ACTs in Tanzania (PI: Hugh Reyburn, LSHTM)

2010-11: $ 215,028 from Bill & Melinda Gates Foundation via ACT Consortium for a mixed method study to investigate strategies for optimizing the accurate elicitation of patient-reported data relating to drug safety, nested in pharmacokinetic trials in South Africa and Tanzania. (PI: Elizabeth Allen, University of Cape Town)

2010-12: $36,850 from Bill & Melinda Gates Foundation via ACT Consortium for a qualitative evaluation of the impact of the introduction of RDTs in drug shops on referrals to the public health system in Uganda. (PI: Anthony Mbonye, Uganda Ministry of Health)

2009-11: Part of $1,664,00 from Bill & Melinda Gates Foundation via ACT Consortium to study the operational effectiveness of four different approaches to malaria diagnosis and treatment in Afghanistan. (PIs: Toby Leslie, Amy Mikhail, Mark Rowland, LSHTM)

2008-11: $30,000 from Bill & Melinda Gates Foundation via ACT Consortium for a qualitative and economic study of the use of RDTs by public health workers in Ghana. (PI: Evelyn Ansah, Ghana Health Service)

2009-12: Part of $775,212 from Bill & Melinda Gates Foundation via ACT Consortium for a mixed-method study to develop and evaluate an adverse event monitoring form for low-literacy workers. (PI: David Lalloo, University of Liverpool)

Teaching

At LSHTM: Module organizer and lecturer for Medical Anthropology module; Seminar leader for Principles of Social Research module; Lecturer for Malaria module, Applying Public Health Principles in Developing Countries module, Diploma in Tropical Medicine & Hygiene course; tutor for Public Health in Developing Countries and Public Health MSc courses. I am also PhD advisor or co-supervisor to 8 PhD students.
External: Research methods training workshops for WHO and LSHTM in 6 African countries.

Additional roles

2011- WHO Roll Back Malaria Case Management Working Group member
2011- LSHTM Centre for Evaluation of Public Health Interventions (CEPHI) committee member
2010- London International Development Centre (LIDC) working groups: Impact Evaluation; Access to Medicines
2010- LSHTM Malaria Centre Head of Social Science
2009- AMFm Operational Research working group, TDR and Global Fund
2008- Biosocial Society committee member
2008- Health Information for All by 2015 (HIFA2015) advisory board

Peer reviewed publications

Chandler, C.I.R., Mangham, L., Njei, A.N., Achonduh, O., Mbacham, W.F., Wiseman, V. **'As a clinician, you are not managing lab results, you are managing the patient': how the enactment of malaria at health facilities in Cameroon compares with new WHO guidelines for the use of malaria tests.** *Social Science & Medicine. In Press.*

Wiseman, V., Mangham, L.J., Cundill, B., Achonduh, O.A., Nji, A.M., Njei, A.N., Chandler, C.I.R., Mbacham, W.F. **A cost-effectiveness analysis of provider interventions to improve health worker practice in providing treatment for uncomplicated malaria in Cameroon: study protocol for a cluster randomized controlled trial.** *Trials. In Press.*

Reynolds, J.L., Kizito, J., Ezumah, N., Mangesho, P., Allen, E., Chandler, C.I.R. **Quality assurance of qualitative research: a review of the discourse.** *Health Research Policy & Systems. In Press.*

Davies, E.C., Chandler, C.I.R., Innocent, S.H., Kalumuna, C., Terlouw, D.J., Lalloo, D.G., Staedke, S.G., Haaland, A. **Designing Adverse Event Forms for Real-World Reporting: Participatory Research in Uganda.** *PLoS One. In Press*

Chandler, C.I.R., Hall-Clifford, R., Turinde, A., Magnussen, P., Clarke, S., Mbonye, A.K. 2011. **Introducing Malaria Rapid Diagnostic Tests at Registered Drug Shops in Uganda: Limitations of Diagnostic Testing in the Reality of Diagnosis**. *Social Science & Medicine,* 72: 937-944.

Mbonye, A.K., Ndyomugyenyi, R., Turinde, A., Magnussen, P., Clarke, S., Chandler, C.I.R. **The feasibility of introducing Rapid Diagnostic Tests for malaria in drug shops in Uganda**. *Malaria Journal,* 9:367

Lester, R., Hamilton, R., Charalambous, S., Dwadwa, T., Chandler, C.I.R., Churchyard, G.J., Grant, A.D. **Barriers to implementation of isoniazid preventive therapy in HIV clinics: a qualitative study in South Africa.** *AIDS supplement, Suppl 5:S45-8.*

Chandler, C.I.R., Whitty, C.J.M., and Ansah, E. (2010) **How can malaria rapid diagnostic tests achieve their potential? A qualitative study of a trial at health facilities in Ghana**. *Malarial Journal*, 9:95

Whitty, C.J.M., Leslie, T., Chandler, C.I.R., Staedke, S.G. (2010) **Management of malaria and other severe infections in rural Africa and Asia.** *Brit Med J,* 17;340:c1527

Chandler, C.I.R., Chonya, S., Mtei, F., Reyburn, H., & Whitty, C.J.M. (2009) **Motivation, money and respect: a mixed-method study of Tanzanian non-physician clinicians**. *Social Science and Medicine,* 68(11):2078-88

Manongi, R., Nasuwa, F., Mwangi, R., Reyburn, H., Poulsen, A., and Chandler, C.I.R. (2009) **Conflicting priorities: evaluation of an intervention to improve nurse-parent relationships on a Tanzanian paediatric ward**. *Human Resources for Health*, 7:50

Al-Taiar, A., Chandler, C.I.R., Al-Eryani, S., & Whitty, C.J.M. (2009) **Malaria knowledge and practices in Yemen: the importance of gender in planning policy.** *Health Policy and Planning,* 24(6):428-37

Chandler, C.I.R., Jones, C.O., Boniface, G., Juma, K., Reyburn, H., & Whitty, C.J. M. (2008) **Guidelines and mindlines: why do clinical staff overdiagnose malaria in Tanzania?** *Malaria Journal*, 7, 53.

Chandler, C.I.R., Chonya, S., Boniface, G., Juma, K., Reyburn, H., & Whitty, C.J.M. (2008) **The importance of context in malaria diagnosis and treatment decisions – a quantitative analysis of observed clinical encounters.** *Tropical Medicine & International Health, 13, 9*.

Chandler, C.I.R., Mwangi, R., Mbakilwa, H., Olomi, R., Whitty, C.J.M., & Reyburn, H. (2008) **Malaria overdiagnosis: is patient pressure the problem?** *Health Policy and Planning*, 23, 3, 170-8.

Mwangi, R., Chandler, C.I.R., Nasuwa, F., Mbakilwa, H., Poulsen, A., Bygbjerg, I.C. and Reyburn, H. (2008), **Experience of paediatric care among staff and caretakers in 13 public hospitals in northern Tanzania.** *Transactions of the Royal Society of Tropical Medicine & Hygiene, 102, 805—810*

Chandler, C.I.R., Nadjm, B., Boniface, G., Juma, K., Reyburn, H., & Whitty, C.J.M. (2008) **Assessment of children for ARI in hospital outpatients in Tanzania – what drives good practice?** *Am J Trop Med Hyg*. 79(6):925-32

Bukirwa, H., Nayiga, S., Lubanga, R., Mwebaza, N., Chandler, C.I.R., Hopkins, H., Talisuna, A., Staedke, S.G. (2008) **Pharmacovigilance of antimalarial treatment in Uganda: community perceptions and suggestions for reporting adverse events.** *Tropical Medicine & International Health, 13, 9*.

Whitty, C.J.M., Chandler, C.I.R., Ansah, E., Leslie, T., Staedke, S.G. (2008) **Deployment of ACT antimalarials for treatment of malaria: challenges and opportunities.** *Malaria Journal, 7(Suppl 1): S7*

Chandler, C.I.R., Drakeley, C.J., Reyburn, H., & Carneiro, I. (2006) **The effect of altitude on parasite density case definitions for malaria in northeastern Tanzania.** *Trop Med Int Health*, 11(8), 1178-1184.

24.5.4 Dr Julius Atashili

October, 2011

Curriculum vitae

Identification

Name: Julius ATASHILI

Nationality: Cameroonian

Profession: Physician/epidemiologist

Address: Fac Health Sciences,

University of Buea,

PO Box 63, Molyko Buea

Phone: (237) 97 33 03 37

Email: atashili@yahoo.ie

Speciality: Public Health

Sub-speciality: Epidemiology

Education

Institution and location	Degree	Year(s)	Field of study
University of North Carolina – Chapel Hill, USA	PhD	May 2009	Epidemiology (minor in Biostatistics)

University of North Carolina – Chapel Hill, USA	MPH	May 2005	Epidemiology
Faculty of Medicine and Biomedical Sciences, University of Yaounde I, Yaounde, Cameroon	MD (Upper class Honors)	April 2002	Medicine (General)

Current position

- Assistant Lecturer, Faculty of health Sciences, University of Buea (July 2008-)

Previous Positions and Employment

- WHO/TDR R&D Career Development Fellow, Malaria Development Team, Pfizer USA (June 2010 –Jul 2011).
- Epidemiologist, Center for the Study and Control of Communicable Diseases (CSCCD), Faculty of Medicine and Biomedical Sciences, University of Yaounde I, Cameroon. (May 2005-)
- Fogarty AITRP (AIDS International Training and Research Program) fellow, University of North Carolina, Chapel Hill, USA (UNC). (Aug 2003- May 2009)
- Graduate Research assistant UNC- GSK Worldwide epidemiology (Apr 2007 – May 2009)
- Consultant International epidemiologic Databases for the Evaluation of AIDS (IeDEA) region 9-Central Africa (2006-2007)
- Graduate Research assistant UNC- Carolina Mammography Registry (Dec 2005 – June 2006)
- Graduate Teaching assistant UNC 2004, 2005 & 2006
- Intern World Health Organization, Geneva. June - July 2005.
- Research officer, Center for the Study and Control of Communicable Diseases (CSCCD), Faculty of Medicine and Biomedical Sciences, University of Yaounde I, Cameroon (August 2003-May 2005).
- Research assistant at the Center for the Study and Control of Communicable Diseases, University of Yaounde I, Cameroon. 2000 - August 2003.
- Interim Chief medical officer at the Quality Health Unit (QHU) of the Shemka Foundation, a health oriented non-governmental organization in Cameroon. February – July 2003.
- GP at the University Teaching Hospital Yaounde, Cameroon. July 2002 - July 2003.
- Interim chief medical officer of the “Fondation medicale ROS” private clinic, Yaounde Cameroon. March-July 2002.

