An advanced cookstove intervention to prevent pneumonia in children under 5 years old in Malawi: a cluster randomised controlled trial

Protocol

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Trial personnel

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TRIAL PARTNERS

This proposal benefits from 2 public-private partnerships that will be key to the successful conduct of the trial, influencing public policy and the sustainable scale-up of the intervention in the future.

African Clean Energy (ACE) is a Lesotho-based company that has built an industrial scale manufacturing plant in Lesotho as a joint venture with Philips to produce the advanced cookstove we are using as our intervention. Through our partnership with ACE we will have a secure source of the Philips cookstove for the trial. The locally relevant business knowledge that ACE brings, together with the planned economic and qualitative work, will help to plan the up-scaling of the intervention if indicated in the future. ACE has committed to provide these stoves at the lowest possible cost for the trial and up-scaling.

Aprovecho Research Centre (ARC) (www.aprovecho.org) is a not for profit corporation that carries out research, develops and disseminates clean cookstove and other energy technologies. ARC has implemented over 2 million improved cooking and heating stoves around the world. ARC has helped to inform the selection of our intervention and will play a key role in the dissemination of the trial findings to the cookstove research and implementation programme communities.

EXECUTIVE SUMMARY

Background: 700 million people in Africa burn biomass to provide energy for cooking, heating and lighting. The smoke this generates causes considerable morbidity and mortality (4 million deaths a year worldwide). Pneumonia in the under 5s is one of the major diseases associated with biomass smoke exposure and a serious cause of avoidable mortality in less developed countries. There are now efficient biomass-burning cookstoves that substantially reduce smoke emissions and exposures. This trial will evaluate whether provision of an advanced cookstove (Philips fan assisted stove) will reduce pneumonia in young children.

Design: Village-level cluster randomised controlled trial with two arms of equal size.

Population: Children up to 4½ years old in Malawi allowing for a minimum of 6 months data collection before a child's 5th birthday.

Intervention: The Philips fan assisted stove with user training (replacing open fires).

Control: Continuation of traditional cooking methods (open fire).

Primary Outcome: Incidence of pneumonia in children under 5 years of age. Diagnosis made by physicians blinded to trial arm using the WHO Integrated Management of Childhood Illness (IMCI) pneumonia assessment protocol.

Time: 24 months follow up.

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INTRODUCTION

The problem to be addressed

Malawi has one of the world's highest infant and under five mortality rates (69 and 110 per 1000 live births respectively in 2009) despite having made progress towards meeting the Millennium Development Goal of reducing child mortality (1). Pneumonia is the leading cause of death and one of the commonest causes of morbidity. Malawi Ministry of Health (MoH) and World Health Organization (WHO) estimate around 300 per 1000 children under the age of 5 are diagnosed with pneumonia every year with a case fatality rate between 2.7 and 13.2 per 1000 (2,3). Exposure to smoke produced when biomass fuels (animal or plant material) are burned in open fires is a major avoidable risk factor for pneumonia (4, 5). In Malawi, where at least 95% of households depend on biomass as their main source of fuel and household air pollution levels are high (6), biomass smoke exposure is likely to be responsible for a substantial burden of this disease (4,5).

Why a trial is needed now and why is it needed in the proposed location

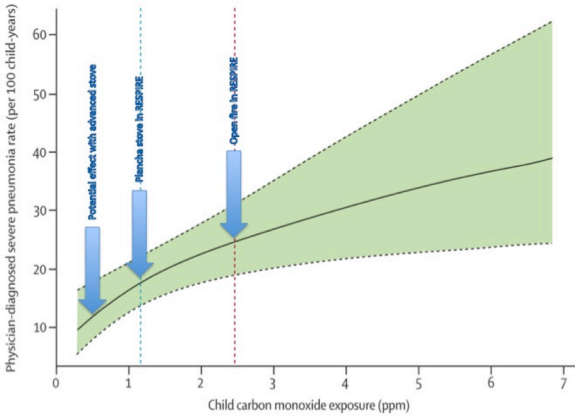
700 million people in Africa use biomass fuel to provide energy for cooking, heating and lighting. Women and young children experience high levels of smoke exposure when meals are cooked over open fires in the home due to partial combustion of fuel and poor ventilation (5). Household air pollution from open fires is a major threat to health, ranking 10th in the WHO comparative risk assessment for the global burden of disease (7). WHO estimates 4 million premature deaths are caused by household air pollution worldwide every year. Around half a million of these deaths are due to pneumonia in young children (7, 8). Other adverse health effects associated with biomass smoke exposure include stillbirth, low birth weight, chronic obstructive pulmonary disease and lung cancer (5, 9-11). Effective strategies for reducing both biomass fuel consumption and smoke exposure include improved stoves, ventilation, cleaner fuels and behaviour modification. Some of the more advanced biomass-burning cookstoves reduce emissions by as much as 90% by incorporating technologies (*e.g.* fans) that improve combustion efficiency (12). Access to smoke exposure reduction technologies is limited by poverty in much of the developing world. The Global Alliance for Clean Cookstoves (GACC) was launched in 2010 to tackle the lack of access to clean affordable energy through public-private partnerships (http://cleancookstoves.org/). A central aim of the alliance is for 100 million homes to adopt clean and efficient stoves and fuels by 2020. There is, however, very limited evidence to assess the potential health benefits of such an approach. A trial is needed now in Africa to deliver relevant and timely evidence about the health and economic impacts seen when households adopt advanced cookstove technologies to impact on communities and policy makers.

Relevant systematic reviews and the need for this trial in light of these reviews

We have published a systematic review and meta-analysis of the literature relating to indoor air pollution from unprocessed solid fuel use and increased pneumonia risk in children below 5 years of age (8). We calculated an overall pooled odds ratio (OR) of 1.78 (95% CI 1.45-2.18) for the association between solid fuel use and pneumonia using data from 24 studies. A more recent estimate from Po *et al* (13) suggests a higher OR of 3.52 (95% CI 1.94-6.43). This substantial increased risk of pneumonia in young children in relation to unprocessed solid fuel use calls for intervention studies to identify effective and cost effective approaches to reduce this risk.

How the proposed trial will differ from or complement any relevant planned, ongoing or recently completed trials internationally

Only two trials have been carried out anywhere in the world (Mexico and Guatemala) to evaluate the effects of biomass smoke exposure reduction interventions on health outcomes (14, 15). Both trials used stoves that reduce exposure mainly by venting emissions to the outdoor environment with a chimney rather than by improving combustion efficiency. Romieu *et al* compared a Patsari stove intervention with traditional open fire on respiratory symptoms and lung function in 552 women in Mexico (14). Adherence to the intervention was poor (50%) but the Patsari stove reduced respiratory symptoms (*e.g.*rate ratio (RR) 0.29 (95% CI 0.11-0.77) for wheeze) and lung function decline (31ml *vs* 62ml over 1 year, p=0.01) in those who used the stove. The RESPIRE trial randomised 534 households with a pregnant woman or infant in highland Guatemala to a Plancha stove or open fire and assessed the impact on pneumonia in children <18 months (15). The Plancha gave a non-significant reduction in incidence of physician-diagnosed pneumonia (primary outcome) with a RR of 0.84, 95% CI 0.63-1.13, p=0.26 (after multiple imputation RR 0.78, 95% CI 0.59-1.06, p=0.10) and a significant reduction in physician-diagnosed severe pneumonia (RR 0.67, 95% CI 0.45-0.98, p=0.04) despite only a 50% reduction in personal smoke and carbon monoxide exposures and an improvement in household air pollution to levels still well above WHO recommended limits. An exposure-response relationship was seen between biomass smoke exposure and pneumonia risk with the risk rising steeply at low levels and flattening off at higher levels of exposure (figure).



The Current Controlled Trials database was searched across all registers using search terms 'biomass', 'stove', 'cookstove' in February 2012. The only relevant trial currently ongoing or planned for a site in Africa will evaluate birth weight and acute lower respiratory tract infection (ALRI) within the first few months of life in Ghana (NCT01335490). We have reviewed the protocol for this trial; this will generate complementary results to ours. One trial of an improved cookstove with ventilation is ongoing in Nepal with ALRI and birth weight outcomes (NCT00786877). There is a striking lack of existing and planned clinical trials evaluating the impact of biomass smoke exposure reduction interventions on health outcomes in Africa. The proposed trial will address an important gap in the clinical trials evidence base by determining whether an advanced cookstove intervention that is expected to reduce smoke exposure to levels well below those seen in RESPIRE can prevent pneumonia in African children under the age of 5.

PRELIMINARY WORK

We have conducted an exploratory randomised controlled trial of a cookstove intervention in Ntcheu, Malawi (PACTR201110000324321). The main focus of this work was to evaluate methodological issues of direct and practical relevance to this proposal. Findings include: 1) we saw high levels of interest from villagers in participating in the trial and active support from village elders and other community leaders such that 1 field worker was able to recruit 51 households from 5 villages over 5 visits; 2) the outcome measurements used (questionnaires, exhaled carbon monoxide, oxygen saturations, carbon monoxide exposure) were acceptable although 2 participants withdrew because of superstitious beliefs about HIV and oxygen in relation to these assessments. Superstitions and misbeliefs are not uncommon in Malawi and will be tackled in the proposed trial through careful community engagement exercises. We will also explore these issues through qualitative work described in a later section.

TRIAL DESIGN

Village-level cluster randomised controlled open trial with two arms of equal size.

RESEARCH QUESTIONS

1) Can an advanced cookstove intervention that substantially reduces biomass smoke exposure relative to an open fire prevent pneumonia in children under 5 years old in Malawi?

2) What is the association between exposure to household air pollution (carbon monoxide) and the development of pneumonia in children under the age of 5 in rural Malawi?

3) What is the prevalence and determinants of obstructive lung disease in adults in rural Malawi and to what extent does exposure to household air pollution explain the rate of decline in lung function in adults in rural Malawi?

4) How affordable and cost effective is the intervention from household, healthcare system and societal perspectives?

5) What can be learned from trial participants and non-participants about adoption of the intervention that could inform effective implementation of the trial findings in the future?

TRIAL POPULATION

Trial sites

The trial will benefit from strong support from the Malawi Liverpool Wellcome (MLW) Programme, a major overseas programme of the Wellcome Trust and research unit within the College of Medicine (COM), University of Malawi (http://www.mlw.medcol.mw). MLW will provide a central hub for the trial, infrastructural and administrative support. We will initiate the trial through the MLW Chikhwawa field site and one other major research centre in Karonga.The Chikhwawa field site has been selected in light of the key strategic research importance of this site, the relevance of this proposal to the MLW Child Survival Initiative in Chikhwawa and the opportunities for this trial to benefit from an existing Wellcome Trust investment whilst providing added value to this research field site through capacity building (including specific clinical trials training) and infrastructure development. The Karonga centre has been selected given the successful implementation of many other research projects at this site, access through this centre to established infrastructure, logistical support and experienced field staff. The sites both benefit from having a District Hospital that trial participants will attend in the event of illness. We anticipate being able to recruit a sufficient number of villages and households through these centres. We have links with other sites in Mulanje that could be opened if needed.

Inclusion/exclusion criteria

We will include children up to 4½ years old in Malawi because of the high burden of morbidity and mortality from pneumonia in the under 5s and to ensure a minimum of 6 months data collection before a child's 5th birthday. Households with children under 4½ will be recruited from Chikhwawa, and Karonga.To maximise generalisability of the findings the trial will be broadly inclusive and open to all consenting households with a child under 4½ (including households where babies are born during the trial). Children known to have HIV (around 5%) will be eligible for inclusion.

Households with at least one adult aged 18 years or older will be eligible for inclusion in the sub studies involving adult participants.

Sources of recruitment

An initial mapping exercise will be conducted to identify 150 suitable village level clusters across Chikhwawa and Karonga. A community engagement exercise will be carried out simultaneously to seek community leader and villager support for the trial (including careful discussion about the importance of having a control group and the chance of being a control village).

Following allocation to intervention or control group, field workers will visit each village to recruit individual households to the trial. We will include approximately 4012 households (with an average of 2.5 eligible children each) from 150 village level clusters. From our exploratory RCT in Ntcheu we found that one field worker could recruit and obtain baseline data from an average of 10 participating households in one day. Recruitment will therefore require about 530 full days of fieldwork. With 15 fieldworkers working at a maximal rate for 5 days a week this work would take 7 weeks. A more realistic timescale is 6 months that will allow for preparatory work for field visits, community engagement, training and distribution of cookstoves, illness, leave and logistical challenges.

ALLOCATION OF INTERVENTIONS

Within each district, villages that have agreed to participate will be randomly allocated to the intervention and control arms using a computer-generated randomisation schedule with stratification by site, distance from (or accessibility to) health centre and size of cluster.
This randomisation will be performed by the trial statistician using dummy codes “A” and “B” only to represent intervention and control groups; to ensure the statistician remains blinded, the identity (allocation) of “A” and “B” will be determined by a person independent of the study. Within each village all households with children up to 4½ years old will be invited to participate. After informed consent has been given by a member of the household with authority to do so, the household will be enrolled and given a Household Trial Number; each child in the household will be given a Participant Trial Number linked to the household number.

The interventions

Experimental arm –The Philips fan assisted stove with user training (replacing open fires). The Philips stove is an advanced cookstove technology that incorporates a fan to improve combustion efficiency and reduce smoke emissions by 90% (12). The stove has undergone vigorous laboratory and field evaluation by our trial partners. This work provides confidence that the Philips stove is a suitable intervention for emissions reduction, robust and acceptable to the end user. The need to charge the battery that powers the fan from time to time has not been a barrier to adoption during our pilot work; the stoves will be supplied with solar charging solutions. We will provide two stoves to each household since the ability to cook using only one pot at a time was seen as a disadvantage of the Philips stove compared to the open fire in our preparatory work.

Control arm – Continuation of traditional cooking methods (open fire). Control households will be offered two Philips stoves at the end of their period of participation in the study in the interests of fairness and to help achieve high levels of post-recruitment retention.

The duration of treatment period
The intervention and follow-up period for included households will be 24 months.

OUTCOME ASSESSMENT

Outcome measures

Primary: Incidence of IMCI defined pneumonia in children under 5 years of age.

Secondary efficacy: Incidence of all pneumonia (including those not meeting IMCI criteria), severe pneumonia and death in children under 5 years of age. We will also assess respiratory symptoms and burns, conduct spirometry (adult members of households only), household air pollution and personal exposure, measure cookstove use and conduct economic and health service evaluations.

The frequency and duration of follow-up

Fieldworkers will visit included villages every 3 months for 2 years to collect primary and secondary outcome data, repair/replace cookstoves and mobile phones if necessary and troubleshoot. This will be backed up by telephone contact with a village representative every 4 weeks.