Honors and Awards:

- 2010: WHO/TDR R&D Career Development Fellowship.
- 2009: European and Developing Countries Clinical Trials Partnership (EDCTP) forum 2009 Travel award

- May 2009: Delta Omega Public health honorary society (USA)
- Aug. 2003 -2007: Fogarty AITRP fellowship.
- 2007, 2008: Profiled in *Marquis© Who is Who in America*
- 2007: International Society for Sexually Transmitted Diseases Research (ISSTDR) travel grant
- 2007: UNC Center for AIDS Research (CFAR) Developmental Award (USD 20,000)
- 2007: Young Investigator Award, Conference on Retroviruses and Opportunistic Infections (CROI) 2007
- 2007: Honorable Mention to the SAS® Global Ambassador Program
- 2005: International Internship Award (UNC University Center for International Studies)
- 2005, 2006: Nominated to the US national Chancellor's List.
- 2003: International Society for Infectious Diseases (ISID) HIV training award
- 2002: Best student of the 2002 batch of graduates of the Faculty of Medicine and Biomedical Sciences, University of Yaounde I.
- 1998, 2001: Cameroon Government excellence award to university students.
- 2000: North-West students' merit award.

Memberships:

- Cameroon National Medical Council.
- World Health Organization's Maximizing Positive Synergies Collaborative Group Academic consortium
- Research-on-Research (ROR) group (Duke University, USA)
- Shemka Foundation, Cameroon
- International Society for Infectious Disease (ISID) -past
- American Society for Microbiology (ASM) -past

Volunteer/service

- Member of the Editorial board of the journals: *Epidemiology Innovations and Perspectives*, and *Pan African Medical Journal.*
- Peer reviewer for the journals *Sexually Transmitted Infections, and Antiviral Therapy, PLoS ONE, Epidemiology The Lancet,* amongst others
- Member of the UNC Graduate and Professional Students Honor Court (2005-2009).
- Team Epi-aid, an organization of students who volunteer in disease outbreak investigation - (2004-2009)
- Tutor epidemiology methods (Jan 2004 - May 2006).
- MPH students' representative at the Graduate Studies Committee, Epidemiology department, UNC (Aug 2004-Aug 2005).

Research experience

- Consultant Research clinician in 3 clinical trials (2010-2011):

- Phase III open randomized clinical trial of azithromycin and chloroquine combination versus sulfadoxine pyrimethamine for the intermittent preventive treatment of malaria in pregnant women in sub-Saharan Africa;
- a pharmacokinetic study of AZCQ in pregnant women with asymptomatic P falciparum malaria in sub-Saharan Africa;
- a Phase II/III study of the efficacy and safety of AZCQ compared to artemether-lumefantrine in children in sub-Saharan Africa.

- Co-Investigator: Adaptation of a treatment for depression in HIV-positive patients in Cameroon. (design 2007-2008) Implementation 2009- (US NIH funded R21 project)
- Epidemiologist: Baseline Studies of Mother-to-Child transmission in the Buea, Limbe and Tiko Health Disticts, Cameroon. Implementation 2009- (European and Developing Countries Clinical trial partnership EDCTP-funded study)
- Principal investigator: prevalence, severity and predictors of cervical precancerous lesions in HIV-positive women on anti-retroviral therapy: 2008-2009
- Principal investigator: assessing the potential impact of antiretroviral therapy on mortality from cervical cancer in HIV-positive women.
- Research assistant: Assessment of the impact of global health initiatives on the health system in Cameroon, Central African Republic and the Republic of Congo
- Co-Investigator: Epidemiology methods: binomial regression modeling and assessment of confounding, 2005-2008
- Co-Investigator: Potential impact of feeding recommendations in HIV-infected infants, 2005-2008
- Co-Investigator: Global prevalence of Chlamydia trachomatis, 2005-7
- Research assistant, Carolina Mammography Registry, 2006.
- Co-investigator, Meta-analysis: bacterial vaginosis and HIV infection, 2005-06.
- Principal investigator, Trends in HIV prevalence in Cameroon, 2005.
- Research assistant, Analysis of trichomoniasis infections in male partners of infected women 2004.
- Research assistant, African Burial Ground Project in Cameroon, 2002.
- Principal investigator, *Chlamydia trachomatis* and *Neisseria gonorrhoeae* urogenital infections in a group of rural antenatal clinic attenders in Cameroon. – Detection using PCR amplification on urine samples (M.D Thesis), 2002.
- Research assistant, Acute diarrhea in infants in Yaounde (Centre Pasteur Cameroon), 2001.
- Research assistant, Genital herpes in a group of pregnant women in Yaounde (Center for the Study and Control of Communicable Diseases, Yaounde), 2000.
- Research assistant, HIV, Hepatitis B, Hepatitis C infections in Douala, 2000.
- Research assistant, Non-communicable diseases in Yaounde (ANSA project), 1999

Teaching experience

Lectures

- Course master for MPH603 (Principles of Health statistics), graduate level course, University of Buea 2009/2010
- Co-lecturer for graduate level courses, University of Buea (2009/2010): MPH601 (Principles of epidemiology), MPH603 (Principles of Health statistics), MPH 605 (Environmental and Occupational Epidemiology), MPH607 (Communicable and Non-communicable disease epidemiology), MPH 609 (Vaccine preventable diseases).
- Co-lecturer for undergraduate level courses, University of Buea (2009/2010): MED311 (Health Statistics, demographics and ecology), HSC 209 (Health statistics), MLS301 (Laboratory management), MLS410 (Research methods and biostatistics),
- Academic Visitor (Distance course mentor): Certificate course in outcomes research at the Duke University (USA) –NUS Graduate Medical School of Singapore, March 2009 – Oct 2009
- Co-Lecturer for HSC 209: Health Statistics for medical professionals. University of Buea. Semester 1, 2008/2009.
- Teaching assistant for Bios 541: Biostatistics for Health Care professionals, UNC Chapel Hill (USA). August 2006- Dec 2006.
- Teaching assistant EPID 269 (Epidemiologic analysis of binary data), an advanced level epidemiology methods course, UNC Chapel Hill (USA). August 2005- Dec 2005.
- Teaching assistant, Human anatomy and physiology Lab (Biol 45) at UNC-Chapel Hill. May 2004 - May 2005.
- International course on HIV/STIs management for Laboratory Technicians, Yaounde Cameroon: gave lectures and assisted participants on the use of the computer and the Internet for STI research. 2002 – 2003.

Invited academic presentations

- Managing and evaluating research outcomes and outputs. University of Buea Seminar on research methods for final year nursing and medical laboratory sciences students 2009
- Binomial regression. UNC EPID 718 (Epidemiologic analysis of binary data), Oct 2006.
- A SAS macro for model selection. UNC EPID 718 (Epidemiologic analysis of binary data), Sep 2006.
- Bacterial vaginosis. UNC course EPID 140 (Epidemiology of Sexually Transmitted Infections). April 2006.
- Bacterial vaginosis as a risk factor for HIV. UNC ID monthly conference, Oct 2005.
- Is HIV prevalence decreasing in Cameroon? UNC ID Friday morning Conference, April 2005.

Student thesis co-direction

- Impact of malaria co-infection on haematological parameters of HIV-positive patients in Douala, Cameroon (by Gervais Gouana). MSc Microbiology and parasitology thesis, FHS Buea (2010)
- Correlation between CRP levels and lipid profile in diabetic patients in Buea, Cameroon (by Eta Robert). MSc Chemical pathology thesis, FHS Buea (2010)
- Sexual Behaviour and Cervical Precancerous Lesions in a Group of HIV Positive Women in Cameroon (by Meankah Njabanou Noella). MD thesis FMBS Yaounde (2009)
- Parity and precancerous cervical epithelial lesions in HIV positive women initiating HAART in Douala, Limbe and Bamenda (by Wandji Brigitte). MD thesis FMBS Yaounde (2009)

Advisor in student research (sample)

- Impact of HAART on glycemia and transaminase levels in HIV-positive patients in Limbe, Cameroon (by Francisca Ottop Manyi). MSc thesis, FHS, Buea (2010)
- Nurses and challenges faced in the field as clinical educators: a survey of a group of nurses in Cameroon (by Vivian Ayamba Eta) Masters in Nursing Education Thesis, FHS, Buea (2009).
- Exposure to cigarette smoke as a risk factor for precancerous cervical lesions in HIV-infected women in Cameroon (by Egbearong Ashu Mbeng). MD thesis FMBS Yaounde (2009)
- Nevirapine resistance in women in PMTCT care in Cameroon (by Boghuma Titanji). MD thesis, FMBS Yaounde (2008)
- Plasma concentration of soluble Fas(sFas) CD95receptor and sFasL(CD95L) ligands in relation to CD4-T cell depletion and increased HIV viral load in HIV Positive Patients in Yaounde Cameroon. (by George Mondinde Ikomey). MSc in Immunology thesis, FMBS Yaounde (2008)
- Nasal carriage of *Staphylococcus aureus* amongst hospital personnel in Yaounde. (by Agnes Bedie Eyoh). MSc in Microbiology thesis, FMBS Yaounde (2008).
- Quinolone and fluoroquinolone resistance in Enterobacteriaceae isolated from hospitalised and community patients in Cameroon. (by Emilia Lyongha). MSc in Microbiology thesis, FMBS Yaounde (2008).
- Immunoglobulin A (IgA) levels in healthy blood donors in Yaounde: Implications in blood transfusion. (by Emmanuel Akongnui) MSc in Immunology thesis, FMBS Yaounde (2008).
- A comparison of antigen p24 assay and a PCR based HIV-RNA assay to measure HIV type 1 viral load in Cameroon (by Valentine Aguh); MD thesis, FMBS Yaounde (2007)
- Prevalence of glucose abnormalities in HCV infection in Cameroon (by Elvis Temfack). MD thesis, FMBS Yaounde (2007)
- HIV infection and the prevention of mother-to-child transmission of HIV in the Buea health district (by Joffi Ella Musonge). MD thesis FMBS Yaounde (2006)

Other experiences

- Computing and statistics: can use SAS, STATA, SPSS, SUDAAN, Excel, Epi Info, Nvivo (qualitative research and analysis), TreeAge (for decision analysis).
- Other Important courses completed:

  "Workshop on Ethical conduct of research studies for investigators" organized by the Cameroon National Ethics Committee. Yaounde, September 2011

  "Good Clinical Laboratory Practices" organized by WHO and the University of Buea, January 2010.