How the outcome measures will be measured at follow up

Primary outcome case definition: Pneumonia in children under 5 years of age will be diagnosed by physicians, medical officers or other appropriately trained staff at local healthcare facilities, blinded to intervention allocation. The WHO IMCI pneumonia assessment protocol (16) will be used to make the diagnosis since chest X-rays are not universally available in the study areas. Briefly, pneumonia is diagnosed using the IMCI protocol by the presence of cough or difficult breathing and signs of pneumonia - fast breathing (60, 50 or 40 breaths per minute or more in those <2 months, 2-12 months and 1-5 years respectively), chest in-drawing, stridor or any general danger sign (inability to drink or breastfeed, vomiting, convulsions, being lethargic or unconscious). Severe IMCI pneumonia is identified by the presence of any general danger sign, chest wall in-drawing or stridor in a calm child. Oxygen saturation <90% will be included as an additional and objective marker of severity. Where available, additional data supporting the diagnosis of pneumonia (e.g. presence of pyrexia, chest X-ray findings) will be collected. The clinical information recorded in health passports used to make each diagnosis of pneumonia and assess its severity will be subject to review by a fully blinded Independent Endpoint Review Committee comprising 3 paediatric specialists not otherwise involved with the trial. A further level of pneumonia diagnosis validation will be possible at the Chikhwawa field site by capitalising on the improved diagnostics (e.g. blood cultures) being developed by MLW at this site. Pneumonia diagnoses made within a month of each other will be counted as the same episode but otherwise as separate episodes. We will record all deaths and try to distinguish deaths due to pneumonia from other causes. If a child dies at home and it is acceptable to do so, we will undertake verbal autopsies.

Practical details: Clinical assessment and treatment at the local health facilities will be based on clinical need and conducted by independent physicians or medical officers blinded to allocation. A supply of antibiotics that reflects local prescribing practice for pneumonia will be provided to local health facilities for use if antibiotics are indicated but would otherwise be unavailable. We will support local health services to achieve high quality clinical assessments and documentation of pneumonia diagnoses, severity assessment and ensure the trial does not present a burden on these services. In addition to educational and trial promotion exercises we will facilitate high quality assessments and documentation by providing all trial participants with a new health passport if they do not currently have one with a sufficient number of blank pages. These are medical records which patients in Malawi keep. A sticker will be inserted in the passport explaining that the patient is in a trial with a brief summary of the IMCI pneumonia assessment protocol and boxes to tick if the patient is diagnosed with pneumonia and if so whether this was severe or not. Malaria will be tested for (at the study sites a rapid diagnostic test is generally used) and treated as indicated as part of routine clinical practice and the result of this recorded in the health passport. During or after the attendance, the trial team will be notified by text or phone call about

the event by health facility-based staff or a member of the household using a phone and airtime credit provided to a nominated CAPS village representative. Deaths will be reported in the same way. Fieldworkers will review the health passports of all children in the trial at 3-monthly visits to the villages to obtain information about episodes of pneumonia and deaths not otherwise detected by this system.

Secondary outcomes: We will include assessment of respiratory symptoms, burns and lung function as secondary outcomes. We will do this by active surveillance in the villages every 3 months using respiratory symptoms and burns questionnaires and every 12 months using spirometry (up to 2000 adult members of households across the CAPS trial sites). There is a dedicated burns unit at the Queen Elizabeth Central Hospital (QECH) run by the College of Medicine; we will be able to capture clinical information about particularly serious burns using the Wellcome Trust funded QECH electronic patient tracking system (SPINE).

Household air pollution, personal exposure and concordance: Household air pollution (PM2.5, carbon monoxide) and personal exposure (randomly selected child under age of 4½: carbon monoxide, carboxyhaemoglobin; randomly selected adult member of household: as for children plus black carbon and PM2.5, induced sputum alveolar macrophage carbon) will be measured in a random sample of up to 2000 households across the CAPS trial sites using previously described methodology (17,18). Specific detail including quality control and quality assurance processes will be set out in Standard Operating Procedures. Up to 48 hours of continuous indoor air quality monitoring will be conducted every 6 months to ensure we have a series of repeated measures from each monitoring episode. Similar methodology will be applied for the personal exposure assessments aspect except that the monitoring devices will be worn on the person and in addition, black carbon exposure and carboxyhaemoglobin will be assessed.

Utilisation of the advanced cookstove will be assessed using University California Berkley Stove Use Monitors (coin-sized heat detecting and recording devices that can be attached to the stoves) in 10% of trial households randomly selected from the intervention trial arm.

Taken together these measurements will allow us to determine if the substantial reductions in household air pollution levels observed from our preliminary work are also seen during the trial and how these relate to stove use and they will inform exposure-response relationship analyses.

Case Report Forms (CRF): Each child and adult included in the trial will have their own CRF that will identify the child via their Household Trial Number, Participant Trial Number, initials and date of birth. An electronic CRF will be used to make the large number of CRFs manageable and provide real-time data entry, internal validity and consistency checks. CRFs will be treated as confidential documents and held and backed up onto two secure servers.

Training clusters

At each site one additional (intervention) cluster will be included to provide an opportunity for the trial protocol to be implemented outside of the context of the main trial for training purposes, to ensure any local challenges are overcome, and that sufficient experience is gained in study methodology including the use of the electronic CRFs, using the cookstoves to maximize reductions in air pollution exposures attaining proficiency in air pollution monitoring. Twenty households will be included in the training clusters where all aspects of the full trial protocol will be implemented. Data collected from these clusters will not be included in the main trial analyses.

POST-RECRUITMENT RETENTION STRATEGIES

Potential problems with compliance

The transition from cooking over an open fire to using an advanced cookstove represents a large change in an activity that usually takes up a considerable part of the day, can be part of the social fabric of the village and associated with particular beliefs and superstitions. Nevertheless, we found high levels of cookstove adoption in our exploratory RCT in Ntcheu and in an acceptability study in Lesotho. With careful community engagement, support from community leaders and training in the use of the stove, initial innovation adoption is therefore likely to be successful. We expect that the advantages of the advanced cookstove in terms of reduced time needed for cooking, fuel consumption, smoke emissions and improved safety will help maintain high levels of use. The RESPIRE study helped to sustain high levels of compliance by providing a maintenance and repair service for the Plancha stove (15). We will do the same in this study. We will also assess compliance with the intervention through self-reporting and by Stove Use Monitors in 10% of intervention households. Compliance with the protocol and SOPs by field staff will be maximised through training events to include GCP training, and periodic quality control audits.

Likely rate of loss to follow-up

We will work to minimise loss to follow-up through active community engagement, responding promptly to trial-related difficulties, repairing and replacing stoves as needed and providing additional benefits to the participating villages (e.g. mobile phone access).

SAFETY MONITORING AND ADVERSE EFFECTS

Potential risks to the safety of the trial participants

Trial households will be recruited from populations living in often poor conditions in Malawi who live with relatively high day-to-day risks. The open fire that control households will continue to use is one contributor to these risks. The advanced cookstove is likely to be safer than the open fire since it contains the fire in a stable construction with outside surfaces that are cool to touch during use. All participating villages will benefit from a mobile phone with airtime and guaranteed availability of antibiotics for pneumonia treatment. Overall we expect participation in the trial in either the intervention or control group will reduce risks to participants.

Risk assessment

See appendix A for full risk assessment.

Data and safety monitoring

See Trial management section.

Adverse event reporting requirements

An adverse event (AE) is any unfavorable and unintended sign, symptom, syndrome or illness that develops or worsens during the period of observation in the study. A Serious Adverse Event (SAE) is an adverse event following the intervention that results in a) death, b) a life-threatening adverse event, c) hospitalization or prolongation of an existing hospitalization, d) disability or incapacity, e) congenital anomaly in the offspring of a participant.

The advanced cookstove intervention we will be using in this trial is a non-medical intervention and is not known to increase the risk of any adverse event. It is a particularly low-risk intervention that offers potential safety benefits (e.g. reduced risk of burns and fires). Nevertheless, we will collect data about adverse events. Data about AEs that are not serious will be collected at the routine three monthly field visits. Study participants will be asked to report SAEs immediately to the trial coordinating centre. The trial coordinating centre will collect details about the SAE using a proforma in accordance with a specific SOP. This information will then be passed immediately to Kevin Mortimer and Stephen Gordon who will conduct a causality assessment (not related/improbable, possible, probable, definite), assess seriousness and expectedness, take any appropriate medical action and inform COMREC and LSTM REC of any events deemed related to the trial intervention within 7 days of knowledge of the event. All other SAEs will be reported as part of an annual report to COMREC and LSTM REC. All SAEs will be followed to resolution.

DATA COLLECTION AND MANAGEMENT

This is described in the section on outcome assessments. An electronic data collection and management system will be used with in-built consistency, range and logic tests to maximize quality. The data collection tools will be GPS enabled allowing us to map the location of data collection episodes using Google Earth Pro. This will facilitate internal quality control checks and independent monitoring visits.

Progress and final reports
Progress reports will be sent annually with a final report at the end of the trial to the MRC, endorsed by the TSC. This will be submitted using the template in Appendix 3 of the MRC GCP guidelines (http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002416).

SAMPLE SIZE

The sample size has undergone much consideration as this project has developed as explained and justified below together with our final sample size plan:

Original sample size assumptions

Following feedback from the JGHT Panel in December relating to our outline proposal we substantially increased the sample size to a) account for a change in design to village-level cluster randomization, b) reflect the effect size seen in the RESPIRE trial of a cookstove intervention on severe pneumonias (15) and c) use the latest available estimates of a health centre IMCI pneumonia diagnosis rate of 9 per 100 child-years from Karonga, Malawi.

In our full application we considered the potential impact of the introduction of pneumococcal vaccination on baseline pneumonia rates and took into account informed estimates suggesting around a 20% reduction in pneumonia rates could be expected in the Malawi-specific context (Neil French personal communication). Trials of the 9-valent pneumococcal vaccine in Soweto (19) and The Gambia (20) found a 17% (95% CI 4 to 28) and 37% (95% CI 27 to 45) vaccine efficacy on first episodes of radiologically-confirmed pneumonia in children respectively. There was higher vaccine efficacy on pneumococcus-specific disease in both trials but it is the overall impact on all-cause pneumonia that is most relevant for our trial. The 2009 Cochrane review of pneumococcal conjugate vaccines on invasive pneumococcal disease and X-ray defined pneumonia in young children pooled data from 11 publications and found the vaccine efficacy on WHO X-ray defined pneumonia was 27% (95% CI 15 to 36) and clinical pneumonia was 6% (95% CI 2 to 9) (21). In our original power calculation we allowed for a greater than expected impact of pneumococcal vaccination –a 45% reduction in pneumonias – to allow for unpredictable factors such as herd protection effects from nationwide vaccination. We therefore used the conservative assumption that only 5% of control group children will develop pneumonia of sufficient severity to require treatment at a health centre every year.

The effect size included in the original power calculation was a 20% reduction in pneumonia risk that approximated the reduction in physician-diagnosed pneumonia seen in RESPIRE (RR 0.84 or 0.78 after multiple imputation). Importantly we powered the trial to detect a smaller effect size than was seen in RESPIRE on severe pneumonias (RR 0.67). We used a conservative between-cluster coefficient of variation of 0.1. Furthermore the intervention we plan to use is an advanced cookstove that reduces smoke emissions and exposures by 80 to 90% while the *plancha* stove used in RESPIRE just vented emissions to the outdoor environment; there is therefore greater potential for impact with the advanced cookstove than was seen with the *plancha*.

Based on these various considerations we originally proposed a sample of 59 villages per group each with an average of 77 children (allowing for 10% loss to follow up from the average of 85 children per village) followed for an average of 1.7 years (affected by age of child at enrolment) and this sample size provided 80% power to detect a 20% reduction in the risk of pneumonia in the intervention group from 5% to 4% per annum and 90% power to detect a reduction to 3.8% (α=0.05). With 118 villages in total each with an average of 85 children per village, and 1.7 years average follow up this provided a *potential* total of just over 17,000 child years of follow up.

Final sample size

The sample size has been re-considered in the light of improved data now available from the currently planned CAPS sites in Chikhwawa and Karonga. Some of the assumptions underpinning the sample size calculations have also been re-considered.
The total number of children under the age of 5 years in Chikhwawa was estimated as being 5,027 in 2008. It is considered reasonable to assume that this number has now increased to approximately 5,600. There are 50 villages (clusters) in this district, giving an average number of children per cluster of 112.

The total number of children under the age of 5 years in Karonga was estimated recently as being 4,750. It is considered reasonable to assume that this number has increased to approximately 5,000. There are 278 villages (clusters) of 20-30 households in this district, giving an average number of children per cluster of 18.

This disparity in the average cluster size between the two study districts has implications for the power of the study. A paper by Eldridge, Ashby and Kerry (22) found that variation in cluster size reduces the statistical power of a cluster randomised trial - and that this effect increases as the variation in cluster size increases.

As the clusters in Karonga are relatively small, they can be combined to form larger clusters. To do so would appear to be counter-intuitive as cluster randomised trials work best with a large number of small clusters. However, this has to be weighed against the negative impact of having a large range of different cluster sizes. A compromise is needed between these two conflicting influences on the statistical power of this study.

The sample size calculations were re-worked extensively to identify a "best" compromise. In this context, "best" was defined as creating sufficient clusters to produce a feasible design structure (manageable number of clusters to be randomised) and to provide acceptable statistical power.

The compromise recommended is to collapse the current 278 clusters in Karonga to just 100 clusters. Combined with Chikhwawa this will provide a total of 150 clusters (75 clusters per intervention group). The total number of children in these clusters will be approximately 10,600. The average number of children per cluster will now be 70.7.

Assuming that actual cluster sizes range between 50 and 150 (a conservative estimate), the coefficient of variation in cluster size would be in the region of 30 - 35%. In which case, the paper by Eldridge, Ashby and Kerry recommends that the intra-cluster correlation (ICC) value assumed for the sample size calculations be increased by 20%.

The outcome measure for the CAPS study is the number of pneumonia cases in children under the age of 5 years recorded in each cluster over the two years of the study period. No loss to follow-up is now assumed in the sample size calculation, as the eligible number of children in an individual cluster can reasonably assumed to be constant. For each child who reaches their 5th birthday and hence becomes ineligible for the study, they will be replaced by (at least) one newborn child.

For the same reason, the number of child-years of follow-up in each cluster will be the number of children in the cluster at the start of the study period multiplied by two.

As previously, a conservative value of 0.1 has been assumed for the ICC (intra-cluster correlation). In line with the recommendation of Eldridge, Ashby and Kerry, this was increased by 20% to 0.12 for the sample size calculation.

A total of 150 clusters containing a total of 10,600 eligible children randomised in equal numbers to the two intervention groups will provide, over the whole study period, 21,200 years of follow-up and 90.3% power to detect a reduction in the (annual) risk of pneumonia from 5% in the control group to 4% in the intervention group (proportionally, a 20% reduction in risk), assuming an effective ICC value of 0.10 and a coefficient of variation in cluster size of 30-35%.

The same sample size will provide 80.4% power to detect a reduction in the (annual) risk of pneumonia from 5% in the control group to 4.125% in the intervention group (proportionally, a 17.5% reduction in risk), under the same assumptions.

Additional justification for sample size for air pollution exposure and lung function sub studies

Incidence-exposure analyses (children)
2000 children will be included in the incidence-exposure study and followed up until the end of the CAPS study period, giving an expected total of 2000*2.0= 4000 years of follow-up ("exposure"). Based on the work of Fullerton et al (6), it will be assumed that the mean levels of CO in children will be 16.31 (22.77) ppm. The anticipated annual pneumonia incidence rate averaged across the trial arms is 4.5%, which corresponds to an expected incidence rate of 7.53% per child. Assuming a Poisson model, the expected total number of pneumonia episodes is 150 – but as 5 children are predicted by this model to have more than one episode, the expected number of children who will experience at least one pneumonia episode will be 145. On a simple comparison of the 145 children who will experience pneumonia against the 1855 who will not, this study will have 90% power to detect a mean difference of 6.53 (40%) ppm or greater in mean CO levels between these two groups. If it is necessary to match each child who experiences pneumonia with just one child who does not on one or more confounding factors, the minimum detectable difference between the two groups will be 8.92 (55%) ppm.

Respiratory symptoms and lung function analyses (adults)
a) Baseline spirometry measurements will be recorded for the 2000 adults aged 18 and above recruited into this sub study (replicating the sample size taken for the BHS and BOLD study currently ongoing in the urban setting of Chilomoni ward) along with relevant demographic/clinical characteristics considered to potentially influence the development of chronic respiratory disease. Participants will be stratified into two age groups: 18-39 years and 40 years or above. If 500 males and 500 females (total 1000 individuals) fall into each age group, an estimate of obstructive lung disease prevalence in each gender / age stratum will be obtained with a precision (95% CI) of ±2.6 to ±3.8% (assuming a prevalence of 10 to 25%). Allowing for unequal age and gender distributions, refusals and inability to provide spirometry measurements of acceptable quality, a sample of just 300 participants in any one gender / age stratum will provide an estimate of obstructive lung disease prevalence in this stratum with a precision (95% CI) of ±3.3 to ±5.0% (again assuming a prevalence of 10 to 25%) [this minimal sample size is informed by the BOLD protocol].
b) The same 2000 adults will then be followed with repeated spirometry measurements for two years (the full duration of inclusion in CAPS). Assuming an ICC of up to 0.25 for possible clustering effects within villages, this study will have 90% power to detect a correlation between CO/particulate matter exposure and change in FEV1 level of 0.102 (or greater) in both age groups combined and 0.144 (or greater) in each age group separately.

ANALYSIS

Statistical analyses

All primary analyses will use intention to treat principles; secondary per protocol analyses will also be done. Generalised estimating equation modeling methods will be used to evaluate the primary response variable (occurrence of pneumonia episodes in children aged <5 years during study period), adjusting for clustering effects within villages; time to each event will be analysed using (multiple event) Cox regression methods, while number of events per child will be analysed using Poisson, negative binomial regression or logistic regression methods as appropriate. Terms will be included in these models for treatment arm, cluster (village) and important confounders and covariates (*e.g.* baseline characteristics) considered *a priori* to strongly influence outcome.

Incidence-exposure analyses (children)

Initially, the mean CO levels of those children who did and who did not experience any pneumonia episodes will be compared using linear regression models. The association between personal exposure to CO and actual number of pneumonia episodes will then be assessed using Poisson regression analyses with (logarithm of) time of follow-up ("exposure") as an offset; exposure response curves will be constructed for personal exposure to CO against pneumonia episodes. Finally, if sufficient pneumonia episodes are observed, Cox regression models will be used to evaluate time between episodes, allowing for multiple episodes per child. All analyses will include appropriate adjustments for important factors and covariates.

Respiratory symptoms and lung function analyses (adults)

(a) The BOLD data will be analysed in accordance with the BOLD protocol (www.boldstudy.org). Response rates, the characteristics of the study participants, and COPD prevalence estimates will be reported with 95% CIs. A logistic regression model will be used to explore factors associated with COPD prevalence.

(b) Longitudinal spirometry data will be analysed using the using the linear random-intercept models proposed by Romieu et al, with adjustment for potential confounders including age, gender, height, location, socioeconomic status, smoking status, passive tobacco smoke exposure and HIV status where known (15). The extent to which personal exposures to CO and particulate matter explains the change in FEV1 over time will be explored.

All analyses will be performed using the Stata v13 statistical software package.

A detailed statistical analysis plan will be presented to and approved by the Data Monitoring Committee (DMC) prior to trial commencement.

Interim analysis plan

One blinded interim analysis will be carried out by the independent statistician on the DMC halfway through the follow-up period. The aims of this analysis will be to determine a) whether there are grounds to stop the trial for safety or efficacy (the Peto-Haybittle rule ($p<0.001$) will be used to guide stopping for efficacy) and b) whether the incidence of pneumonia episodes being observed is compatible with the assumptions made in the sample size calculations detailed above. If there is concern that the observed overall event rate is very different from that anticipated, a blinded revision of the total sample size estimate will be done using the methods advocated by Gould (23,24); this simple formula is based on the predicted and current (*i.e.* at time of the interim analysis) proportion of participants overall who have experienced a pneumonia event, and has a considerable advantage in that it "preserve[s] the power [of the study] and [does] not affect the type I error rate materially" (25). If subsequently there is concern that the observed overall event rate is much higher than anticipated and hence there might be concerns over safety, a blinded comparison of the event rates in the two study groups will be carried out using the methods advocated by Wassmer et al (25) and by Posch and Bauer (26).

Planned subgroup analyses
We will estimate benefit in relation to reductions in household air pollution, personal exposure and stove use in the subgroups for which we have those data.

Methods for protecting against sources of bias
We will use cluster randomisation, allocation concealment and a control group. An open design is unavoidable given the intervention. To minimise the risk of bias from a non-blinded study we will a) provide specific training to fieldworkers to ensure participants are treated in the same way irrespective of trial arm; b) schedule the same frequency (3-monthly) of field visits to intervention and control villages to repair/replace cookstoves and mobile phones if necessary, troubleshoot trial-related problems; c) collect primary outcome data in the same way for intervention and control villages; d) provide training to local healthcare workers about how to make an IMCI diagnosis of pneumonia, the importance of carrying out assessments and treatment based on clinical need and without enquiring about trial allocation to achieve blinded assessment of the primary outcome e) submit the evidence upon which all pneumonia diagnoses are made for review by a fully blinded Independent Endpoint Review Committee.

ETHICAL ASPECTS

We will request ethical review of the trial protocol and other documents by the College of Medicine Research Ethics Committee (COMREC) in Malawi and LSTM Research Ethics Committee (REC) in the UK. The trial will not commence until we have ethical approval from both committees.

Participant information and consent

Following community sensitisation events and distribution of written information sheets in English, Chichewa or Chitumbuka, consent to conduct the study in the cluster will be obtained from a village-level representative (see appendix B)

All participants will be given a written information sheet using the University of Malawi College of Medicine template (see appendix B) to read in English, Chichewa or Chitumbuka. This will be read out to all participants to facilitate discussion and ensure that inability to read is not an obstacle to participation.

Written informed consent will be obtained from all participants (see appendix B). A mark witnessed by someone independent to the study will be accepted where participants are unable to sign.

The informed consent process will emphasise that participation in the trial is voluntary, that consent to participation can be withdrawn at any time, without giving a reason and without this affecting their current or future medical care or benefits to which the participant is entitled. No trial-related interventions will be conducted prior to obtaining informed consent.

Participants will be informed about any relevant information about the intervention that becomes available during the course of the trial. Where necessary, the participant information sheet and consent form will be amended and, following ethical approval, renewed consent to continue participation requested.

TRIAL MANAGEMENT

Trial protocol review and registration

The protocol will be submitted for review by The Lancet and the final approved protocol will be registered with Current Controlled Trials Ltd (http://www.controlled-trials.com/) and published in an open access format.

Arrangements for day-to-day management

A full time on-site qualified and experienced Clinical Trials Manager (CTM) will be appointed and have responsibility for day-to-day management issues, supervision of field workers and data manager, protocol compliance, security of the randomisation process, recruitment, data management, problem identification and resolution, distribution and maintenance of trial materials, budget control and production of annual progress reports. The CTM will be supported by a middle-grade clinician (Malawian graduate), Kevin Mortimer (KM) and Stephen B Gordon (SBG).

A Trial Management Group (TMG) led by the CTM will be established to manage the trial on a day-to-day basis and will include the middle grade clinician, KM or SBG and the senior fieldworker(s). The TMG will meet at least monthly and will monitor trial conduct, progress (including recruitment, withdrawals and losses to follow-up), adherence to the protocol and SOPs, CRF completion, accuracy and completeness of data collection, data validity and where necessary act to safeguard trial participants and quality standards. The TMG will receive logistic and infrastructural clinical trials support from MLW and The Wellcome Trust Tropical Centre in Liverpool.

Responsibilities of the co-investigators

The investigators are a collaborative group of international experts in household air pollution, public health, clinical trial design and implementation, biostatistics, health economics, qualitative research and improved cookstove development and dissemination. We will be drawing on valuable experience gained from conducting the RESPIRE trial in Guatemala; wide ranging knowledge, skills and expertise from academic groups at LSTM, the Universities of Liverpool, London, California and Malawi; considerable local knowledge and ability to implement research and aid programs in challenging environments. All applicants have been involved in the trial design. Specific responsibilities during the implementation, analysis and dissemination phases will be: **Stephen B Gordon** (SBG) and **Kevin Mortimer** (KM) will share Principal Investigator responsibilities and, together with a dedicated local clinical trials clinician, will provide full time on the ground clinician oversight and support for the CTM. SBG has lived and worked in Africa for 15 years and has particular expertise in field, clinical and laboratory research on the adverse effects of biomass smoke exposure on health and alveolar macrophage function and pneumococcal disease. KM has run clinical studies in respiratory medicine in the UK, conducted pilot work in Ntcheu, and has experience of working in Queen Elizabeth Hospital in Blantyre. He will commit 50% WTE to trial implementation, management and oversight activities with flexibility to work from the UK or Malawi as necessary.**Moffat Nyirenda**, Associate Director of MLW, will lead on high-level trial implementation activities and ensuring the trial delivers benefits in line with MLW research strategy. **Anja Terlouw** leads and conducts epidemiological research at the MLW Chikhwawa field site and brings particular local knowledge, skills and expertise that will help the successful implementation of the trial at this site and ensure the trial provides added value to research activities there. **Jonathan Grigg** (JG) is an experienced paediatrician with expertise in the management of childhood pneumonia and research expertise in air pollution exposure assessments that includes fieldwork in Africa involving induced sputum macrophages as exposure biomarkers. He will lead a working group on household air pollution and personal exposure to deliver this aspect of the proposal. **Nigel Bruce** (NGB), **John Balmes** (JB) and **Dan Pope** (DP) bring wide-ranging benefits to the trial through their experience of conducting the RESPIRE trial in Guatemala. NGB and JB have played key roles in the GACC Health Working Group (NGB co-chair), the World Health Organisation Department of Public Health and Environment (NGB) and other international organisations with particular strategic relevance to disseminating the results of this trial at high level meetings and ensuring the findings inform policy and decision makers. NGB

and JB will lead on these activities. JG and JB will establish the Independent Endpoint Review Committee. DP will lead on updating our systematic review to include the trial findings. **Brian Faragher** has extensive experience as the statistician for numerous large trials in Africa and elsewhere. He will be the statistician for this trial, oversee the establishment of the DMC and use opportunities provided by this trial to build Malawi-based capacity in statistics. **Lesong Conteh** brings expertise in health economics and health system research in sub Saharan Africa and will lead this on this aspect of the trial. **Margaret Matinga** will conduct the qualitative work and is particularly well placed to do this as a Chichewa speaking Malawian woman (highly relevant for the interviews with female villagers) with a PhD in energy anthropology.

Responsibilities of the staff employed on the grant
The CTM will have the responsibilities set out in above. A dedicated local clinical trial clinician will, together with SBG and KM, provide full time accessible clinician oversight and support for the CTM. The fieldworkers will undertake community engagement and support activities, baseline mapping of villages, recruitment, implementation of randomization schedule, collection of baseline and follow up data and data entry into electronic CRF. The data manager will train and support fieldworkers in the use of the electronic CRF, manage and maintain the data collection and management systems used, generate summary datasets when needed for the DMC, produce a full cleaned dataset at the end of the data collection period for the trial statistician. We have included a contribution to LSTM/MLW administrative, governance and finance support.

Research governance arrangements
Trial oversight committees (TMG, TSC and DMC) will be established. The trial will be run according to the MRC Guidelines for Good Clinical Practice in Trials. MLW/LSTM will perform an initial start up and then annual GCP compliance visits to ensure and document complete compliance. All trial staff and investigators will protect the rights of the trial's participants to privacy and informed consent. Internal quality control monitoring will be conducted 3-monthly to ensure understanding of protocol and SOPs, protocol and GCP compliance, conduct source document (health passports) verification and confirm all participating households have given written informed consent. Participation in the trial involves low risk interventions and procedures that are not expected to increase the risk of Serious Adverse Events (SAE) above the normal baseline for poor people in Malawi. All SAEs will be reported to the TSC and DMC and via onward reports to COMREC and LSTM REC. Trial participants and trial staff will be covered by LSTM indemnity and insurance. The Principal Investigators will maintain all records and documents regarding the conduct of the study and retain these for at least 7 years or for longer if required. The Trial Master File and trial documents shall be finally archived at secure archive facilities at LSTM or MLW.

Data Monitoring Committee
The DMC will be independent of the investigators, sponsor and funder with an independent chair (Professor Stephen T Holgate CBE) and independent statistical support. The DMC will meet initially before the trial commences to review the protocol and agree Terms of Reference (TOR) and then once more when half the potential follow-up experience has accrued to review indications to stop the trial for efficacy, safety or futility. The DMC will report to the TSC.

Trial Steering Committee
A TSC will be established to provide overall supervision of the trial and ensure the trial is delivered in accordance with the MRC's Guidelines for Good Clinical Practice.The TSC will have an independent chair (Professor Anne E Tattersfield OBE), include 2 other independent members (independent membership being the majority), SBG and KM. Representatives of the Trial Funder and Sponsor will be invited in advance to all TSC meetings, receive papers and minutes. The TSC will initially meet face-to-face prior to trial initiation to agree the trial protocol and TOR (aligned with MRC GCP guidelines (http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002416) and then convene at least annually thereafter through conference calls and 1 further face-to-face meeting if needed. KM in association with the chair will take responsibility for calling and organising TSC meetings.

ECONOMIC EVALUATION AND HEALTH SERVICE RESEARCH

An economic evaluation will be conducted to identify the incremental costs and benefits to health care providers and households associated with using cookstoves compared to open fires. Cost effectiveness ratios will be presented from 3 perspectives: i) intervention costs alone; ii) potential costs/savings to health providers (MoH); iii) potential societal costs/savings.