  "Principles of STD/HIV and research course" organized by the University of Washington, Seattle, July 2004.

  'HIV training course for physicians in developing countries' organized by the International Society for Infectious Disease and the NIH, in Bethesda MD, April 2003.

Languages: **English and French: spoken and written fluently**

Hobbies: **Tennis, electronic games, soccer.**

Peer-reviewed Publications

**: indicates articles indexed in PUBMED/MEDLINE*

1. **Atashili J**, Adimora AA, Ndumbe PM, Ikomey GM, Myers M, Eron J, Smith JS, Miller WC. High prevalence of cervical squamous intraepithelial lesions in women on antiretroviral therapy in Cameroon: is targeted screening feasible? Accepted and In press with *Cancer Epidemiology.*

2. Njabanou NM, **Atashili J**, Mbanya D, Mbu ER, Ikomey GM, Kefie CA, Kinge TN, Etogo D, Adimora AA, Ndumbe PM. Sexual Behavior of HIV-Positive Women in Cameroon. *J Int Assoc Physicians AIDS Care (Chic).* 2011. [Epub ahead of print] PubMed PMID: 21951727.*

3. Vannappagari V, Nkhoma ET, **Atashili J**, Laurent SS, Zhao H. Prevalence, severity, and duration of thrombocytopenia among HIV patients in the era of highly active antiretroviral therapy. *Platelets*. 2011 May 25. *

4. **Atashili J**, Smith JS, Adimora A A, Eron J, Miller CW, Myers ER. Potential impact of antiretroviral therapy and screening on cervical cancer mortality in HIV-positive women in sub-Saharan Africa: a simulation. *PLoS ONE*. 2011 4;6(4):e18527 *

5. Ndumbe PM, Efuetnkeng B, Ikomey GM, **Atashili J**. Comparison of an Automated and a Manual Method of Viral Load Determination in HIV-Infected Persons in Yaounde, Cameroon. *J Int Assoc Physicians AIDS Care (Chic)*. 2011 Apr 1.*

6. Eta VEA, Atanga MBS, **Atashili J**, D'Cruz G. Nurses and challenges faced as clinical educators: a survey of a group of nurses in Cameroon. *Pan African Medical Journal* 8, 28, 20-Mar-2011.

7. Fokunang CN, Chia J, Ndumbe P, Mbu P, **Atashili J**. Clinical studies on seroprevalence of rubella virus in pregnant women of Cameroon regions. *African Journal of Clinical and Experimental Microbiology* 2010; 11(2): http://ajol.info/index.php/ajcem/article/view/53913

8. Toukam M, Lyonga E.E, Assoumou M.C.O, Fokunang C.N, **Atashili J**, Kechia A.F, Gonsu H.K, Mesembe M, Eyoh A, Ikomey G, Akongnwi E, Ndumbe P. Quinolone and fluoroquinolone resistance in Enterobacteriaceae isolated from hospitalised and community patients in Cameroon. *J. Med. Med. Sci.* 2010 1(10): 490-494

9. Nelson AE, Braga L, Renner JB, **Atashili J**, Woodard J, Hochberg MC, Helmick CG, Jordan JM. Characterization of individual radiographic features of hip osteoarthritis in African American and White women and men: the Johnston County Osteoarthritis Project. *Arthritis care & research* 2010;62(2):190-7.*

10. Pettifor A, Delany S, Kleinschmidt I, Miller WC, **Atashili J**, Rees H. Use of injectable progestin contraception and risk of STI among South African women. *Contraception* 2009;80(6):555-60.*

11. Nelson AE, Braga L, Braga-Baiak A, **Atashili J**, Schwartz TA, Renner JB, Helmick CG, Jordan JM. Static knee alignment measurements among Caucasians and African Americans: the Johnston County Osteoarthritis Project. *J Rheumatol.* 2009;36(9):1987-90. *

12. **World Health Organization Maximizing Positive Synergies Collaborative Group**,Samb B, Evans T, Dybul M, Atun R, Moatti JP, Nishtar S, Wright A, Celletti F, Hsu J, Kim JY, Brugha R, Russell A,

Etienne C. An assessment of interactions between global health initiatives and country health systems. *Lancet.* 2009; 373(9681):2137-69.*

13. Ikomey GM, **Atashili J**, Okomo-Assoumou MC, Mesembe M, Ndumbe PM. Dried blood spots versus plasma for the quantification of HIV-1 RNA using the manual (PCR –ELISA) Amplicor Monitor HIV-1 version 1.5 assay in Yaounde, Cameroon. *JIAPAC* 2009;8(3):181-4*

14. **Atashili J**, Ndumbe P, Poole C, Adimora AA, Smith JS. Bacterial Vaginosis as a risk factor for HIV infection: A meta-analysis of published studies. *AIDS, 2008;22(12):1493-501.**

15. **Atashili J**, Kalilani L, Seksaria V, Sickbert-Bennet E. Potential impact of infant feeding recommendations on mortality and HIV-infection in children born to HIV-infected mothers in Africa: a simulation. *BMC Infectious diseases,* 2008; 8: 66.*

16. de Bosset V, **Atashili J**, Miller W, Pignone M. Health insurance-related disparities in colorectal cancer screening in Virginia. *Cancer Epidemiol Biomarkers Prev.* 2008; 17(4):834-7.*

17. **Atashili J**, Ta ML. A SAS® Macro for Automating the 'Change-in-Estimate' Strategy for Assessing Confounding. Proceedings of the SAS® Global Forum 2007 Conference. SAS Institute Inc. Cary, NC, 2007. http://www2.sas.com/proceedings/forum2007/032-2007.pdf

18. Sena AC, Miller WC, Hobbs MM, Schwebke JR, Leone PA, Swygard H, **Atashili J**, Cohen MS. Trichomonas vaginalis infection in male sexual partners: implications for diagnosis, treatment, and prevention. *Clin Infect Dis.* 2007; 44(1):13-22. *

19. Hobbs MM, Lapple DM, Lawing LF, Schwebke JR, Cohen MS, Swygard H, **Atashili J**, Leone PA, Miller WC, Sena AC. Methods for detection of Trichomonas vaginalis in the male partners of infected women: implications for control of trichomoniasis. *J Clin Microbiol*. 2006; 44(11):3994-9. *

20. **Atashili J**, Kalilani L, Adimora AA. Efficacy and clinical effectiveness of influenza vaccines in HIV-infected individuals: a meta-analysis. *BMC Infect Dis*. 2006; 6:138. *

21. **Atashili J**. Adult male circumcision to prevent HIV? *Int J Infectious Dis,* 2006; 10: 202-5*

22. Kalilani L and **Atashili J**. Measuring additive interaction using the odds ratio. *Epidemiology Innovations and Perspectives, 2006;* 3(1): 5*

Oral Presentations

Conference

1. **Atashili J**, Smith JS, Adimora AA, Eron J, Miller WC, Myers E. Potential impact of antiretroviral therapy and screening on cervical cancer mortality in HIV-positive women in Cameroon. Cameroon National Medical Conference, Dec 2009, Yaounde, Cameroon.

2. **Atashili J**, Adimora AA, Ndumbe PM, Ikomey GM, Myers M, Eron J, Smith JS, Miller WC. High prevalence of cervical squamous intraepithelial lesions in women on antiretroviral therapy in Cameroon: is targeted screening feasible? Fifth EDCTP (European and Developing Countries Clinical Trials Partnership) Forum, October 2009, Arusha, Tanzania

3. **Atashili J,** Ndumbe PM. Any impact of Global health initiatives on primary level health care facilities? Case of the Kumba and Limbe Health districts in Cameroon. WHO meeting on Maximizing Positive Synergies, Geneva, March 2009.

4. **Atashili J,** Schmid G, Smith JS**.** Prevalence of *Chlamydia trachomatis* urogenital infection: a global review. ISSTDR/IUSTI conference. Seattle, 2007. Abstract O-011.

5. **Atashili J,** Ta ML. A SAS® Macro for Automating the 'Change-in-Estimate' Strategy for Assessing Confounding. SAS Global Forum 2007 April 16-19, 2007, Orlando, Florida.

6. **Atashili J**, Smith JS, Adimora AA. Quantifying the correlation between gender inequality and HIV prevalence. Oral presentation at the International Conference on Women and Infectious Diseases, Atlanta, March 16 – 18, 2006.