Costs to healthcare providers and households associated with cookstove use will be collected as part of routine trial data collection, with supplementary cost and resource use data collected where necessary. In addition, the economic costs to providers of treating 150 inpatient and 150 outpatient visits in which pneumonia is the primary diagnosis will be calculated from a representative subsample of health facilities.

A standardised costing template will be used in all the sites to record resource use associated with personnel, drugs, materials and supplies, equipment, transport, utilities and buildings. A standard ingredients approach will be used which involves costing the quantity used and the value of each unit of input needed to provide an inpatient or outpatient visit. Effects will be based on trial outcomes. Specifically, the cost per episode of childhood pneumonia averted and Disability Adjusted Life Year (DALY) saved will be calculated.

A threshold analysis will explore at which point the intervention is no longer cost effective at changing epidemiological and economic parameters. Probabilistic sensitivity analysis will be conducted to investigate the uncertainty surrounding model assumptions and the key drivers of outcomes.

Qualitative analyses will explore quality of life attributes, attitudes, beliefs and behaviours that may be relevant for scale-up of the intervention. Specifically we will identify opportunities for change, motivations and barriers to change and skills required to support the various change (adoption) stages, under themes of: understanding cultural values of the fireplace; gender dynamics in technology adoption; food preparation and taste; knowledge and cultural interpretations of respiratory infections; actual and perceived affordability; functional and desirability (*e.g.* convenience, aesthetics and prestige) perceptions.

CONSUMER INVOLVEMENT

Local health service involvement

We will work with local health service leaders and providers to ensure this trial does not have local health service cost implications. Assessment of the primary and secondary health outcomes for the trial will not demand additional work beyond good standard practice *i.e.* use of the IMCI pneumonia protocol for patient assessment and documentation of the diagnosis and treatment in the patient's health passport. To help achieve high standards of clinical assessment and documentation we will provide training in use of the IMCI pneumonia assessment protocol for paediatric healthcare workers at 6 monthly training events (which will include additional educational activities *e.g.* case discussions) at local health facilities. We will use these opportunities to raise and maintain awareness of the trial, the importance of fully documenting pneumonia diagnoses and severity assessment in patients' health passports avoiding enquiry about trial arm allocation.

Planned ongoing involvement of community groups in the trial

We plan ongoing involvement of trial participants, other community members and community leaders through trial set-up, implementation and dissemination phases. Specifically there will be community engagement meetings led by field workers before trial initiation to obtain input into trial implementation plans and wording of participant information and consent forms, there will be meetings every 3 months during implementation with an open agenda and when the study results are available these will be presented and discussed at community meetings in all included villages.

REPORTING, DISSEMINATION AND NOTIFICATION OF RESULTS

How the results of this trial will be used

High quality clinical trial evidence about the health and economic impacts seen when households adopt advanced cookstove technologies is needed to inform policy and decision makers across commercial, health, development and community sectors at local, regional and international levels. The results of this trial will be relevant to local policy makers in Malawi who will have new efficacy, economic, acceptability and uptake data to guide decisions about funding advanced cookstove programmes for improving child health; to regional commercial, non-governmental (NGO) and governmental organisations in sub Saharan Africa making and distributing cookstove solutions with uncertain health benefits; and to international (*e.g.* WHO) decision and policy makers by contributing new evidence about health, exposure-response and economic impacts of an advanced cookstove intervention of broadly generalisable relevance to areas of the world where biomass fuel use is common. We have established local (*e.g.* community leaders), regional (*e.g.* commercial, NGO, MoH) and international (*e.g.* WHO and GACC) links that will help us disseminate the trial findings effectively at all levels to a wide range of stakeholders, policy and decision makers.

How the results of the trial will be generalisable beyond the immediate research setting of the trial

The key question this trial will answer is whether an intervention that substantially reduces biomass smoke exposure compared to open fires can prevent pneumonia in children under the age of 5 living in poverty in a developing country. There is good evidence from the RESPIRE trial that the major determinant of health benefits from a cookstove intervention is the extent of biomass smoke exposure reduction rather than the intervention *per se* (15). Although we will be studying a specific stove our findings will be applicable to biomass smoke exposure reduction interventions more generally given that smoke exposure reduction is the mechanism of beneficial effects. Our findings will also be generalisable beyond Malawi; should we see a reduction in childhood pneumonia from an effective biomass smoke exposure reduction intervention the implications of this finding will be relevant to people throughout the developing world who cook over open fires.

Links which are likely to improve the likelihood of successful implementation of results of the trial.

We are part of an established network of local, national and international links that will facilitate the successful wide dissemination and implementation of the results of the trial. This network includes grass root community representatives, NGOs, local healthcare workers, ACE, ARC, Malawi MoH, COM, MLW, WHO and GACC Health Working Group.

Publication policy

The trial findings will be presented at international conferences and published in peer-reviewed journals with open access.

Approach for managing, preserving and sharing data generated

In line with The Wellcome Trust Data Sharing Policy and Guidance and The MRC Data Sharing Policy we will make our full research database publically available once we have published our findings. The only limits to data sharing will be to safeguard research participants' confidentiality. We will provide a link from the LSTM website to study-related resources including the protocol, participant information sheets, standard operating procedures, publications and the database. These resources will be maintained in this low cost format (covered by budget) for the long-term.

Disseminating results to the public

We will communicate the findings of our work to participating villages in Malawi through a series of community engagement meetings. We will present our work through other community engagement activities held by the College of Medicine, MLW and LSTM in Malawi and the UK. We will actively participate in DFID, MRC and Wellcome Trust public engagement opportunities available to us.

Intellectual property/commercial exploitation

We will follow customary academic practice and the Liverpool School of Tropical Medicine's (LSTM) standard approach to managing project related intellectual property which is that ownership will reside with the institution that generates the same. LSTM has extensive experience in managing similar projects such as the EU funded AntiMal project www.lstmliverpool.ac.uk/research/major-research-projects/antimal/) and the BMGF funded Innovative Vector Control Consortium (www.lstmliverpool.ac.uk/research/major-research-projects/ivcc/) and has clear objectives to make the outcomes of its research available, as soon as is practicable, for the benefit of the poor in developing countries. Wherever possible, outcomes from the trial will be published and made available on an open access basis and any potential exploitation of the results will be managed by LSTM.

Although the trial will use a specific commercially-produced cookstove as the means of achieving the intervention, the key intervention of interest is the reduction in biomass smoke exposure rather than the cookstove *per se*. Positive outcomes from this trial could be commercially exploited by manufacturers of other advanced cookstoves that substantially reduce smoke exposure. This could stimulate investment in further innovation and improvement in affordable, acceptable and accessible cookstove technologies and a thriving market in clean cookstoves. These beneficial effects would therefore fully align with the objectives of the United Nations Foundation-sponsored Global Alliance for Clean Cookstoves, which is "a public private partnership that seeks to save lives, improve livelihoods, empower women and combat climate change by creating a thriving global marker for clean and efficient household cooking solutions" (www.cleancookstoves.org/). None of the potentially commercially exploitable results will be based on tissues or samples derived from participants.

PATHWAYS TO IMPACT

We are part of an established effective network of local, national and international partners (BREATHE-Africa consortium) committed to improving health and reducing poverty in sub Saharan Africa and other less developed areas of the world. This trial will deliver new high quality evidence regarding health, societal and economic effects seen when households adopt advanced cookstove technologies. There are pathways to beneficial impacts in the locale of the study, in the sub Saharan Africa region and internationally:

In the locale of the study, we will achieve economic, societal and environmental impact by engagement with research participants and staff, predominantly within the *modus operandi* of the study.
At regional level we will achieve health policy and commercial impact during the life of the grant by planned engagement with Malawi Ministry of Health and NGO partners.
At international level, the results of the trial will inform international policy through national governments, the Health Working Group of the Global Alliance for Clean Cookstoves [Prof Stephen B Gordon (SBG) is a member and Prof Nigel Bruce (NGB) is co-Chair] and WHO (NGB seconded).

Impact in the locale of the study

Economic Impact: This study will take place among very impoverished people. All participating households will receive benefits from taking part including two efficient-burning cookstoves either at the beginning or end of the trial. Reduced fuel consumption will translate to less time spent gathering wood and the potential for alternative profitable activity. We will maximise the economic impact of these interventions by working with carbon trading partners in Malawi to secure carbon credits for villages beyond the trial implementation phase. We have experience of community engagement and carbon trading while measuring domestic exposures and in a pilot stove intervention evaluation.

Societal: The study will ask for changed cooking behaviour and will have a high local profile. Discussion around health, pollution, reduced burns risk and diet offer the opportunity for diverse educational messages including diet, access to health care (reinforced by phone and antibiotic availability) and the health effects of cooking smoke. The telephone and regular visits provided to each village will increase communication and access generally. Margaret Matinga has particular expertise in this area in both South Africa and Malawi. We will conduct a series of village-level events ("msonkhano" is the accepted means of community announcement and discussion) to maximize the local benefits of the trial.

Environmental: The study will directly reduce the amount of wood burned and will therefore reduce environmental destruction. Extensive work by Concern Universal has indicated that cookstove uptake is highest in villages with limited wood availability.

Local staff: Local people will be employed on the project and other local people involved indirectly. The training and experience gained (including specific training in clinical trial design, conduct and analysis) will lead to improved work opportunities in the future, particularly in Non-Governmental Organisation (NGO)-funded poverty alleviation programmes. Further, there will be immediate financial benefits for individuals receiving a salary and their families. In our previous studies (WT grant 2008, pilot study 2010) field workers in air monitoring or cookstove studies adopted altered cooking practice and health care seeking behaviour in their own homes.
These local impacts will all be achieved as a direct result of protocol implementation (including the Focus Group Discussions of the economic evaluation) and will be monitored by Dr Kevin Mortimer (KM).

Sub Saharan Africa Regional impact

Women and children living in poverty in developing countries
The primary outcome sought is a reduction in childhood pneumonia from an effective biomass smoke exposure reduction intervention. Secondary outcomes will include other health benefits, economic advantage, educational benefit and increased societal engagement with innovation. Increased awareness of the primary goal and the potential secondary benefits will be achieved by quality video presentation in a format similar to BBC News website articles targeted at the NGO and professional Malawian community. We will commission a video team in year 1 to film a piece which will describe the background, study questions and time-line of the study. This video will be used in website, face-to-face and webinar presentations to engage stakeholders. Experience in other sectors (solar power, wind power) indicates that urban-based, web-browsing professional Malawians are influential in their home village communities. Further, the Partnership for Clean Indoor Air (PCIA) of which we are members, has made increased use of webinar and web-based media to share experience among the energy sector NGO community. We have used video web-based media in the NIHR within the UK (SBG, Liverpool BRC) and SBG will deliver on this goal with help from Malawi Liverpool Wellcome Trust (MLW) and LSTM public engagement officers. We will maximize the dissemination and impact of trial findings regionally through full engagement with the press including press releases and media interviews and translation of research findings into regionally appropriate formats with lay summary information on accessible websites.

Public Sector
We have experience of outreach Continuing Medical Education (CME) activity in Malawi, both in the public sector and private sector. These have been welcomed in the past when operated from the MLW programme. KM and SBG will provide regular supportive training to local healthcare facilities to deliver CME at each centre. Material will include the use of the Integrated Management of Childhood Infection (IMCI) pneumonia assessment protocol as well as core medical topics.

Business/Industry
The Philips stove that has been chosen for this project will be keenly watched by the sector; stove production has been sponsored in the sub Saharan Africa region in anticipation of a sustainable production and sales pipeline. Our study data will set the standard required of less expensive stoves and these data will be released when available and in conjunction with the WHO Indoor Air Standards Committee (NGB, Chair).

Third Sector
NGOs implementing cookstove programmes require exposure-response data regarding the health effect of biomass smoke reduction strategies. We will deliver this impact by continued engagement with relevant NGOs and PCIA. We will attend the PCIA annual conference and offer a webinar with presentation of our data when available.

Higher Educational Institutions
The College of Medicine and MLW have a strong track record of successful public engagement programs to increase public awareness and understanding of science, economic and societal issues. We will engage fully with these activities that include public lectures, exhibitions, open days and conferences.

Impact on international policy
The trial findings have a clear pathway to impact on international policy through our established high-level involvement with policy and decision making organisations:

WHO Indoor Air Quality Standards: NGB chairs this advisory panel and will ensure that our data impact on future revisions of the standards due to be published in 2012.

Global Alliance for Clean Cookstoves Health Working Group (HWG): SBG (member) and NGB (Chair) serve on the HWG in order to advise research strategy to maximize health benefit in indoor air pollution initiatives. The HWG has been charged with advising Wellcome Trust, Gates, MRC, DFID, NIH and other major donors. The alliance is mobilising expertise to assess options for market development and innovative finance in partnership with governments, NGOs and private partners worldwide that will provide a framework for scaling up interventions based on outcomes of trials like this. Our trial maps directly onto research priorities identified by the HWG in 2011.

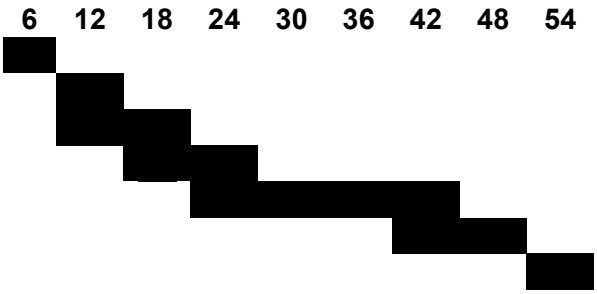
Carbon Finance Initiatives: Carbon credits offer a sustainable method of delivery for future cook stove initiatives. We will ensure that our project video and data reach Carbon Financing groups via NGOs in Malawi, PCIA, Global Alliance for Clean Cookstoves and WHO globally.

Measures of success of our impact activities

We will assess the success of our impact activities through qualitative evaluations conducted at village-level by Margaret Matinga, quarterly community engagement discussion forums, feedback questionnaires at project events, stakeholder (public sector, business, third sector and other) surveys and website statistics. Impact on international policy will be assessed using conference and publication citations linking our trial findings to policy and public health decisions.