7. **Atashili J**, Ndumbe P, Poole C, Adimora AA, Smith JS. Is bacterial Vaginosis a risk factor for HIV infection? A meta-analysis of published studies. Oral presentation at the ISSTDR conference. Amsterdam, 2005. Abstract TO-106.

Poster Presentations

1. Vannappagari V, **Atashili J**, Nkhoma E, St. Laurent S , Zhao H.Prevalence of thrombocytopenia in HIV-infected patients. International Association of Physicians in HIV Care (IAPAC) conference Nov 31-Dec 1, 2009, New Orleans, USA.

2. Titanji B, Ndumbe PM, **Atashili J**, Yang C, Diallo K, Shanmugam V, McNulty A, Nkengasong J. Patterns of antiretroviral resistance following PMTCT of HIV in a group of Cameroonian women. Fifth EDCTP (European and Developing Countries Clinical Trials Partnership) Forum, October 2009, Arusha, Tanzania.

3. **Atashili J,** Miller CW, Swygard H, Leone PA, Sena AC**.** Male circumcision and other male partner (non)correlates of bacterial vaginosis in a group of STD clinic attendees in the United States. ISSTDR/IUSTI conference. Seattle, 2007. Abstract P-646.

4. Menezes P, **Atashili J**, Napravnik S, Wohl D, Eron JJ. Effect of baseline body mass index (BMI) on virologic response (VR) to initial highly active antiretroviral therapy (HAART) among treatment naïve HIV positive persons in the Southeast United States, US. IAS conference Sydney, Australia. Abstract WEPEB087.

5. **Atashili J**, Kalilani L, Seksaria V, Sickbert-Bennet E. Shorter duration of breastfeeding in infants of HIV-infected women in Africa may substantially reduce infant HIV infection but not mortality: A Simulation Study. CROI 2007, February 25-28, Los Angeles, Abstract number 771.

6. Callens S, Lusiama J, Okitolanda W, Kitetele F, Edidi S, **Atashili J**, Colebunders R, Van Rie A, Behets F. The CDC CD4 classification underestimates the proportion of children in need of antiretroviral treatment in sub-Saharan Africa. CROI 2006, February 5 – 9 2006, Denver. Abstract Number R-170

24.5.5 Professor Sisira Hemananda Siribaddana

Personal Details

Name	Sisira Hemananda Siribaddana
Address	259, Temple Road, Thalapathpitiya, Nugegoda, 10250 Sri Lanka
IRD address	393/3, Lilly Avenue, off Roabert Gunawardane Mawatha, Battaramulla
Anuradhapura address	Professorial Medical Unit, Teaching Hospital Anuradhapura
Telephone	+94 112 779 354 (H), +94 777 326 940 (M), +94 115 662 895 (O)
Email Address	nipuna@stmail.lk (preferred method of communication)
Fax	00 94 11 2863084
Date of Birth	20th May 1961, Sri Lanka
Nationality	Sri Lankan

Current Employment

- Foundation Professor of Medicine & Chair, Department of Medicine Faculty of Medicine & Allied Sciences Rajarata University since 2011
- Consultant physician and endocrinologist Nawaloka Hospitals Colombo since 1998
- Senior academic Sri Lankan Twin Registry, Institute of Research & Development since 2003
- Honorary lecturer Kings College, University of London since 2006

Previous Posts

1. House Officer Paediatrics/ Surgery-Base hospital Negombo. 1986-1987
2. Senior house officer Medicine and Obstetrics & gynaecology-Base hospital, Negombo 1988 -9
3. Senior house officer, Medical intensive care unit-Sri Jayewardenepura Postgraduate Teaching Hospital. 1990-91
4. Registrar, Medicine-Sri Jayewardenepura Postgraduate Teaching Hospital, 1992-94
5. Registrar- Medical Rotation 1994-95-Institute of Neurology, Institute of Cardiology. Rheumatology, Psychiatry, Respiratory Medicine & Dermatology National Hospital of Sri Lanka (NHSL)
6. Senior Registrar-Endocrinology NHSL, Professorial Unit of Clinical Medicine, University of Colombo, -Responsible for undergraduate and post-graduate teaching of internal Medicine, 1995-6
7. Clinical Research Fellow in Endocrinology -Department of Diabetes and Endocrinology, Princess Alexandra Hospital, Brisbane 1997
8. Honorary Research Advisor, Department of Medicine -University of Queensland, Brisbane, 1998
9. Tutor, Examiner in Medicine, the Department of Medicine-University of Queensland, Brisbane, 1997-1998

10. Honorary Director National Twin Registry 1998-2003
11. Staff Specialist in Medicine Sri Jayewardenepura Postgraduate Teaching Hospital and examiner Sri Jayewardenepura University 1998 2003
12. Part of the 4 member team that manned the psychosocial desk voluntarily at the Centre for National Operations (CNO) set up by the President of Sri Lanka after the 26th December Tsunami (2005 Jan-Feb)
13. Visiting Senior Lecturer Post Graduate Institute of Science, University of Peradeniya.(M.Sc. in Disaster Management) Academic year 2005/6
14. Honorary Coordinator Bioethics initiative, Institute for Research and Development (2003-2010)
15. Visiting Senior Lecturer in Medicine Department of Medicine, Faculty of Medicine & Allied Sciences; Rajarata University2010 -2011
16. Visiting Senior Lecturer in Bioethics in Biotechnology, Kelaniya University since 2007-2011

Academic Qualifications

- MBBS (Colombo) 1986
- MD Internal Medicine (Colombo) 1995
- Member of the Ceylon College of Physicians 1995
- Specialist in General Medicine 1997
- Fellowship of the Ceylon College of Physicians (FCCP) 2009

Registration as a Medical Practitioner

Full registration with the Ceylon Medical Council as General Physician (Reg. No 9134)

Registered with the Medical board of the Queensland, Australia in 1997 Jan to 1998 June (Reg. no 963279)

Publications - Books

1. Nutritional Guidelines for the Management of Osteoporosis 2002 (With Devaka Fernando) Published by OSSL, ISBN 955-8706-00-0
2. Research Ethics from a Developing World Perspective 2003 (With Athula Sumathipala) Published by Vijitha Yapa, ISBN 955-8095--27-3
3. Guidelines on management of Diabetes in Sri Lanka 2000 (Participated in the consensus development panel) Published by SLMA, ISBN 955-9386-05-0
4. Guidelines for management of Osteoporosis 2002 (Participated in the consensus development panel) Published by OSSL, ISBN 955-8706-01-9
5. Management of Medically Unexplained Symptoms 2006 (with Athula Sumathipala, Sonia Mangwana and Padmal de Silva) Sponsored by WHO & Published by IRD ISBN 955-8973-01-7

6. Chapter on 'Culture Bound Syndromes' in the book on Cultural Psychiatry 2007(Editor Dinesh Bhugra, Kamaldeep Bhui) with Athula Sumathipala and Dinesh Bhugra (published by the Cambridge University Press ISBN-13: 9780521856539)

7. Research capacity for mental health in Low- and Middle-income countries: results of a mapping project. Published by Global Forum for Health Research & WHO 2007 ISBN 2-940286-54—x. Member of the South Asian team

8. Psychosis, severe depression, medically unexplained symptoms, epilepsy and heavy alcohol use 2009 (with Athula Sumathipala, Sudath Samaraweera, Gominda Ponnamperuma & Chesmal Siriwardane) Sponsored by WHO & Published by IRD ISBN 978-955-8973-02-8

9. Advisor to the book on "paryeshana lokayata pivisemu by Dr Godwin Kodituwakku (2010) IRD, Colombo. ISBN 978-955-8973-03-5

Major Publications

Original Articles (average citations per article 2.86, citations are without self citations as in science citation index except Biomed Central Journals)

1. Fernando DJS, Siribaddana SH, Perera N, Perera S, De Silva DR. The prevalence of macrovascular disease and lipid abnormalities amongst diabetic patients in Sri Lanka. **Postgraduate Medical Journal** 1993; 69:557-561. citations-9

2. Fernando DJS, Siribaddana SH, De Silva DR, Subasinghe Z. Prevalence of retinopathy in a Sri Lankan diabetes clinic. **Ceylon Medical Journal** 1993; 38:123-126. citations-6

3. Siribaddana SH, Perera N, Perera S, Fernando D, Weerasinghe N. Prevalence of lipid abnormalities in Sri Lankan patients with non-Insulin dependent diabetes mellitus. **Ceylon Medical Journal** 1994; 39:22-24. citations-1

4. Siribaddana SH, Fernando DJS. The dilemma of Cushing's sans tumor (research letter) **Ceylon Medical Journal** 1994; 39:110.

5. Fernando DJS, Siribaddana SH, De Silva DR. Impaired glucose tolerance and diabetes mellitus in a suburban Sri Lankan community. **Post Graduate Medical Journal** 1994; 70:342-349. citations-8

6. Wijesundera Anula, Siribaddana SH. Tuberculous pericarditis (research letter). **British Medical Journal** 1994; 308:535. IF 7.038. citations-1

7. Siribaddana SH, Herath CA, Wickremaratna DJ. Emphysematous pyelonephritis. **Post Graduate Medical Journal** 1994; 70:736-737.citations-1

8. Fernando DJS, Siribaddana SH, De Silva DR, Perera SD. The prevalence of obesity and other coronary risk factors in a suburban Sri Lankan community. **Asia Pacific Journal of Clinical Nutrition** 1994; 3:155-159.

9. Wijesundera A, Siribaddana SH. Kikuchis disease; an important cause of lymphadenopathy in young females (research letter). **Ceylon Medical Journal** 1995; 40:46.