SUMMARY TIMELINE

Task	Description
1	Ethical and other regulatory approvals
2	Staff recruitment
3	Practical trial set up activities
4	Mapping, recruitment and randomisation
5	Follow up and study completion
6	Data analysis
7	Report writing and dissemination activities





TRIAL FUNDING ARRANGEMENTS

Funders
DfID, Medical Research Council, Wellcome Trust

REQUIREMENTS AND JUSTIFICATION OF RESOURCES

Staff

A full time on-site qualified and experienced Clinical Trials Manager (CTM) will be appointed and have responsibility for day-to-day management issues, supervision of field workers and data manager, protocol compliance, security of the randomisation process, recruitment, data management, problem identification and resolution, distribution and maintenance of trial materials, budget control and production of annual progress reports. A dedicated local trial clinician will, together with Stephen Gordon (SBG) and Kevin Mortimer (KM), provide full time accessible clinician oversight and support for the CTM. A full time data manger is needed to train and support fieldworkers in the use of the electronic CRF, manage and maintain the data collection and management systems used, generate summary datasets when needed for the DMC, produce a full cleaned dataset at the end of the data collection period for the trial statistician. 15 fieldworkers will be needed to undertake community engagement and support activities, baseline mapping of villages, recruitment, implementation of randomisation schedule, collection of baseline and follow up data and data entry into electronic CRF. This includes some float for sickness, maternity leave and other possible threats to the availability of this body of staff critical for day-to-day trial implementation activities. A 50% WTE Malawian research assistant will conduct the health economics work under the supervision of Lesong Conteh. We have also included support for research governance (10% WTE) finance (10% WTE) and administration costs at LSTM (25% WTE) and MLW (100% WTE).

Staff – directly allocated posts

SBG and KM will share PI responsibilities with 5% and 50% WTE commitment respectively to trial implementation, management and oversight activities with flexibility to work from the UK or Malawi as necessary. Other Co-Is will dedicate up to 5% WTE to the project. Anja Terlouw will oversee trial implementation at the MLW Chikhwawa field site and ensure the trial brings added value to research activities there. Jonathan Grigg (JG) will lead a working group on household air pollution and personal exposure to deliver this aspect of the proposal. Moffat Nyirenda (MN), Nigel Bruce (NGB) and John Balmes (JB) will lead on trial strategy and high-level implementation activities. MN will ensure the trial delivers benefits in line with MLW research strategy. JG and JB will establish an Independent Endpoint Review Committee. Dan Pope (DP) will lead on updating our systematic review to include the trial findings. Brian Faragher will be the trial statistician, oversee the establishment of the DMC and use opportunities provided by this trial to build Malawi-based capacity in statistics. Lesong Conteh will lead on the health economic evaluation aspect of the trial. Margaret Matinga (MM) will conduct the qualitative work.

Travel and subsistence

We will make maximal use of telephone and web-based conferencing facilities to keep international travel and subsistence costs to a minimum. However a relatively high number of international trips will be essential to ensure sufficient training and support for Malawi-based trial staff, direct trial work and oversight. We have included funding for a total of 6 return trips from the UK to Malawi per year to cover trips by SBG and KM, 2 return trips over the course of the grant for LC for economic evaluation work, 2 trips for JG and a technician to provide training and follow up in household air pollution measurements, exposure and stove use monitoring and induced sputum processing and analysis. MM will make 2 return trips from South Africa to conduct the qualitative work. International flights and subsistence costs are included for 2 face-to-face TSC and DMC meetings. The LSTM/MLW clinical governance teams will incur some travel costs. We have also included and funding for a total of 6 individual international trips shared between co-investigators (including subsistence and conference fees) to enable us to disseminate our findings widely on the international stage.

Other directly incurred costs

Directly incurred costs in the UK are justified here. Most of these costs will be incurred in Malawi and are justified under ‘exceptions’.

We will register the trial with Current Controlled Trials Ltd and pay the fees associated with the LSTM REC review.
We have included the costs of convening a monthly teleconference between UK and Malawi-based staff and 3 annual TSC meetings.
Incidental costs additional to travel, subsistence and teleconferences incurred in convening the TSC and DMC meetings are included.
The Independent Endpoint Review Committee will require around 70 hours work for 3 consultant-level doctors.
An electronic CRF will be used and therefore development and support costs for this are included.
A UK trial insurance policy is required.

Impact
We have included the costs of 4 open access publication of our main trial findings, a trial website and associated data depository and Pathways To Impact video creation. Malawi-based impact activities are justified under 'exceptions'.

Other Directly Allocated Costs
N/A.

Research facilities (at Research organisations)
N/A.

Pooled and infrastructure technicians
N/A.

Exceptions
Our estimates of Malawi-based costs are based on our current experience of conducting community studies in Malawi including the ACTia trial in Chikhwawa.
We will pay the fees associated with the COMREC review.
Fieldworkers will need to make the following trips to each village: two mapping and community engagement visits by motorbike before randomisation, a visit by 4x4 to distribute the main consignment of stoves and 8 follow-up visits over two years using motorbikes. We will be required to pay a locally agreed standard monthly field allowance of £40 per fieldworker.
12000 cookstoves (allowing for 10% requiring replacement during the trial) will be purchased and shipped from Lesotho to Malawi. Our trial partner African Clean Energy has committed to making these stoves available to us at the lowest possible price. This commitment extends beyond the trial to up scaling of the intervention if indicated.
The battery that powers the fan in the cookstove requires charging intermittently and we have requested funds to cover these costs.
Each fieldworker and the trial clinician will need a smartphone for data collection during field visits and use for other tasks. The data manager, trial manager, research assistant and administrative assistance will also need a computer each. An external hard drive will be needed at each centre for data backup. A combination printer/scanner and consumables will provide for printing and scanning needs.
Each member of trial staff will need a mobile telephone and airtime credit to allow them to communicate effectively from different locations.
Funding has been included for all trial staff to receive GCP training and for 4 senior Malawian staff to do an online MSc in Clinical Trials (or similar) that will be relevant to the conduct of this trial and contribute to local capacity building.
Three annual GCP compliance visits by the MLW/LSTM governance teams have been included.
Local trial insurance cover is required.
There are infrastructure and support cost contributions for each research centre (including office space rental, utilities, internet and landline telephones).
Funding is requested for stationary and printing costs which will be minimised through the use of IT wherever practical.

All villages will be provided with a mobile phone with an airtime voucher that will be kept by a CAPS village representative.
A supply of antibiotics that reflects local prescribing practice for pneumonia will be provided to local health facilities if antibiotics are indicated following clinical assessment but otherwise unavailable.
We have included an emergency fund to allow us to assist with the transfer of sick children to hospital if necessary.
A new health passport will be provided to all children included in the trial, if needed. A sticker will be inserted in the front of each passport explaining that the patient is in a trial with a brief summary of the IMCI pneumonia assessment protocol and boxes to tick if the patient is diagnosed with pneumonia and if so whether this was severe or not. These measures are to facilitate high quality clinical assessments and documentation.
To help achieve high standards of clinical assessment and documentation we will provide training in use of the IMCI pneumonia assessment protocol for paediatric healthcare workers at local health facilities every 6 months. Although healthcare workers and the local health centers' will not be expected to do anything beyond good standard practice *i.e.* use of the IMCI pneumonia protocol for patient assessment and documentation of the diagnosis and treatment in the patient's health passport, the trial outcomes will be highly dependent on the quality of these assessments and their documentation. We therefore include some additional value for the healthcare workers and centers' by providing an allowance for attendance at the training sessions to include provision of a personal finger pulse oximeter which will be used for pneumonia severity assessments, additional locally tailored educational sessions during the training days and a contribution towards the medical equipment fund for each district hospital involved.
To conduct the household air pollution and exposure monitoring, stove use monitoring and induced sputum work, household air pollution monitors ($PM_{2.5}$, carbon monoxide), personal exposure monitors (black carbon, carbon monoxide, carboxyhaemoglobin), stove use monitors and associated software.
We have included funding for presentation events in Malawi and funding for a half day or evening event at each of the 150 included villages at which the trial findings will be presented in a locally tailored format with refreshments.

BUDGET

This is a summary budget for the Malawi-based costs.

Directly Incurred Costs

	Description	
EXCEP	Laptop computers incl. software to provide mobile IT access for each fieldworker, trial doctor, data manager, trial manager, economic research assistant (incl.TreeAge and @Risk software) and adminis	£19,353
EXCEP	Electronic CRF development and implementation	£4,900
EXCEP	GCP training at MLW	£6,151
EXCEP	MLW and LSTM research governance costs including 3 monitoring visits per year 13500	£13,500
EXCEP	Data Monitoring Committee costs (travel, subsistence and teleconference costs elsewhere)	£900
EXCEP	Trial steering committee costs (travel, subsistence & teleconference costs elsewhere)	£1,800
EXCEP	College of Medicine Research Ethics Committee processing fee	£64
EXCEP	Mobile phones for each fieldworker, trial doctor, data manager, trial manager, research assistant and administrative assistant	£400
EXCEP	Malawi-based telephone airtime costs	£14,553
EXCEP	Mobile phone for each village with £10 airtime per quarter per village	£14,040
EXCEP	£100 annual pigeon peas or maize allocation for villages to cover the 'inconvenience'of trial participation	£31,200
EXCEP	Emergency fund to assist the transfer of sick children to hospital if necessary	£3,960
EXCEP	Supply of antibiotics for the treatment of pneumonia where antibiotics are indicated but unavailable at local healthcare facilities.	£2,640
EXCEP	New health passport with trial sticker (approx. 60p together) for each included child	£7,956
EXCEP	A village-based impact event at the end of the trial to share and discuss trial findings using a locally suitable format. £2 budget per household	£10,608
EXCEP	Office consumables including stationary, photocopying and printing costs for trial centres	£17,000
EXCEP	6 monthly training events at healthcare centres for IMCI training including room hire and refreshments	£10,000
EXCEP	Time and equipment (pulse oximeters, pens) allowance for healthcare workers involved with assessment of children for the trial who attend training sessions. Finger pulse oximeters (approx £60 each)	£7,500
EXCEP	Contribution to medical equipment fund for health centres to support engagement with the trial	£4,000
EXCEP	Household air pollution and personal exposure monitors for CO (x8), PM2.5 (x4) and carboxyhaemoglobin (x2) measurements. Black carbon monitors already available.	£7,096
EXCEP	Sputum induction kit (nebuliser and spirometer) and consumables for total of 600 tests	£6,330
EXCEP	Stove use monitors with attachments and software	£11,343
EXCEP	Malawi-based scientific presentations and science communication support	£2,500
EXCEP	Hard drive for data back up at each of 4 research centres	£380
EXCEP	Rental of office and storage space including utilities, internet access and furniture forthe four research centres estimated at £10,000 per year per centre for 48 months	£180,000
EXCEP	Stove battery charging costs	£15,600
EXCEP	Wood cutting tool costs (for cutting wood to size for use in stoves)	£15,600
EXCEP	1 combination printer/scanners for each site	£2,396
EXCEP	Trial insurance premium (local)	£8,000
	Total £	**£419,770**

Staff

Directly Allocated Posts

Role	Name /Post Identifier	Start Date	Period on Project	% of Full Time	Scale	Increment Date	Basic Starting	London	Super-	Total cost
Researcher	Fieldworker_1*	01/03/2013	42	100%	N/A	01/03/2014	£7,200	£0	£0	£27,433
Researcher	Fieldworker_2*	01/03/2013	42	100%	N/A	01/03/2014	£7,200	£0	£0	£27,433
Researcher	Fieldworker_3*	01/03/2013	42	100%	N/A	01/03/2014	£7,200	£0	£0	£27,433
Researcher	Fieldworker_4*	01/03/2013	42	100%	N/A	01/03/2014	£7,200	£0	£0	£27,433
Researcher	Fieldworker_5*	01/03/2013	42	100%	N/A	01/03/2014	£7,200	£0	£0	£27,433
Researcher	Fieldworker_6*	01/03/2013	42	100%	N/A	01/03/2014	£7,200	£0	£0	£27,433
Researcher	Fiedworker_7*	01/03/2013	42	100%	N/A	01/03/2014	£7,200	£0	£0	£27,433
Researcher	Fieldworker_8*	01/03/2013	42	100%	N/A	01/03/2014	£7,200	£0	£0	£27,433
Researcher	Fieldworker_9*	01/03/2013	42	100%	N/A	01/03/2014	£7,200	£0	£0	£27,433
Researcher	Fieldworker_10*	01/03/2013	42	100%	N/A	01/03/2014	£7,200	£0	£0	£27,433
Researcher	Fieldworker_11*	01/03/2013	42	100%	N/A	01/03/2014	£7,200	£0	£0	£27,433
Researcher	Fieldworker_12*	01/03/2013	42	100%	N/A	01/03/2014	£7,200	£0	£0	£27,433
Researcher	Fieldworker_13	02/03/2013	42	100%	N/A	02/03/2014	£7,200	£0	£0	£27,433
Researcher	Fieldworker_14	03/03/2013	42	100%	N/A	03/03/2014	£7,200	£0	£0	£27,433
Researcher	Fieldworker_15	04/03/2013	42	100%	N/A	04/03/2014	£7,200	£0	£0	£27,433
Researcher	Data Manager*	01/03/2013	42	100%	N/A	01/03/2014	£14,740	£0	£0	£61,038
Researcher	Malawian registrar-level doctor *	01/03/2013	42	100%	N/A	01/03/2014	£15,600	£0	£0	£59,438
Researcher	Clinical Trials Manager in Malawi*	01/09/2012	48	100%	N/A	01/09/2013	£15,600	£0	£0	£68,919
Researcher	Administrative Assistant in Malawi*	01/09/2012	48	100%	N/A	01/09/2013	£6,000	£0	£0	£58,078
Researcher	Finance support at MLW *	01/09/2012	48	50%	N/A	01/09/2013	£8,880	£0	£0	£19,615
Researcher	Economic analysis research assistant*	01/09/2012	48	50%	N/A	01/09/2013	£11,600	£0	£0	£25,624
										£704,207

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Appendix A

Risk Assessment (including possible constraints)

We have used the Clinical Trial Tool Kit risk assessment guidance and checklist (www.ct-toolkit.ac.uk) to conduct an assessment of and management approach for the risk to a) research participants and b) the successful completion of the trial. The risk assessment matrix below was used to score risk levels of potential hazards according to the likelihood and impact of their occurrence.

Impact		Likelihood				
		1 Remote	2 Unlikely	3 Possible	4 Likely	5 Certain
	1 Low	1	2	3	4	5
	2 Moderate	2	4	6	8	10
	3 Significant	3	6	9	12	15
	4 Severe	4	8	12	16	20
	5 Catastrophic	5	10	15	20	25

Key	Risk Level	Action and Time Scales
A	CATASTROPHIC	Immediate action must be taken to manage the risk. Control measures should be put into place which will have the effect of reducing the impact of an event or the likelihood of an event occurring. A number of control measures may be required.
B	SEVERE	Significant resources may have to be allocated to reduce the risk. Where the risk involves work in progress urgent action should be taken.
C	SIGNIFICANT	Efforts should be made to reduce the risk, but the costs of prevention should be carefully measured and weighed against the impact of an event. Establish more precisely the likelihood of harm as a basis for determining the need for improved control measures.
D	MODERATE	On or below this level a risk is acceptable. Existing controls should be monitored and adjusted. No further action or additional controls are required. Consideration may be given to a more cost-effective solution or improvement that imposes no additional cost burden.
E	LOW	Acceptable risk. No further action or additional controls are required. Risks at this level should be monitored, and reassessed at appropriate intervals.

http://www.ct-toolkit.ac.uk/_db/_documents/MPTrials2.pdf

1 Risks to Research participants

1.1 Risks from interventions

Risk level

Low (likelihood unlikely; impact low)

Risk management

Trial households will be recruited from populations living in poverty in Malawi who live with high day-to-day baseline risks. The open fire that control households will continue to use is one contributor to this risk. The advanced cookstove is likely to be safer than the open fire since it contains the fire in a stable construction with outside surfaces that are cool to touch during use.Stoves will be quality control checked before they leave the factory. Tools used for cutting wood may increase the risk of injury although probably not significantly beyond the baseline risk since such tools are in common use outwith the trial.The trial will only commence after full research ethics committee (REC) approval. An adverse event reporting system will be in place and adverse events will be reviewed by a data monitoring committee (DMC) that will report to the trial steering committee (TSC).

1.2 Risks from research team

Risk level

Low (likelihood unlikely; impact low)

Risk management

The applicants are a collaborative group of international experts in household air pollution, public health, clinical trial design and implementation, biostatistics, health economics, qualitative research and improved cookstove development and dissemination. We will be drawing on valuable experience gained from conducting the RESPIRE trial in Guatemala; wide ranging knowledge, skills and expertise from academic groups at the University of California, Liverpool, London and Malawi; considerable local knowledge and ability to implement research and aid programs in challenging environments.We have consulted widely about the optimal structure and requirements of the research team on the ground to ensure there will be adequate numbers of appropriately trained and experienced staff supported by a management and trial oversight structure. All staff recruited to work on the trial will undergo good clinical practice (GCP) training and full training in trial-specific methodologies and standardised operating procedures (SOP).

1.3 Risks from invasive tests and exposures

Risk level

Low (likelihood unlikely; impact low)

Risk management

We will not conduct any invasive tests or exposures. An adverse event reporting system will be in place and adverse events will be reviewed by a DMC that will report to the TSC.

1.4 Risks from consent process failures

Risk level

Moderate (likelihood possible; impact low)

Risk management

We will obtain consent for participation at two levels. Firstly we will obtain consent from the village leadership for the village to participate as a cluster. We will then obtain consent from a parent or guardian with authority to do so for the household and the children aged up to 4½ years old within the household to be included. The trial information giving and consent process will undergo ethical review and approval before implementation. Fieldworkers obtaining consent will be trained in GCP and the details of the trial specific SOPs relating to the informed consent process. Internal quality control monitoring will be conducted three monthly to confirm all participating households have given written informed consent.Liverpool School of Tropical Medicine will perform two GCP compliance visits to ensure and document complete compliance with the consent process. All trial staff and investigators will protect the rights of the trial's participants to informed consent.

1.5 Risks from failure to maintain confidentiality

Risk level

Low (likelihood unlikely; impact low)

Risk management

Each child included in the trial will have their own case report form (CRF) that will identify the child via their Household Trial Number, Participant Trial Number, initials and date of birth. An electronic CRF will be used to make the large number of CRFs manageable and provide real-time data entry, internal validity and consistency checks. CRFs will be treated as confidential documents and held and backed up onto two secure servers. Access to CRFs will be restricted to personnel approved by the Principal Investigators and recorded on the Trial Delegation Log. All trial staff and investigators will protect the rights of the trial's participants to confidentiality. We will not collect any particularly sensitive data. REC approved processes will be followed.

2 Risks to the successful completion of the trial

2.1 Organisational complexity

Risk level

Low (likelihood remote; impact moderate)

Risk management

The trial will benefit from strong support from the Malawi Liverpool Wellcome (MLW) Programme, a major overseas programme of the Wellcome Trust and a research unit within the College of Medicine (COM), University of Malawi. MLW will provide a central hub for the trial, clinical trials infrastructural and administrative research support. We will initiate the trial through the MLW Chikhwawa field site and one other major research centres Karonga. All centres have established infrastructure, logistical support and experienced field staff. A full time on-site qualified and experienced Clinical Trials Manager (TM) will be appointed and have responsibility for day-to-day management issues management issues, supervision of field workers and data manager, protocol compliance, security of the randomisation process, recruitment, data management, problem identification and resolution, distribution and maintenance of trial materials, budget control and production of annual progress reports. The TM will be supported by a middle-grade clinician (Malawian graduate), Kevin Mortimer (KM) and Stephen Gordon (SBG). A Trial Management Group (TMG) led by the TM will be established to manage the trial on a day-to-day basis and will include the middle grade clinician, KM or SBG and the fieldworkers. The TMG will meet at least monthly and will monitor trial conduct, progress (including recruitment, withdrawals and losses to follow-up), adherence to the protocol and SOPs, CRF completion, accuracy and completeness of data collection, data validity (through checks of range and consistency) and where necessary act to safeguard trial participants and quality standards. The TMG will receive logistic and infrastructural clinical trials support from The Wellcome Trust Tropical Centre in Liverpool. High standards of data collection and entry will be achieved through fieldworker training, an electronic CRF with inbuilt consistency and range checks, data manager support, regular data quality checks and audit of source data verification. A TSC will be established to provide overall supervision of the trial and ensure the trial is delivered in accordance with the MRC's Guidelines for Good Clinical Practice.

2.2 Study power and recruitment

Risk level

Significant (likelihood possible; impact significant)

Risk management

The proposed sample size is based on calculations by our clinical trials statistician, informed by the latest available data from Malawi and reflects what can be practically delivered on the ground. Our recruitment plan and schedules are based on experience with other studies at the proposed field sites, ongoing cookstove implementation programmes and our pilot work. Our inclusion criteria are deliberately broad to maximise the generalisability of our findings and this inclusivity will also facilitate recruitment. Through our major centres we have access to a large pool of potential participating villages. Post recruitment retention approaches are in place with a particular emphasis on full community engagement and additional village-level benefits (including mobile phone access, new health passports, access to assistance from fieldworkers) from participation. These approaches will help minimise withdrawals and maximise compliance.

2.3 Study results

Risk level

Significant (likelihood unlikely; impact significant)

Risk management

All trial staff will receive generic and specific training to ensure the trial is conducted to the highest possible standards. All trial procedures will be described in detail in SOPs. The inclusion criteria are deliberately broad with little risk of violation in a way that would impact materially on the trial. Randomisation will be conducted centrally and implemented at village level by a team of experienced staff supervised by a Clinical Trial Manager with little risk of misallocation. Health passports are looked after by individual patients in Malawi and therefore will be kept by the trial participants. There is a risk that these source documents could go missing and then be unavailable for data collection and source document verification. These risks will be low given how valuable these documents are to individuals and the importance of taking care of health passports will be emphasised at village engagement visits. Data monitoring, audit and interim reports overseen by the Clinical trial Manager will further maximize data quality. We have a results dissemination and publication plan in place. We are part of an established network of local, national and international links that will facilitate the successful wide dissemination and implementation of the results of the trial. This network includes grass root community representatives, non governmental organisations, local healthcare workers, African Clean Energy, Aprovecho Research Centre, Malawi Ministry of Health, COM, MLW, WHO and Global Alliance for Clean Cookstoves. We will make our full research database publically available once we have published our findings.

2.4 Staff competence and experience

Risk level

Moderate (likelihood unlikely; impact moderate)

Risk management

The trial will benefit from support from existing research infrastructure, experienced and able field and research staff. Existing and newly recruited staff will be appropriately qualified and receive generic and specific training to deliver the trial to the highest possible standard. An extensive support structure for trial staff will be in place including dedicated Clinical Trial Manager support. Regular project team meetings (monthly) led by the Clinical Trial Manager will help maintain high standards and allow any difficulties to be identified and resolved in a prompt and proactive way. Administrative support will be in place. The proposed size and composition of the research team is based on wide consultation of requirements and has been fully budgeted for.

2.5 Road traffic accidents

Risk level

Significant (likelihood possible; impact significant)

Risk management

The roads in Malawi can be dangerous at times. All journeys will be made during daylight hours except under exceptional circumstances. This is especially important for journeys made using main roads. For particularly long journeys, large sturdy vehicles will be used with a dedicated driver. The importance of sticking to speed limits and taking regular breaks will be emphasised. Motorcycles will be used for many of the trips into villages. Helmets will be worn when fieldworkers are travelling by motorbike and all will be fully licenced to drive these vehicles. All study vehicles will be regularly maintained and insured.

Appendix B:

Information Sheets English

University of Malawi College of Medicine, Malawi Liverpool Wellcome Trust, University of Liverpool School of Tropical Medicine Information Sheet - Cluster Level English.

Information and Consent Form for the Cluster level/Village head.

An advanced cookstove intervention to prevent pneumonia in children under 5 years old in Malawi: a cluster randomized controlled trial.

1. Introduction
Burning biomass fuels (dung, crops residues, wood, and charcoal) in open fires and basic cookstoves creates smoke that can be harmful to health. We need to develop affordable and effective ways to reduce exposure to this smoke. One way of doing this is to burn biomass fuels in an advanced cookstove instead of open fires or other basic cookstoves. Advanced cookstoves may have health benefits but we do not know. We are doing this trial to find out whether an advanced cookstove called the Philips fan-assisted stove has health benefits and particularly whether it reduces pneumonias in young children.

This consent form is being done so that the village head/chief should understand fully what is happening in their village and to his/her subjects concerning the cooking and pneumonia study process before any procedure is done in the village by the CAPS staff.

2. Why has your village been chosen?
Your village is in an area of Malawi where this trial is being conducted and your village has been randomly selected to participate.

3. Does my village have to take part in the study?
We will only ask your subjects to participate in this study if you, as the village leader, has agreed for your village to participate. Your village does not have to take part even if other villages have agreed to take part. Your agreement to help with this research study is completely optional and if you would prefer for your village to not participate, this will be without penalty or loss of benefits to which your village would be otherwise entitled. You can choose for your village to leave the study at any time, without providing a reason.

4. What will be involved if I agree for my village to take part in this study?
Firstly we will explain whether your village is in the intervention or control group. This will be decided using a process called randomization. This means your village will go into one of the two groups in a way that cannot be predicted or influenced.

All households in the intervention group will be given two advanced cook stoves to use to replace all open fires and basic cook stoves. It is very important that the advanced cook stoves are used for all cooking tasks and that open fires and any other cook stoves are no longer used. One in 10 of the advanced cook stoves will have a small monitor fitted that will record information about how much the cookstove is used over the course of the trial.

This information is needed to help us understand how much these cookstoves are used in a real life setting. We will provide training about how the advanced cook stoves work and how to use these to the best possible effect. All households in the control group will be asked to continue to

cook in their usual way until the end of the trial when each control household will also receive two advanced cook stoves.

We will give the children under 5 in your village household a new health passport if they do not currently have one with enough blank pages in it and will put a sticker in the passport about the trial. We will ask that village subjects show this sticker to the staff at the health centre if his/her child requires medical attention during the trial since this will help the staff collect the information we need for the trial. After any attendance at the health centre we will ask the village subject to contact the trial team using the phone and airtime credit provided to the community advisory group member.

We will collect some basic information about each participant's family at the beginning of the study using a small computer. Then every three months for 24 months, the fieldworkers will visit your village to review the health passports of all the children in the trial to collect information about episodes of pneumonia. We will also collect information about any children who die.

In addition to information about pneumonias in children, we will also collect information about respiratory symptoms and burns. We will measure levels of air pollution in some of the subjects' homes at the beginning of the study and every 6 months, using small monitors we will leave in their homes for up to 5 days.

In a small sample of households we will conduct some additional monitoring which will help us understand how much smoke the children in the trial and their mothers are exposed to. This is an additional and optional part of the study. The village subjects can decide whether or not to participate in this part of the study without affecting their participation in the main trial. Participants in this group will undergo the following assessments:

We will place a small peg-like device on the child's finger and his/her mother's finger for a few moments to take a measurement of the levels of carbon monoxide in their body. This measurement does not involve taking a blood sample and does not cause any discomfort.
We will place a small air pollution monitor on the child's clothing and his/her mother's clothing for up to 2 days to allow us to measure air pollution exposure. These are non-intrusive monitors that will not stop you going about your day-to-day activities.

At no time during the CAPS study, will we be required to draw blood or take any blood samples.

5. Will there be any risks involved in the study?
Your village subjects may be inconvenienced by the time commitment involved in taking part in the study, the information we need to record and the measurements we need to take. All of the study procedures are routine and involve minimal risks.

6. Will there be any benefits involved in being in the study?
All households will receive two advanced cook stoves, either at the beginning (intervention group) or end (control group) of the study. We will also ensure that supplies of antibiotics for the treatment of pneumonia are available for trial participants through the local health centers, and even children not enrolled in the study will benefit from the supplied drugs if there is a shortage of government drug supplies.

7. Who is organising the study?
The research is being done by researchers at the College of Medicine, Malawi Liverpool Wellcome Trust, University of Liverpool School of Tropical Medicine, University of London and Imperial College London.

8. Who will know what we find out?
We will record the information we collect using a small computer. This information will be transferred to a computer database, but without using your name or address, so that you could not be identified from this information. This database will be analyzed by researchers at the College of Medicine, Malawi Liverpool Wellcome Trust and Liverpool School of Tropical Medicine. We will share the results of this study with you and your community, at local charity or research meetings, and will present the findings at an international conference and in journals. We will not share any information that would allow you to be identified.

9. What happens if a villager changes his /her mind?
If your village subject agrees to join the study he/she can change his mind and withdraw his consent at any time.

If you have any questions about this study, please contact our **Project Manager, Chifundo Ndamala** on **[+265 999 981 409].**

For any questions regarding participant rights in the scope of this study, please contact the chairman of the local ethics committee (COMREC). This committee has reviewed and approved all of these studies. The contact details are: COMREC Secretariat, College of Medicine, P/bag 360, Blantyre 3. Telephone number: **[+265 111 989 766]**

University of Malawi College of Medicine, Malawi Liverpool Wellcome Trust, University of Liverpool School of Tropical Medicine Information Sheet - Household Level English.

Information and Consent Form for the Head of the household, guardian or parent of the children in the household

An advanced cookstove intervention to prevent pneumonia in children under 5 years old in Malawi: a cluster randomized controlled trial.

1. Introduction
Burning biomass fuels (dung, crops residues, wood, and charcoal) in open fires and basic cookstoves creates smoke that can be harmful to health. We need to develop affordable and effective ways to reduce exposure to smoke. One way of doing this is to burn biomass fuels in an advanced cookstove instead of open fires or other basic cookstoves. Advanced cookstoves may have health benefits but we do not know. We are doing this trial to find out whether an advanced cookstove called the Philips fan-assisted stove has health benefits and particularly whether it reduces pneumonias in young children.

2. Why have you been chosen?
You live in an area of Malawi where this trial is being conducted and your village has been selected to participate.

3. Do I have to take part in the study?
We will only ask you to participate in this study if your village leaders have agreed for your village to participate. You do not have to take part even if other members of the village agree to take part. Your agreement to help with this research study is completely optional and if you would prefer not to participate, this will be without penalty or loss of benefits to which you would be otherwise entitled. You can choose to leave the study at any time, without providing a reason.