10. Siribaddana SH, Wijesundera A. Autoimmune hemolytic anemia responding to anti-TB treatment. **Tropical Doctor** 1997; 27: 243-244.IF 0.404. citations-5

11. Siribaddana SH, Wijesundera A, Fernando R. Toluene diisocyanate exposure in a glove manufacturing plant. **Journal of Toxicology-Clinical Toxicology** 1998; 36:95-98 IF 1.739

12. Dissanayake A, Hewage UCL, Siribaddana SH, Fernando DJS. An audit of the (ab) use of thyroid function tests. **Ceylon Medical Journal** 1998; 43:52-53

13. Weerasuriya N, Siribaddana SH, Wijeweera I, Dissanayake A, Wijesekare J, Fernando DJS. The prevalence of peripheral neuropathy in newly diagnosed patients with NIDDM. **Ceylon Medical Journal** 1998; 43:19-21

14. Siribaddana SH, Deshabandu R, Rajapaksa A, De Silva K, Fernando DJS. The prevalence of gestational diabetes in a Sri Lankan antenatal clinic. **Ceylon Medical Journal** 1998; 43:88-91

15. Weerasuriya N, Siribaddana SH, Dissanayake A, Subasinghe Z, Wariyapola D, Fernando DJS. Long-term complications in newly diagnosed Sri Lankan patients with type 2 diabetes mellitus**. Quarterly Journal of Medicine** 1998; 91:439-443 citations-16

16. Sumathipala A., Fernando DSJ, Siribaddana SH, Abeysinghe MRN, De Silva N, Dissanayake V, Jayasekare RW. Establishment of a National Twin Register in Sri Lanka. **Twin Research** 2000; 3: 202-202. IF 1.713 citations-2

17. Sumathipala A, De Silva N, Siribaddana SH, Fernando DSJ, Abeysinghe MRN, Cross cultural adaptation and preliminary validation of a zygosity determination questionnaire for Sri Lanka. **Twin Research** 2000; 3: 205-212. IF 1.713

18. Sumathipala A, Siribaddana SH, Fernando DSJ, Abeysinghe MRN, De Silva N, Sivayogam S. Feasibility of using different approaches for recruiting younger twins for Sri Lankan Twin Registry **Twin Research** 2001; 4:459-463 IF 1.713 Funded by Wellcome Trust UK

19. Sumathipala A, Siribaddana SH, De Silva N, Fernando DSJ, Abeysinghe MRN, Dayaratne R, De Silva D, Warnasuriya N, Hotopf M. Sri Lankan Twin Registry. **Twin Research** 2002; 5: 424-426 IF 1.713 Funded by Wellcome Trust UK citations-2

20. Malavige GN, De Alwis NM, Weerasuriya N, Fernando DJS, Siribaddana SH, Increasing diabetes and vascular risk factors in a sub-urban Sri Lankan population [Short report). **Diabetes Research and Clinical Practice**. 2002; 57(2): 143-5. Funded by NSF Sri Lanka. Selected for presidential award for research. Citations-3

21. Sumathipala A, Siribaddana SH. Psychological distress among university students. **Ceylon Medical Journal** 2002; 47:74-75

22. Sumathipala A, Siribaddana SH, De Silva N. Qualitative Research **Ceylon Medical Journal**2003; 48:136-139

23. Sumathipala A, Siribaddana SH, Fernando DSJ, Abeysinghe MRN, De Silva N, Hotopf M. Challenges in recruiting older twins for the Sri Lankan Twin Registry **Twin Research** 2003; 6:67-71 IF 1.713 Funded by Wellcome Trust UK citations-3

24. Sumathipala A, Siribaddana SH, Samaraweera S. Dayaratne DARK, Capacity building through multi-disciplinary research: a report from Sri Lanka. **British Journal of Psychiatry** 2003; 183; 457-458 IF 4.175

25. Sumathipala A, Siribaddana SH, Bhugra D. Dhat Syndrome - neither culture bound nor culture specific. **British Journal of Psychiatry** 2004 184: 200-209 IF 4.175 citations-26

26. Sumathipala A, Siribaddana SH, Samaraweera S. Do patients' volunteer their life weariness and suicidal ideations? A Sri Lankan Study. **Crisis** 2004; 25, 103-107.

27. Sumathipala A, Siribaddana SH, Revisiting 'freely given informed consent' in relation to the developing world. Role of an ombudsman. A qualitative study. **The American Journal of Bioethics** 2004; 4(3): W1-W7 IF 3.367 citations-3

28. Sunita Dodani, Chandrakant Pandav, Siribaddana SH, Ronald E La Porte, Paras Pokharel. Hope of prevention training in South Asia (research letter) **British Medical Journal** 2004; 329:293-4.IF 7.038 citations-2

29. Siribaddana SH, Lekamwasam S. Osteoporosis in Sri Lanka **Clinical Calcium** 2004; 14:128-133.

30. Sumathipala A, Siribaddana SH, Patel V. Under-representation of developing countries in the research literature: ethical issues arising from a survey of five leading medical journals. **BMC Medical Ethics** 2004, 5:5 citations-5

31. Siribaddana SH. Sumathipala A. Essential Drugs, Senaka Bibile and Sri Lanka; Rejoinder to a Eurocentric debate led by WHO on TRIPS agreement. **Innovation Matters** February7 2005 Vol3 Issue 3

32. Sumathipala A, Siribaddana SH Research and clinical ethics after the tsunami: Sri Lanka **Lancet** 2005;366: 1418-1429 IF 21.713 citations-2

33. Sumathipala A, Siribaddana SH, Perera C, Management of dead bodies as a component of psychosocial interventions after the Tsunami; a view from Sri Lanka **International Review in Psychiatry** 2006:18:249-253. Citations-3

34. Siribaddana SH, Siriwardane WD, Hewage SN, Athukorale ADMD, Sumathipala A, Hotopf M Update from Sri Lankan Twin Registry: Establishment of a Population-Based Twin Register and Ongoing Project on Common Mental Disorders, Alcohol Abuse and Suicidal Ideations **Twin Research & Human Genetics** 2006;9 868-874 IF 1.713 Funded by Wellcome Trust UK citations-2

35. Samaraweera S, Sumathipala A. Sivayogan S, Bhugra D, Siribaddana SH. RCT of Cognitive Behaviour Therapy in active suicidal ideation- a feasibility study in Sri Lanka. **The European Journal of Psychiatry** 2007;21: 175-178 IF 1.191

36. Sumathipala A, Siribaddana SH, Hewage SN, Lekamwattege M, Athukorale, Chesmal Siriwardane C, Murray J, Prince M. Ethics review committee approval and informed consent: analysis of biomedical publications originating from Sri Lanka **BMC Medical Ethics** 2008, 9:3. Funded by Wellcome Trust UK

37. Samaraweera S, Sumathipala A, Siribaddana SH, Sivayogan S, Bhugra D. Completed suicide among Sinhalese in Sri Lanka. A Psychological autopsy study. **Suicide & Life-Threatening Behavior** 2008;38:221-8 IF 1.118 citations-1

38. Siribaddana SH, Kovas Y, Fernando DJS Quantitative Ultrasound of Bone and Calcium Intake in Sub-Urban Males in Sri Lanka. **International Journal of Rheumatic Diseases** 2008;**11**: 407–413

39. Sumathipala A, Siribaddana S Abeysingha N, De Silva P, Dewey M, Prince M. Cognitive behavioural therapy vs. structured care for medically unexplained symptoms. A randomised controlled trial. **British Journal of Psychiatry** 2008;193: 51-59 Funded by Wellcome Trust UK IF 5.43 citations-3

40. Siribaddana SH, Ball HA, Hewage SN, Glozier N, Kovas Y, Dayaratne DARK, Sumathipala A, McGuffin P, Hotopf M. Colombo Twin and Singleton Study (CoTASS): A description of a population based twin study of mental disorders in Sri Lanka **BMC Psychiatry** 2008, 8:49 Funded by Wellcome Trust UK citations-1

41. Sumathipala A, Siribaddana SH, Hewage SN, Lekamwattege M, Athukorale, Siriwardane C, Murray J, Prince M. Informed consent in Sri Lanka: a survey among ethics committee members **BMC Medical Ethics** 2008, 9:10. Funded by Wellcome Trust UK

42. Sumathipala A, Siribaddana SH, Hewage SN Sumathipala K, Prince M, Mann A. Understanding the explanatory model of the patient on their medically unexplained symptoms and its implication on treatment development research: a Sri Lanka Study. **BMC Psychiatry** 2008, 8:54 Funded by Wellcome Trust UK

43. Ball H, Sumathipala A, Siribaddana S, Kovas Y, Glozier N, McGuffin P Hotopf M Genetic and environmental contributions to depression in Sri Lanka **British Journal of Psychiatry** 2009 195, 504–509. doi: 10.1192/bjp.bp.109.063529 Funded by Wellcome Trust UK

44. Ball H, Siribaddana S, Kovas Y, Glozier N, McGuffin P Sumathipala A Hotopf M Epidemiology and symptomatology of depression in Sri Lanka: : A cross sectional population-based survey in Colombo District **Journal of Affective Disorders** 2010; 123: 188–196 Funded by Wellcome Trust UK

45. Ball H, Siribaddana S, Sumathipala A, Kovas Y, Glozier N, McGuffin P, Hotopf M Environmental exposures and their genetic or environmental contribution to depression and fatigue: a twin study in Sri Lanka **BMC Psychiatry** 2010 , 10:13. Funded by Wellcome Trust UK

46. Samaraweera S, Sumathipala A, Siribaddana SH, Sivayogan S, Bhugra D Prevalence of suicidal ideation: A population sample in Sri Lanka **Crisis 2010;31** DOI10.1027/0227-5910/a000010IF 1.463

47. Sumathipala A, Siribaddana SH, Hewage SN, Lekamwattege M, Athukorale, Siriwardane C, Munasingha K, Murray J, Prince M. Understanding of research and informed consent: a Sri Lankan Perspective **BMC Medical Ethics** 2010, 11:7 Funded by Wellcome Trust UK