4. What will be involved if I agree to take part in this study?
Firstly we will explain whether your village is in the intervention or control group. This will be decided using a process called randomization. This means your village will go into one of the two groups in a way that cannot be predicted or influenced.

All households in the intervention group will be given two advanced cookstoves to use to replace all open fires and basic cookstoves. It is very important that the advanced cookstoves are used for all cooking tasks and that open fires and any other cookstoves are no longer used. One in 10 of the advanced cookstoves will have a small monitor fitted that will record information about how much the cookstove is used over the course of the trial. This information is needed to help us understand how much these cookstoves are used in a real life setting. We will provide training about how the advanced cookstoves work and how to use these to the best possible effect.

All households in the control group will be asked to continue to cook in their usual way until the end of the trial when each control household will also receive two advanced cookstoves.

We will give the children under 5 in your household a new health passport if they do not currently have one with enough blank pages in it and we will put a sticker in the passport about the trial. We will ask you to show this sticker to the staff at the health centre if your child requires medical attention during the trial since this will help the staff collect the information we need for the trial. After any attendance at the health centre we will ask you to contact the trial team using the phone and airtime credit provided to the community advisory group member.

We will collect some basic information about you and your family at the beginning of the study using a small computer. Then every three months for 24 months fieldworkers will visit your village

to review the health passports of all the children in the trial to collect information about episodes of pneumonias. We will also collect information about any children who die.

In addition to information about pneumonias in children we will also collect information about respiratory symptoms and burns. We will measure levels of air pollution in your home at the beginning of the study and every 6 months using small monitors we will leave in your home for up to 5 days.

In a small sample of households we will conduct some additional monitoring which will help us understand how much smoke the children in the trial and their mothers are exposed to. This is an additional and optional part of the study. You can decide whether or not to participate in this part of the study without affecting your participation in the main trial. Participants in this group will undergo the following assessments:

We will place a small peg-like device on the child's finger and his/her mothers finger for a few moments to take a measurement of the levels of carbon monoxide in their body. This measurement does not involve taking a blood sample and does not cause any discomfort.
We will place a small air pollution monitor on the child's clothing and his/her mother's clothing for 2 day to allow us to measure air pollution exposure. These are non-intrusive monitors that will not stop you going about your day-to-day activities.

At no time, during the CAPS study, will we be required to draw blood or take any blood samples.

5. Will there be any risks involved in the study?
You may be inconvenienced by the time commitment involved in taking part in the study, the information we need to record and the measurements we need to take. All of the study procedures are routine and involve minimal risks.

6. Will there be any benefits involved in being in the study?
All households will receive two advanced cookstoves either at the beginning (intervention group) or end (control group) of the study. We will ensure that supplies of antibiotics for the treatment of pneumonia are available for trial participants through the local health centers.

7. Who is organizing the study?
The research is being done by researchers at the College of Medicine, Malawi Liverpool Wellcome Trust, University of Liverpool, Liverpool School of Tropical Medicine, University of London and Imperial College London.

8. Who will know what we find out?
We will record the information we collect about you using a small computer. This information will be transferred to a computer database but without using your name or address so that you could not be identified from this information. This database will be analyzed by researchers at the College of Medicine, Malawi Liverpool Wellcome Trust and Liverpool School of Tropical Medicine. We will share the results of this study with you and your community, at local charity or research meetings and will present the findings at an international conference and in journals. We will not share any information that would allow you to be identified.

9. What happens if you change your mind?
If you agree to join the study you can change your mind and withdraw your consent at any time.

If you have any questions about this study, please contact our Project Manager, **Chifundo Ndamala** on **[+265 999 981 409].**

For any questions regarding participant rights in the scope of this study, please contact the chairman of the local ethics committee (COMREC). This committee has reviewed and approved

all of these studies. The contact details are: COMREC Secretariat, College of Medicine, P/bag 360, Blantyre 3. Tel no: **[+265 111 989 766].**

Information sheets Chichewa

University of Malawi College of Medicine, Malawi Liverpool Wellcome Trust, University of Liverpool School of Tropical Medicine Information Sheet - Cluster Level Chichewa

Ndondomeko ndi chilolezo cha kwa mfumu ya mudzi.

Mbaula za makono zophikira, zothandiza kupewa chibayo kwa ana ochepera zaka zisanuM'malawi: Kafukufuku ku gulu losankhika.

1. Malonje
Moto wa ndowe, zinyalala, nkhuni ndi makala umatulutsa utsi omwe siwabwino ku umoyo wathu, motero ndi koyenera kuti tipeze njira zotsika mtengo komanso zodalirika zomwe zingathandize kuchepetsa utsi ndi mavuto ena amene amabwera ndi njira zimenezi. zomwe zingateteze anthu ku utsi umenewu. Njira imodzi mwa izo ndi kugwiritsa ntchito mbaula zamakono m'malo mwa njira zapambalambanda. Mbaula za makono zikhoza kukhala ndi ubwino ku umoyo wathu, koma pakadali pano sitinganene kuti ubwino wake ndiwotani. Tikuchita kafukufukuyu kuti tipeze ngati mbaulazi, zomwe tikuzitcha Philips zili ndi ubwino ku umoyo, makamaka kuchepetsa nthenda ya chibayo kwa ana.

Chikalata chopempha chilolezochi chapagindwa motero kuti amfumu athe kumvetsetsa zimene zikuchitika m'mudzi mwawo kwa anthu awo zokhuzana ndi ndondomeko ya kafufuku wa kulimbana ndi chibayo kwa ana, tisanayambe ntchito ya kafukufukuyi.

2. Mudzi wanu wasankhidwa chifukwa chani?
Mukukhala mudera limene kafukufukuyu m'Malawi muno akuchitikira, komaso mudzi wanu wasankhidwa mwa mayere kuti utenge nawo mbali.

3. Ndikoyenera kuti mudzi wanga utenge nawo gawo mu kafukufukuyu?
Monga mkulu kapena mwini mudzi, tikukupemphani chilolezo mwa ufulu wanu kuti anthu a mmudzi wanu atenge nawo gawo mu kafukufukuyu. Kutenga agawo kwa anthu anu mukafukufukuyu, sikukuyendera kuti midzi ina ya mudera lanu atero kapena ai, komaso anthuwo sakukakamizidwa kutenga gawo ngati aona paokha kuti sikoyenera kutero ngakhale inu monga mfumu mutavomereza. Ndipo sipazakhala kulipilitsidwa china chili chonse kapena kumanidwa zomwe mudzi wanu ukuyenera kulandira. Anthu atha kusankha kusiya kapena kutenga nawo gawo mu kafukufukuyu nthawi ina iliyonse yakufuna kwawo popanda kupereka chifukwa chimene asiyira.

4. Chidzachitike ndi chani ngati mudzi wanga utatenga nawo gawo mu kafukufukuyu?
Poyambilira, tizawafotokozera anthu a mudzi wanu gulu lomwe mudzi wanu uli pakati pa gulu lolandira mbaula zamakonozi kapena lozalandira kumapeto kwa kafukufukuyu. Tizakhala ndi mayere omwe azapatule midzi yotenga nao gawo mu magulu awiriwa. (Kugwiritsa mbaula za makono kapena kugwiritsa ntchito njira zomwe amaphikira nthawi zonse) Dziwani kuti kusankhidwa kwa mayereku sikungapangidwe kapena kusinthidwa mwa njira ina ili yonse.

Makomo onse a mugulu lozalandira mbaulazi, azapatsidwa mbaula zamakono ziwiri zomwe azagwiritse ntchito m'malo mwa njira yawo yakale yomwe amaphikira. Kotero njira zonse zakale sizizagwiritsidanso ntchito. Ndikofunikira kuti mbaula zimenezi zizagwiritsidwe ntchito pa zophikidwa zonse. Mbaula imodzi pa mbaula khumi zili zonse, izakhala ikuwunikidwa mwapadela, pa nthawi yonse ya kafukufukuyu.

Zotsatira za kuunikaku zizathandiza kutiziwitsa m'mene mbaulazi zingagwilire ntchito pa panthawi yonse yamukafukufuku izi zitatinthandza ife kumvetsetsa m'mene mbaulazi zingagwiritsidwe ntchito pa moyo wathu watsiku ndi tsiku. Anthu a mmudzi olandira mbaula azaphunzitsidwa kagwiritsidwe ntchito koyenera ka mbaula zamakonozi. Makomo onse a mmidzi ya mu gulu

losalandira mbaulazi azapemphedwa kuphika m'mene amaphikila nthawi zonse, koma nawo azapatsidwa mbaula zamakonozi kumapeto kwa kafukufukuyu. Kuphatikiza pa mbaula zamakono.

Tidzapereka ziphaso zakuchipatala, zatsopano kwa ana ochepera zaka zisanu omwe alowa mu kafukufuku mmidzi yonse ya mukafukufukuyu ngati atapezeka kuti alibe chiphaso kapena chiphaso chakale chatsala ndi malo ochepa olembapo a dotolo. Tidzamata mu chiphasochi chizindikiro chofotokoza za kafukufuku ameneyu, ndipo anthu onse otenga nawo mbali mu kafukufukuyu adzapemphedwa kuonetsa chizindikirochi kwa ogwira ntchito kuchipatala pa nthawi imene ana adwala ndipo apita ku chipatala ngati mwana afunika thandizo la mankhwala mu kafukufukuyu. Izi zizatithandiza kutsata bwino matenda ena omwe ana a mukafukufuku angadwale nthawi imene kafukufuku ali kuchitika. Pa nthawi iliyonse yomwe kholo kapena omuperekeza mwana kuchipatala wachoka kolandira chithandizo kuchipatala, adzapemphedwa kuziwitsa ogwira ntchito mu kafukufukuyu poimba lamya, pogwiritsa nchito maunitsi omwe anaperikedwa kwa akomiti a amudzi wao.

Tizatenga mbiri ya umoyo wa mabanja onse a mukafukufuku poyambilira pa kafukufukuyu pogwiritsa ntchito makina amakono osungira uthenga ndi mbili.Pakapita miyezi itatu iliyonse, kwa zaka ziwiri, ogwira ntchito mukafukufukuyu azayendera ndikuona mu ziphaso za ana a mukafyukufuku ngati anapezeka ndi nthenda ya chibayo, komanso ngati alipo wina mwa ana amene amwalira.

Kuphatikiza pa izi, tizaonanso ngati pali ana amene anadwala nthenda yokhuzana ndi kuvutika mu mapumidwe, komanso ngati ena anapsya ndi moto. Tidzayezanso kuchuluka kwa mpweya oyipa mwa ana komanso mnyumba zowerengeka ndi makina oyezera mpweya omwe azaikidwe mu nyumba za otenga nao gawowa kufikira masiku asanu, ndipo tizachita chimodzi modzi pakatha miyezi isanu ndi umodzi mu nthawi ya kafukufukuyu.

Tidzayendera ndi ku unika nyumba zowerengeka zosakhidwa kuchokera mmayere zamukafukufuku, izi zizathandiza kudziwa kuchuluka kwa utsi umene ana komanso amayi amayandikana nawo. Iyi ndi mbali imodzi yowonjezera mukafukufukuyu. Anthu atha kutenga kapena kusatenga nawo mbali mugawo limeneli ndipo izi sizizakhuzana ndi kutenga kwawo mbali mu kafukufuku wankuluyu. Anthu onse omwe adzatenge nawo mbali pa kafukufuku woonjezerayu tizachita nawo izi:

Tidzayika kanthu kokhala ngati pegi pa chala cha mwana komanso mayi ake kwa mphindi zochepa kuti tione mulingo wa mpweya oyipa mu thupi mwao. Kuyeza kumeneku sikumakhuzana ndi kutenga magazi komanso sikubweretsa vuto lililonse.Tidzayika kanthu kamene kamaunika mpweya oyipa pa chovala cha mwana komanso mayi ake, kwa masiku awiri kuti tizayeze mpweya oyipa omwe amayandikana nawo. Zipangizo zimenezi ndizosalemera komanso sizingasokoneze kagwiridwe ka ntchito yapakhomo ya tsiku ndi tsiku.

Choti mudziwe ndichakuti mukafukufukuyi munthu otenga nawo mbali sadzapephedwa kuti atengedwe magazi ayi.

5. Kodi padzakhala kuopsya kulikonse mukafukufukuyu?
Anthu akhonza kudzasiya zochita zina ndi zina pa nthawi imene akukutenga nao mbali mu kafukufukuyu, makamaka tikadzafuna kudziwa zina ndi zina kuchoka kwa iwo komanso tikamazayeza tatchulazi. Ndondomeko zonse zakafukufukuyu zili mwa tsatane tsatane komanso sizowopsya.

6. Kodi pali ubwino wanji wotenga nawo mbali mukafukufuku ameneyu?
Makomo onse amene adzatenge nao gawo mugulu lozalandira mbaulali lidzalandira mbaula zamakono ziwiri komanso makomo onse a mu gulu losalandira mbaulazi lizalandira mbaula za mtundu omwewu kumapeto kwa kafukufukuyu. Tidzaonetsetsa kuti mankhwala a chibayo

adzapezeke mzipatala zonse zomwe zili pafupi ndi onse otenga mbali. Komanso ana onse omwe sanalowe mukafukufuku azathandizidwa ngati mankhwala ali osakwanira mzipatala.

7. Kodi akuchititsa kafukufukuyi ndi ndani?
Kafukufukuyi akuyendetsa ndi a kusukulu ya ukachenjede ya College of Medicine, bungwe la kafukufuku la Malawi Liverpool Wellcome Trust, Liverpool School of Tropical Medicine, sukulu London ndi Imperial College London.

8. Kodi adzadziwe ndi ndani zotsatira za kafukufuku?
Tizasunga zonse mwachinsinsi ku ma ofesi athu popanda kutchula maina kapena kumene anthu anu akukhala. Zomwe tidzakambilane ndi kupeza, zizafotokozedwa ndi akulu akulu a College of Medicine, Malawi Liverpool Wellcome Trust ndi Liverpool School of Tropical Medicine kuzera mmisonkhano yomwe tidzakonze mu dera lanu, kuonjezera apo, tidzapereka zotsatira zonse ku msonkhano waukulu wa maiko otenga nawo mbali ndi olemba nkhani. Tidzachita chotheka kuwasungira anthu anu chinsinsi chawo.

9. Chingachitike ndi chani ngati otenga mbali atasintha maganizo?
Munthu aliyense otenga nao gawo mu kafukufukuyu ali ndi ufulu wosiya nthawi iliyonse.