48. Ball H, Sumathipala A, Siribaddana SH, Kovas Y, Glozier N, McGuffin P, Hotopf M The aetiology of fatigue in Sri Lanka and its overlap with depression. **British Journal of Psychiatry** 2010 ; 197: 106–113.Funded by Wellcome Trust UK

49. Siribaddana SH, Fernando B, Goonertne R. Neurobiological Stress Markers in Tsunami Survivors; A case study **Asian Bioethics Review** 2010;2:162-166

50. Sumathipala A, Jafarey A, De Castro LD. Ahmed A, Marcer D, Srinivasan S, Kumar N, Siribaddana SH, Sutaryo S, Bhan A, Waidyarathne D, Beneragama S, Jayasekare C, Edirisinghe S, & Siriwardane C. Ethical Issues in Post-Disaster Clinical Interventions and Research: A Developing World Perspective. Key Findings from a Drafting and Consensus Generation Meeting of the Working Group on Disaster Research and Ethics (WGDRE) 2007 **Asian Bioethics Review** 2010;2:124-142

51. Chandrasena LG, Peiris H , Williams S, Siribaddana SH Observations on haemoglobin variants in patients with type 2 diabetes mellitus **The South East Asian J of Tropical Medicine & Public Health** 2010: 41:1247-1251

52. Ball H, Siribaddana SH, Sumathipala A, Kovas Y, Glozier N, Rijsdijk F, McGuffin P, Hotopf M Genetic and environmental contributions to the overlap between psychological, fatigue and somatic symptoms: a twin study in Sri Lanka **Twin Research & Human Genetics** 2011; 1453-63

53. Siriwardane C, Sumathipala A, Siribaddana SH, Samaraweera S, Abeysinghe N, Prince M, Hotopf M. Reducing the scarcity in mental health research from low and middle income countries: A success story from Sri Lanka. **International Review of Psychiatry** 2011:23: 77-83

54. Samarasekara N, Davies MLM, Siribaddana SH The stigma of mental illness in Sri Lanka: the perspectives of community mental health workers. **Stigma Research and Action** (accepted)

55. Siribaddana SH. Cardiac dysfunction in the CABG patient **Current Opinion in Pharmacology** (accepted)

56. Lang TA, Siribaddana SH. Clinical Trials Have Gone Global - Is This a Good Thing? **PLoS Medicine** (accepted)

57. Siribaddana SH, Rossuw MT, Siribaddana N. Immunization-related adverse events: balancing individual risk and social benefit through public discourse **Asian Bioethics Review** (submitted)

Minor Publications

Publications in non indexed journals, published abstracts cited in science citation index and letters

1. Weerasuriya N, Suranimala AC, Hewage UCL, Siribaddana SH, Fernando DJS. An evaluation of hirsutism grading scores in a Sri Lankan Endocrine clinic. **Sri Lanka Journal of Obstetrics and Gynecology** 1996; 18:30-32

2. Siribaddana SH, Fernando DJS. Low HDL cholesterol in NIDDM patients attending a diabetic clinic. **The Kandy Medical Journal** 1994; 3:17-20.

3. Fernando DJS, Siribaddana SH, Z Subasinghe, HGM Chandrika. The cost of screening for diabetic retinopathy at a diabetic clinic. **Journal of Ceylon College of Physicians** 1994; 27:49-52.

4. Siribaddana SH, Fernando DJS. Lack of clarity in presenting statistical data (letter). **Ceylon Medical Journal** 1994; 39; 147.

5. Siribaddana SH, Wijesundera A, Samarasinghe S. Lack of systemic anti fungal agents in Sri Lanka. (Letter) **Ceylon Medical Journal** 1994; 39; 111.

6. Siribaddana SH, Suranimala AC, Sheriff MHR, Fernando DJS. Heart rate variability in diabetic autonomic neuropathy. **Journal of Ceylon College of Physicians** 1996; 29:1:27-28.

7. Siribaddana SH, Rajapaksa A, Fernando DJS. Prevalence of impaired glucose tolerance and diabetes mellitus in women aged between 20-45 in suburban Sri Lankan community. **Kandy Medical Journal** 1996; 4:41-43

8. Siribaddana SH, Fernando DJS. Lipid disorders in non-insulin dependent diabetes mellitus (leading article) **Kandy medical Journal** 1996; 5:41-2

9. Indrakumar, Fernando DJS, Siribaddana SH, Hewage UCL, Sheriff MHR. The clinical features of Cushing's syndrome presenting to a Sri Lankan Endocrine Clinic. **Journal of Ceylon College of Physicians** 1996; 29:1:36-37.

10. Fernando DJS, Siribaddana SH. Glucose tolerance after gestational diabetes in Sri Lankan Women **Diabetalogia** 1997; 40: 858.

11. Siribaddana SH, Hewage U, Fernando DJS. Sri Jayewardenepura community survey of osteoporosis reference data for broadband ultrasound attenuation (BUA) & Stiffness Index **Osteoporosis International** 2000; 11: S83

12. Siribaddana SH, Hewage U, Fernando DJS. Sri Jayewardenepura community survey of osteoporosis; Dietary calcium intake **Osteoporosis International** 2000: 11: S107-S107

13. Sumathipala A, Siribaddana SH. Bridge the existing divide between North-South bio-ethical philosophies. **e BMJ http://www.bmj.com/letters.** 2001 April 19. IF 7.038

14. De Alwis, N. M. W. Siribaddana, S. H. Beneragama, S, et al. Body mass index in Urban and rural Sri Lanka. **International Journal of Obesity** 2003: 27: S149

15. Sumathipala A, Siribaddana SH, Bhugra D The continuing story of dhat syndrome - Reply **British Journal of Psychiatry** 2004: 185: 261-262

16. Siribaddana SH, Dayaratne DARK. Sri Lanka after Tsunami (letter). Journal of **Royal Society of Medicine** 2005;98: 387

17. Lau EMC, Sambrook P, Seeman E, Leong KH, Leung PC, Delmas P. Guidelines for diagnosing, prevention and treatment of osteoporosis in Asia (participated in the consensus meeting which generated the document) **APLAR Journal of Rheumatology** 2006; 9: 24-36

18. Ball HA, Siribaddana S, Sumathipala A, et al. The heritability of depressive tendency in a Sri Lankan twin sample, using an age-dependent categorical phenotype : **Behaviour Genetics** 2007: 37: 736-737

Public education and dissemination of Science

- Siribaddana SH. Osteoporosis in Sri Lanka Osteoporosis Action 2004; 8:4
- Sumathipala A & Siribaddana SH On the Forensic Genetic services Asia Tribune 2005-04-05
- Siribaddana SH Supercourse lecture 7721. Nutritional guidelines in Osteoporosis (http://www.pitt.edu/~super1/ppt.htm)
- Editorial Board Gaveshana ISSN 1391-8168 (tri lingual journal for popularization of research science and ethics)
- Siriwardhana CS, Sumathipala AS, Siribaddana SH. Informed Consent in Sri Lanka: A comprehensive analysis. Newsletter of the International Association of Bioethics. Issue 21. 2008
- Fourteen newspaper articles and interviews in lay press

Telemedicine

- An approach to Telemedicine- Insulin monitoring expert system by Ratnayake WMCR Siribaddana SH, Fernando DJS, Karunananda AS. Presented at the International Information Technology Conference Colombo January 2001.
- Telemedicine Expert System for Diagnosing Heart Diseases Thesis presented successfully by Ratnayake WMCR for Bachelor of Information Technology at the Open University in 2001 and supervised by Siribaddana SH, Fernando DJS, Karunananda AS
- Diabetic Retinopathy-Automatic Diagnosis of Diabetic Retinopathy using color retinal images 2004 Supervision of the dissertation of Thiranjala Hewage for B.Sc in Information Technology.

Medical Education & University activities

- Visiting Senior Lecturer Post Graduate Institute of Science, University of Peradeniya.(M.Sc. in Disaster Management) Academic year 2005/6
- Visiting Senior Lecturer in Bioethics in Biotechnology, Kelaniya University since 2007
- Visiting Senior Lecturer & Examiner in report writing for Health Promotion degree program Faculty of Applied Sciences Rajarata University 2010/2011
- Member of the curriculum development committee Faculty of Medicine & Allied Sciences Rajarata University
- Developed Portfolio and log book to be used by undergraduate medical students for structured learning in clinical medicine
- Ponnamperuma G, Siribaddana S, Samarasekara D, Sumathipala A. (2007). Learner profiling: a multi-purpose tool. Association for Medical Education in Europe (AMEE) Conference, Trondheim, Norway, August 25-29, 2007. Book of abstracts, p. 57.

Supervision of Post Graduate Thesis

1. MSc. in Nutrition by M. Abeywardane (Now Dietician at Sri Jayewardenepura Hospital and Post Graduate Teaching Hospital, Nugegoda). On influence of diet on lipid abnormalities in patients with coronary artery disease. Completed at Kelaniya University in 2000. (co-supervisor)

2. Prevalence of GAD antibodies among Sri Lankan diabetics, M Phil by Dr R Liyanage (Now Senior Lecturer in anatomy. Faculty of Medical Scinces, Sri Jayewardenepura University Nugegoda) in Sri Jayewardenepura University 2008 (sole supervisor) Completed 2008.
3. Epidemiology of Falls among the Elderly in the district of Colombo, Dr A D Ranaweera Registered 2009 Post Graduate Institute University of Colombo MD in Epidemiology and community medicine (examination by thesis only) (co-supervisor)
4. Implement and assess an intervention to develop the thalassaemia reporting system in government hospitals in North-Western province in Sri Lanka Dr Sharika Pieries Registered 2009 Post Graduate Institute University of Colombo MD in Epidemiology and community medicine (examination by thesis only) (co-supervisor)

Journals

Editorial Board

Indian Journal of Medical Ethics

Peer Reviewer

1. International Review of Psychiatry
2. International Journal of Social Psychiatry (SAGE)
3. International Journal of Rheumatic Diseases (Blackwell scientific)
4. Nutrition: The International Journal of Applied and Basic Nutritional Sciences (Elsevier)
5. Ceylon Medical Journal
6. International Journal on Men's Health(Elsevier)

Rating

McMaster Online Rating of Evidence since January 1st 2005 to date

Research Grants

1. 2010 Wellcome Trust; The Colombo twin and singleton study (COTASS) follow up (Hotopf (PI)Mcguffin, Pariante, Sumathipala, Rijsdik) £ 687,783 Grant code 093206
2. 2009 Wellcome Trust; Master's Fellowship in Public Health and Tropical Medicine for Dr Chesmal Siriwardhana. Prevalence of common mental disorders and association with resilience among internally displaced people in Puttlam district of Sri Lanka (Stewert(PI), Sumathipala, Siribaddana) £105 340 Grant code 089401
3. 2009 Institute of Social Psychiatry; Two phase 10/66 Dementia Survey in Sri Lanka (Sumathipala (PI), Prince, Siribaddana)£ 4463
4. 2008 Wellcome Trust Public Engagement; Multiples & twins Engage in Research through Culture (MERC) (Siribaddana (PI) Hotopf, Sumathipala, Mcmullen) £29 400 Grant code 086326

5. 2007 Wellcome Trust; basic and advanced courses on Bio Ethics “Ethics friend of research” (Siribaddana (PI), Sumathipala) Grant code 081325. £5000
6. 2005 Wellcome Trust; Informed consent practices in Sri Lanka (Sumathipala, Prince (PI), Siribaddana) Grant code 074926. £ 19 500
7. 2003-2008 Wellcome Trust: A population based twin study on common mental disorders in Sri Lanka (Hotopf (PI), Sumathipala, Sham, McGuffin, Ball, Siribaddana) £251,417 Grant code 069629 supplementary funding £20 000
8. 2000-2001 Wellcome Trust: Sri Lanka National Twins Register Pilot project (Hotopf (PI), Sumathipala, Fernando, Abeysinghe, Siribaddana, Dayaratne) £8,320
9. Princess Alexandra Hospital private practice research grant 1998 Aus$ 5000
10. National Science Foundation grants clinical epidemiology of obesity in Sri Lanka (Fernando, Siribaddana (PI)) 1996. Rs 200 000
11. Ceylon College of Physician grants to conduct research about obesity 1996. Rs 20 000

Travel Grants

1. Wellcome Trust International Public Engagement Workshop “SCIENCE AND COMMUNITY – ENGAGE TO EMPOWER” - Dialogues about public engagement with science in the developing world - Africa Centre for Health and Population Studies, Somkhele, Northern KwaZulu-Natal, 2008 South Africa
2. Full scholarship by Public Responsibility in Medicine and Research’s (PRIM&R) to attend Annual Human Research Protection Programs Conference: Human Research Protection Programs in an Evolving Research Landscape. Co-sponsored by the Boston University School of Medicine, in collaboration with the Association of American Medical Colleges (AAMC). 2007 Boston USA
3. Wellcome Trust award to attend Biomedical Ethics Summer School entitled 'Public Health: Justice, Autonomy and the Common Good'. 2007, University of Leicester UK
4. International Osteoporosis Foundation Travel grant to attend Advanced Course in Osteoporosis in France, Nice 2006
5. Wellcome Trust travel grant to attend Global Forum for Bioethics in Research 6, Blantyre, Malawi 2005
6. Multiple Birth Foundation travel Grant 2004-11th international conference on twin studies
7. Wellcome Trust travel grant to attend MRC School in Behaviour Genomics at the Social, Genetics and Developmental Psychiatry Research Centre Kings College London. 2002
8. Wellcome Trust travel grant to attend 10th International Society Twin Studies in London 2001
9. Osteoporosis Society Travel Grant to attend Certification course in osteoporosis in Hong Kong 2000
10. Australian Diabetes Society travel grant 1997.

Awards

- E.V. Pieres memorial award 1992, Ceylon College of Physicians.
- EM Wijerama award 1995, Sri Lanka Medical Association.

- Special prize for cardiology1995 Sri Lanka Medical Association
- Sir Frank Gunasekare award 1997. Sri Lanka Medical Association.
- S.E. Seneviratne award 1997. Sri Lanka Medical Association.
- Merit Award Distance learning course of the World Bank Institute and Ministry of Health on Health Outcomes and the poor, Colombo 2004
- Sir Frank Gunasekare award 2004. Sri Lanka Medical Association
- **Presidential award for research 2008 (for 2002 publications)**

Membership in Professional Bodies and Participation

Professional member, The Endocrine Society USA 1998- to date

Member Public Responsibility in Medicine & Research Boston, USA 2008 to date

Professional member European Association for Study of Diabetes 2009 to date

Secretary and founder member Osteoporosis Society of Sri Lanka, 2000-2002 now executive Committee member 2007 to date, President Elect 2010

Executive Committee Member. Asia Pacific Osteoporosis Foundation 2001- 2003Treasurer-South Asian Society for Bone and Mineral research 2007- to date

Council Member; Sri Lanka Medical Association 1996. Member of the steering committee on Prevention of Non Communicable Diseases; Sri Lanka Medical Association 1996 -2002, Member of the steering committee on Academic Affairs; Sri Lanka Medical Association 1996. SLMA Committee on Guidelines for diabetes – A World Bank funded project under the Ministry of Health 1998

Expert Committee on disaster Management, Ministry of Disaster Management 2005 to date

Assistant Secretary; Sri Lanka Medical Library 1996. Treasurer, Sri Lanka Medical Library 1999/2000

Editor; Endocrine Society of Sri Lanka 1996,1999, 2000. Executive Committee member 2009, 2010

Director Sri Lankan Twin Registry 1998 to 2002 and Foundation Member of the Sri Lanka Twin Registry Executive Committee member & Project Leader since 2002 to date

Member; Australian Diabetes Society 1998

Member; Australian Society for Study of Obesity 1997-1998

Member, South Asians Health Preventionists Association (SAHPA)

Professional member, American Diabetic Association 2003

Invited Lectures & Presentations

International Forums, CME & Invited Lectures

Microsoft PowerPoint Introduction Queensland Health 1997, Australia

Microsoft Word Tables/Merge Workshop Queensland Health 1997 Australia

New aspects of alfacalcidiol & D Hormone analogs Loma Linda University School of Medicine Chicago 2000

Osteoporosis – A Certification Course Hong Kong 2000 (Asia Pacific Osteoporosis Foundation)

The Steno Course on Practical Diabetology. Steno Diabetes Center –New Delhi 2000

2nd International Meeting on the Genetic Epidemiology of the complex traits Cambridge 2000

82nd Annual Meeting Toronto 2000. Endocrine Society USA.

World Congress in Osteoporosis 2000, Chicago USA

10th International Congress on Twin Studies London 2001

Symposium speaker 17th World Congress of Social Psychiatry Agra, India 2001.

Behavior Genomic Summer School. Qualitative Genetics Module. Social, Genetics and Developmental Psychiatry Research Centre Kings College London. September 2002

Forth Global Forum in Bioethics Genomic Research October 2002 Brasilia PAHO/WHO

Completed Human Participant Protections Education for Research National Institute of Health. USA (online) 11/30/2003

Pharmacogenetics: Ethical Issues. Responses to the public consultations on the working paper, Nuffield Council of Bioethics, 2003.

Faculty in 2nd Asian Regional IOF (International Osteoporosis Foundation) Conference on Osteoporosis. Guidelines for osteoporosis in Asia (as a panelist) –Hong Kong 2004 and chairman of a free paper session

Composite International Diagnostic interview Version 2.1 Training Institute of Psychiatry, London UK 2004.

Invited speaker. Using school curriculum to popularize twin research 11th International Congress on Twin Studies 2004, Odense, Belgium.

Faculty South Asian Epidemiology Course. Aga Khan University and & University of Pittsburg. WHO collaborating Centre February 2005 Karachi

Sixth Global Forum in Bioethics March 2005 Malawi Invited participant

World wide conference of Osteoporosis Patient societies Bangkok Sep 2005

Fogarty International Training Workshop on Basic and Molecular Epidemiology, Environmental Health, Arsenic exposure and risk assessment Indian Institute oif Chemical Biology Environmental Health Sciences School of Public Health University of California in Kolkota Dec 2005

1st international conference of SAARC Psychiatric Federation, Invited Speaker December Agra. Dec 2005

Seventh Global Forum in Bioethics February 2006 Karachi. Invited participant

Invited speaker; Asian Twin Registries Meeting Tokyo Jan 2006

Faculty: Training workshop on Medically Unexplained symptoms after disaster Department of Psychiatry, Aga Khan University Karachi Feb 2006

15th IOF Advanced Training Course on Osteoporosis 2006 Jan-Feb Lyon

Various CME from medscape and Endocrine society USA

In Sri Lanka

Diabetes. Some myths and fallacies - Diabetes Association of Sri Lanka. World Diabetes Day 1993.

Diabetes complications and prevention - Seminar on nurse's role in diabetes care. Ministry of Health. October 1994.

Short review; Osteoporosis; Sri Lanka Medical Association. January 1996.

Case presentation; Beraridinelli syndrome and Insulin Resistance. Sri Lanka Medical Association. January 1996.

Conducting monthly Audit meeting; Professorial Unit. University of Colombo. 1995-1996.

Complications of diabetes mellitus; Kurunegala branch of Diabetes Association of Sri Lanka. World Health Day 1996.

Case presentation; Gulliver in Lilliput; tallest Sri Lankan citizen. Sri Lanka Medical Association. September 1996.

Evidence based Medicine; some evidence from Sri Lanka. Princess Alexandra Hospital week. 1997

Osteoporosis a Review. Endocrine society of Sri Lanka 1999

Osteoporosis – Invited for lecture. Ceylon College of Physicians 1999

Endocrine problems of pregnancy Endocrine society of Sri Lanka 1999

Precocious Puberty Endocrine society of Sri Lanka 1999

Osteoporosis –Endocrine society of Sri Lanka 1999

Obesity & Diabetes IMPA & SLMA joint meeting

Epidemiology of Osteoporosis - Foundation Meeting of the Osteoporosis Society of Sri Lanka 2000.

Osteoporosis What is new –Ceylon College of Physicians 2000

Osteoporosis SLMA- Anuradhapura Clinical Society 2001

Osteoporosis SLMA- Ruhunu Clinical Society 2001

Multiple medically unexplained symptoms; medical aspects SLMA- Ruhunu Clinical Society 2001

2nd post graduate course in Diabetes-University of Sri Jayewardenepura Resource person 2001

Sexual Dysfunction Workshop SLMA Colombo 2001

Osteoporosis- Post Graduate course on Endocrinology University of Sri Jayewardenepura 2002

Obesity and Diabetes College of GP 2002

Gestational Diabetes Kandy Society of Medicine – Annual academic sessions 2002

Nutrition in Osteoporosis – Review of evidence – 115th Annual academic sessions SLMA 2002

College of General Practitioners of Sri Lanka workshop in Diabetes Mellitus resource person 2002

Ethical aspects of Biotechnology and Human biological material research 2003-Intensive Course in bioethics, Forum for Research and Development 2003

NCD and Mental health-lecture at World Mental Health day Ministry of Health Colombo 2005

Training of RMOs on medically unexplained symptoms Regional Director of Health Services Colombo at BH Homagama 2007

Resource person Inaugural academic sessions of the endocrine society of Sri Lanka 2009

Resource person Advisory panel in the diabetes Interest Group College of General Practitioners 2009

Resource person (Iodization in Thyroid disease) Thyroid day 2011, Endocrine Society of Sri Lanka, 27th June 2011

Key Note address Regional meeting in Physiology 8th July 2011 Rajarata University of Sri Lanka

Resource person Inaugural academic sessions of the endocrine society of Sri Lanka 2011

Published abstracts

Siribaddana SH, Perera S, Fernando DJS. Lipid abnormalities amongst Sri Lankan patients with diabetes. 1st International Medical Congress. University of Peradeniya 1992.

Siribaddana SH, Samarasinghe HHR. Fernando DJS. The prevalence of diabetes in Sri Lanka. A community study. Academic sessions Ceylon College of physicians. 1992.

Siribaddana SH, De Silva S, Fernando DJS. Clinical profile of recently diagnosed diabetes patients in Sri Lanka. Academic sessions Ceylon College of physicians. 1993.

Fernando DJS, Siribaddana SH. Thyroid function an audit. SLMA Sessions 1993.

Siribaddana SH, Perera S, De Silva S, Fernando DJS. Are European standards for diagnosing dyslipidaemia applicable in Sri Lanka? SLMA Sessions 1993.

Siribaddana SH, Wijesundera Anula, Herath CA, Nazar ALM. Adult benign dengue hemorrhagic fever-A new clinical syndrome. SLMA Sessions 1994.

Siribaddana SH, Fernando DJS. Is screening for diabetic retinopathy cost effective? SLMA Sessions 1994. (Poster)

Wijesundera A, Samarasinghe S, Nazar ALM, Siribaddana SH. Choramphenicol resistant Salmonella typhi seen in Sri Jayawardanepura General Hospital. SLMA sessions 1994.

Wijesundara A, Mithrakumar S, Nazar ALM, Siribaddana SH. Safety and efficacy of streptokinase therapy for acute myocardial infarction in a medical ward. SLMA sessions 1994.

Jayathilake MK, Dunuwille AN, Athukorala DP, Shanthiraj WS, Tennekoon R, Siribaddana SH. The effect of magnesium sulfate in acute myocardial infarction. SLMA Sessions 1995.

Wijesundera A, Siribaddana SH, De Zoysa MIM, Alibhoy AT, Nazar ALM. Accidental exposure to toluene diisocyanate (TDI) SLMA Sessions 1995.

Fernando DJS, Siribaddana SH, Kamaladasa S. The high incidence of diabetes mellitus in migrant Sri Lankan workers. SLMA Sessions 1995.

Siribaddana SH, Deshabandu R, Rajapaksa A, De Silva K, Fernando DJS. Outcome of pregnancy in gestational diabetes mellitus. SLMA Sessions 1996.

Weerasuriya N, Siribaddana SH, Wijeweera I, Wijesekare J, Fernando DJS. Subclinical Neuropathy in newly diagnosed diabetic patients. SLMA sessions 1997.

Weerasuriya N, Hewage UCL, Siribaddana SH, Weerasekara K, Fernando DJS. The efficacy of radioiodine therapy in-patients with Graves and toxic nodular goiter. SLMA sessions 1997.

Fernando DJS, Siribaddana SH. Glucose tolerance after gestational diabetes in Sri Lankan women. Poster no. 858; 16th International Diabetes federation, Helsinki; July 1997

Siribaddana SH, Weerasuriya N, Fernando DJS. The relationship between the duration of diabetes and occurrence of autonomic neuropathy: A bimodal distribution, Australian Diabetes Society; Canberra 1997

Siribaddana SH, Weerasuriya N, Fernando DJS. Body mass index a valid bedside tool to measure body fat but not good for assessing regional adiposity in Sri Lankan NIDDM patients. Australian Society for Study of Obesity; Canberra 1997.

Sumathipala A, Fernando DJS, Jayasekare R, Abeysinghe N, Siribaddana SH, Dissanayake V, De Silva N. Establishment of a twin register in Sri Lanka. 9th International Congress on Twin Studies, Helsinki, Finland, June 1998. Twin Research 1998 1(2): 111

Sumathipala A, Fernando DJS, Jayasekare R, Abeysinghe N, Siribaddana SH, Dissanayake V, De Silva N. Establishment of twin register in Sri Lanka. SLMA sessions 1999.

Sumathipala A, De Silva N. Fernando DJS, Jayasekare R, Siribaddana SH, Cross cultural adaptation and preliminary validation of a zygosity determination questionnaire for twins in Sri Lanka. SLMA sessions 1999.

Siribaddana SH, Fernando DJS. The prevalence of obesity and other coronary risk factors in a suburban community, SLMA sessions 2000

Sumathipala A, De Silva N, Sivayogam S, Fernando DJS, Siribaddana SH, Abeysinghe N, Dayaratne DARK. Feasibility of using birth records as a means of establishing a population based register for twins in Sri Lanka. SLMA sessions 2000

Ratnayake WMC, Karunananda AS, Fernando DJS, Siribaddana SH. An Approach to Telemedicine-insulin monitoring expert system. International information technology Conference 2000. Colombo.

Kerr G, Capra S, Ash S, Carey D & Siribaddana S Three Different Dietary Approaches to Weight Management and Glycaemic Control in Clients with Non-insulin Dependent Diabetes Mellitus. Celebrate Food in Sydney. 26-29 April 1998 Sydney, New South Wales Dieticians Association of Australia, Deakin, ACT, 1998

Siribaddana SH Sumathipala A, De Silva N, Sivayogam S, Fernando DJS, Dayaratne DARK Abeysinghe N Feasibility of using Different approaches for recruiting younger twins for Sri Lankan twin registry.10th International Congress of twin Studies 2001. London

Dayaratne DARK Siribaddana SH Sumathipala A, De Silva N, Sivayogam S, Fernando DJS, Abeysinghe N Feasibility of using Different approaches for recruiting older twins for Sri Lankan twin registry.10th International Congress of twin Studies 2001 London

De Silva N Dayaratne DARK Siribaddana SH Sumathipala A, Sivayogam S, Fernando DJS, Abeysinghe N Early report on the availability of island wide twin database. 10th International Congress of twin Studies 2001 London

Sumathipala A, Siribaddana SH, De Silva P, Mann AH. Early report of an ongoing RCT: Cognitive behavior therapy for medically unexplained symptoms.18th World Congress in Social Psychiatry 2001 Agra.

Sumathipala A, De Silva N, Siribaddana SH Fernando DJS, Dayaratne DARK, Abeysinghe N, Warnasuriya ND, De Silva D. An investigation into the twining incidence of the index twins of the National twin registry – SLMA 2002

Malavige GN, De Alwis NMW, Siribaddana SH, Weerasooriya N, Fernando DJS. The rising prevalence of coronary risk factors in a sub urban Sri Lankan population. SLMA 2002

Samaraweera S, Siribaddana SH, Sivayogan S, Sumathipala A. Psychological Autopsy on Completed Suicides of Sinhalese in Ratnapura. SLMA annual academic sessions 2004.

Samaraweera S, Siribaddana SH, Sumathipala A. Sivayogan S. A community based study on suicidal ideations and behaviors in Ratnapura District. SLMA annual academic sessions 2004.

Samaraweera S, Siribaddana SH, Sumathipala A, Sivayogan S. Suicide Trends in Sri Lanka. SLMA annual academic sessions 2004.

Siribaddana SH, Sudath Samaraweera, Athula Sumathipala. Intensive Course on Bioethics; an evaluation. SLMA annual academic sessions 2004.

Siribaddana SH, Sumathipala A, Samaraweera DSD. Intensive Course in Bioethics; Ethics and Twin Research. 11th International Congress on Twin Studies Odense Denmark. 2004.

Extra Curricular Activities

- Book of poetry – Peering into the past ("Atheethawarjanaya")
- Deputy Head prefect. DS Senanayake college
- Leader, Sinhala debating team. Science quiz team Buddhist society and House captain
- Editor – Medical Faculty arts society and Secretary Medical Students' Welfare Society. Procurement officer Medical Exhibition 1984
- Branch Secretary Government Medical Officers Association – Negombo Branch
- Represented school in throwing events
- President Sports Club SJGH 1993