Ngati mungakhale ndi mafunso, chonde funsani nkulu oyang'anira kafukufukuyi ku Chikwawa, bambo Chifundo Ndamala pa nambala ya foni iyi: **[+265 9999 81 409].**

Pa mafunso onse okhuzana ndi ufulu wa otenga mbali mukafukufukuyu, funsani wapampando wa COMREC. Bungweli ndi lomwe limaona ndi kuvomereza ngati kuli koyenera kuchita kafukufuku onga uyu. Mutha kuwapeza pa adilesi iyi, COMREC Secretariat, College of Medicine, P/bag 360, Blantyre 3. Tel no**: [+265 111 989 766].**

University of Malawi College of Medicine, Malawi Liverpool Wellcome Trust, University of Liverpool School of Tropical Medicine Information Sheet - Household Level Chichewa

Ndondomeko ndi chilolezo cha mutu wa banja, oyang'anira nyumba kapena kholo la ana munyumba.

Mbaula za makono zophikira, zothandiza kupewa chibayo kwa ana ochepera zaka zisanu M'malawi: Kafukufuku oyesera ku gulu losankhika.

1. Malonje
Moto wa ndowe, zinyalala, nkhuni ndi makala umatulutsa utsi omwe siwabwino ku umoyo wathu, motero ndi koyenera kuti tipeze njira zotchipa ndi zoyenera zomwe zingateteze anthu ku utsi umenewu.Njira imodzi mwa izo ndi kugwiritsa ntchito mbaula zamakono m'malo mwa njira zapambalambanda. Mbaula za makono zikhoza kukhala ndi ubwino ku umoyo wathu, koma sitikudziwa. Tikuchita kafukufuku oyesayu kuti tipeze ngati mbaulazi, zomwe tikuzitcha Philips zili ndi ubwino ku umoyo, makamaka kuchepetsa nthenda ya chibayo kwa ana.

2. Mwasankhidwa chifukwa chani?
Mukukhala mudera limene kafukufuku oyesa m'Malawi muno akuchitikira, komaso mudzi wanu wasankhidwa kuti utenge nawo mbali.

3. Ndikoyenera kuti nditenge nawo gawo mu kafukufukuyu?
Tikupemphani kutenga nawo gawo pokha pokha ngati akulu akulu a dera lanu avomereza kuti mudzi wanu utenge nawo gawo mu kafukufukuyu. Kutenga kwanu gawo, sikukuyendera kuti anzanu ena amudera lanu atero, kuvomereza kuti muthandize nawo mukafukufuku yu ndi kwakufuna kwanu ndipo ngati mutakonda uti musatenge nawo gawo mukafukufuku, mutha kusankha kusiya kutenga gawo mu kafukufukuyu nthawi ina iliyonse yakufuna kwanu opanda kupereka chifukwa chimene mwasiyira.

4. Chidzachitike ndi chani ngati nditenga nawo gawo mu kafukufukuyu?
Poyambilira, tizakufotokozerani gulu lomwe mudzi wanu uli, tizakhala ndi mayere omwe azapatule midzi yotenga nao gawo mu magulu awiri. (Gulu loima palokha ndi gulu lodalilana) Dziwani kuti kusankhidwa kwa mayereku sikungapangidwe kapena kusinthidwa mwa njira ina ili yonse.

Makomo onse a mugulu lodalilana azapatsidwa mbaula zamakono ziwiri zomwe azagwiritse ntchito m'malo mwa mbaula zakale. Ndikofunika kuti mbaula zamakonozi, zizagwiritsidwe ntchito pa zophikidwa zonse. Ndipo njira zinazonse zapambalambanda zomwe mumagwiritsa ntchito pophika zikuyenera kusiyidwa. Mbaula imodzi pa mbaula khumi zili zonse, izakhala ikuwunikidwa mwapadela, pa nthawi yonse ya kafukufuku oyesayu. Zotsatira za kuunikaku zizathandiza kutiziwitsa m'mene mbaulazi zingagwilire ntchito pa umoyo wathu wa tsiku ndi tsiku. Muzaphunzitsidwa kagwiritsidwe ntchito koyenera ka mbaula zamakonozi.

Makomo onse a gulu loima palokha azapemphedwa kuphika m'mene aphikila nthawi zonse, koma nawo azapatsidwa mbaula ziwiri zamakono kumapeto kwa kafukufuku oyesayu.

Tidzapereka ziphaso zakuchipatala, zatsopano kwa ana ochepera zaka zisanu mu nyumba mwanu, ngati pakadali pano alibe chiphaso kapena chiphaso chakale chatsala ndi malo ochepa. Tidzamata mu chiphasochi chizindikiro chofotokoza za kafukufukuyi, ndipo muzapemphedwa kuonetsa chizinikirochi kwa ogwira ntchito kuchipatala pa nthawi imene mwapita ndi mwana wanu kuchipatala panthawi yonse yakafukufukuyu. Izi zizatithandiza kutsata bwino matenda ena omwe mwana wanu angadwale nthawi imene kafukufuku ali kuchitika. Pa nthawi iliyonse yomwe mwachoka kolandira chithandizo kuchipatala, mudzapemphedwa kuziwitsa ogwira ntchito mu kafukufukuyu poimba lamya ya a komiti amudzi wanu.

Tizatenga mbiri ya chipatala yanu ndi banja lanu poyambilira pa kafukufuku pogwiritsa ntchito makina amakono osungira uthenga ndi mbiri. Pakapita miyezi itatu iliyonse, kwa zaka ziwiri, ogwira ntchito mukafukufukuyu azakuyenderani ndikuona mu ziphatso za ana anu ngati anakhuzidwa ndi nthenda ya chibayo, komanso ngati alipo wina mwa ana amene wamwalira.

Kuphatikiza apo, tizaonanso ngati pali mwana amene anadwala nthenda yokhuzana ndi kuvutika mu mapumidwe ndi kupsya. Tidzayezanso kuchuluka kwa mpweya oyipa munyumba mwanu ndi makina oyezera mpweya omwe azasiyidwe mu nyumba mwanu kwa masiku ofikira asanu, ndipo tizachita chimodzi modzi pakatha miyezi isanu ndi umodzi mu nthawi ya kafukufukuyu.

Tidzayendera ndi kuunika nyumba zowerengeka zosankhidwa kuchokera m'mayere zamukafukufuku, izi zizathandiza kudziwa kuchuluka kwa utsi umene ana komanso amayi amayandikana nawo pophika. Iyi ndi mbali imodzi yowonjezera mukafukufukuyu. Anthu atha kutenga kapena kusatenga nawo mbali mugawo limeneli ndipo sizizakhuzana ndikutenga kwawo mbali mu kafukufu wamkuluyu. Anthu onse omwe adzatenge nawo mbali pa kafukufuku woonjezerayu padzachitika izi:

Tidzayika kanthu kokhala ngati pegi pa chala cha mwana komanso mayi ake kwa mphindi zochepa kuti tione mulingo wa mpweya oyipa mu thupi mwao. Kuyeza kumeneku sikumakhuzana ndi kutenga magazi komanso sikubweretsa vuto lililonse. Tidzayika kanthu kamene kamaunika mpweya oyipa pa chovala cha mwana komanso mayi ake, kwa masiku awri kuti tidzaziwe ngati mumayandikira ndi mpweya oyipa. Zipangizo zimenezi sizimaonekera komanso sizingasokoneze kagwiridwe ka ntchito yanu ya tsiku ndi tsiku.

Choti mudziwe ndichakuti mukafukufukuyi munthu otenga nawo mbali sadzapephedwa kuti atengedwe magazi ayi.

5. Kodi padzakhala kuopsya kulikonse mukafukufukuyu?
Mukhonza kudzasiya zochita zina ndi zina pa nthawi imene mukutenga nawo mbali mu kafukufukuyu, makamaka tikadzafuna kudziwa zina ndi zina kuchoka kwa inu komanso tikamazayeza tatchulazi. Ndondomeko zonse zakafukufukuyu zili mwa tsatane tsatane komanso sizowopsya.

6. Kodi padzakhala ubwino mu kafukufuku ameneyu?
Makomo onse amene adzatenge nawo gawo azalandira mbaula za makono ziwiri, kumayambiliro kapena kumapeto kwa kafukufukuyu. Tidzaonetsetsa kuti mankhwala othandiza chibayo adzapezeke mu chipatala chapafupi ndi onse otenga mbali.

7. Kodi akuchititsa kafukufukuyi ndi ndani?
Kafukufukuyi akuyendetsa ndi a kusukulu ya ukachenjede ya College of Medicine, bungwe la kafukufuku la Malawi Liverpool Wellcome Trust, Liverpool School of Tropical Medicine, sukulu ya ukachenjede yaku London ndi Imperial College London.

8. Kodi adzadziwe ndi ndani zotsatira za kafukufuku?
Tizasunga zonse mwachinsinsi ku ma ofesi athu popanda kutchula maina kapena kokhala kwanu. Zomwe tidzakambilane ndi kupeza, zizafotokozedwa ndi akulu akulu a College of Medicine, Malawi Liverpool Wellcome Trust ndi Liverpool School of Tropical Medicine kuzera misonkhano yomwe tidzakonze mu dera lanu, kuonjezera apo, tidzapereka zotsatira zonse ku msonkhano waukulu wa maiko otenga nawo mbali ndi olemba nkhani. Tidzachita chotheka kukusungirani chinsinsi chanu.

9. Chingachitike ndi chani ngati mutasintha maganizo?
Mutha kusiya kutenga gawo mu kafukufukuyu nthawi iliyonse.

Ngati mungakhale mafunso, chonde funsani nkulu oyang'anira kafukufukuyi ku Chikhwawa, bambo Chifundo Ndamala pa nambala ya foni iyi: **[+265 9999 81 409].**

Pa mafunso onse okhuzana ndi ufulu wa otenga mbali mukafukufukuyu, funsani wapampando wa COMREC. Bungweli ndi lomwe limaona ndi kuvomereza ngati kuli koyenera kuchita kafukufuku onga uyu. Mutha kuwapeza pa adilesi iyi, COMREC Secretariat, College of Medicine, P/bag 360, Blantyre 3. Tel no: **[+265 111 989 766].**

Information sheets Tumbuka

University of Malawi College of Medicine, Malawi Liverpool Wellcome Trust, University of Liverpool School of Tropical Medicine Information Sheet - Cluster Level Tumbuka

Ndondomeka na chizomelezgo cha mwini chikaya

Mbaula za sono zakuphikira, zakuvwira kupewa chilaso kwa wana awo wandakwaniske vyaka vinkhondi.
M'malawi: kafukufuku ku gulu lakusoleka.

1. Pakwamba
Moto wa mavi ya ng,ombe,viswaswa,khuni na makala ukufumiska josi ilo ndi heni ku moyo withu,ntheula nkhwakuyenelera kuti tisange nthowa za kutchipa kweniso zakugomezgeka izo zingativwira kuchepeska josi na masuzgo yanyakhe ayo yakwiza chifukwa cha nthowa izi. Nthowa yimoza mwa izo nja kugwiriska ntchito mbawula za sono kulekana na nthowa za kuphikira pambalambanda. Mbawula za sono panyakhe zingawa na uwemi ku moyo winthu kweni sono tingayowoya yayi uwemi wakhe. Tikuchita kafukufuku uyu kuti tisange para mbaula izi izo zikuzunulika na zina lakuti Phillips zili na uwemi ku moyo chomenechomene kuchepeska nthenda ya chilaso kwa wana.

Chikalata chakupempha chizomelezo ichi chaikika kuti mwini chikaya amanyisiske lvyo vizamchitiva mchikaya chake kwa wanthu wake zaku khwafyana na ndondomeka ya kafukufuku wa kuphika na chilaso, oseweza nchito iyi andayambepo kuseweza ntchito yawo.

2. Mnchifukwa uli chikaya chinu chasoleka?
Mukukhala mchigawa icho, kafukufuku uyu M'malawi muno wakuchitikira kweninso chikaya chinu chasoleka kuti chitole nawo gawo?

3. Mnkhwakwenelera kuti chikaya chane chitolepo gawo mukafukufuku uyu?
Mukupempheka kutola nawo galo pekhapekha ngati walalawalala wa chigawa chinu wa zgomerezga kuti chikaya chinu chitole nawo gawo mukafukufuku uyu.
Kutola gawo kwinu mungatoleranga wanyinu chala kuti wachita ntheula kweninso mungakakamizhikanga kutola gawo yayi pala mwaona kuti mnkhwakwenelera chala muzampereka kanthu kalikonse yayi panyakhe kunoleka lvyo chikaya chinu chikwenera ku pokera. Mungasankha kufuma panji kutola gawo mukafukufuku uyu nyengo iliyose iyo imwe mwakhumba nanga uli kwambula kutipa chifukwa icho mwafumira.

4.Chizamchitika mnchivichi para chikaya chane chatolapo gawo mukafukufuku?
Pakwambira tizamkumphalirani gulu iyo chikaya chinu lilimo, pamzamchitika mayere ayo azampatulmbala vikaya ivyo vikutola nawo gawo mumagulu yawiri kugwriritsa ntchito Mbaula za sono panji kugwiritsa ntchito nthowa ivyo mukaphikiranga nyengo zose. Manyani kuti kusankhika kwa mayere uku kungapangiska yayi panyakhe kusintha mwanthowa iliyose.

Nyumba vyose vya mgulu lakudalirana azampokera mbaula zwiri za sono izo muzamgwirisa ntchito m'malo mwa nthowa kweniso nthowa vyonse vya kale vizamukanizhika. Mkhwakwenelera kuti mbaula za sono izi muzamgwirisa ntchito pakuphika vinthu vyose. Imoza mwa mbaula khumi (10) izamfufuzika mwapadera panyengo yose yakafukufuku uyu tizamuyika kanthu kanyakhe kazamtivwira kumanya umo mbaula zikugwilira ntchito manyengo yonse yakafukufuku.

Ku umaliro kwa kufufuza uku kuzamtivwira kumanya umo mbaula izi tingagwirisira ntchito pa umoyo wazuwa na zuwa. Munzaskambizgika umo mungagwiritsira ntchito kakwenelera ka mbaula za sono izi. Nyumba vyose vya mgulu lakuima palekha zizampempheka kuphika umo akaphikira nyengo vyose, kweni nawo azampasika mbaula za sono ku umaliro wa kafukufuku.

Tizampereka vitupa vya kuchipatala kwa wana awo andakwaniske vyaka vinkhonde chikaya chinu, pala kwanyengo yasono walije chitupa panyakhe chitupa chakale chakhala pachoko kumala. Tizam'matamo muchitupa ichi chimanyikwiro chakudumba vya kafukufuku uyu ndipo muzampempheka kuwalongola wakusewezga kuchipatala panyengo iyo imwe mwaluta na mwana winu kuchipatala. Panyakhe mwana wakukhumbika mvwiri wa mkhwala mu kafukufuku. Ivi vizamtivwira kulondezga makola matenda ayo mwana winu angarwala pa nyengo ya mukafukufuku uyu. Nyengo iliyonse iyo mwafuma kukapokera uvwiri kuchipatala, muzampepheka kumanyiska waku seweza mukafukufuku uyu pa kumanyiska munthu wakuimilira chikaya chinu mukafukufuku pakwimba lamya na maunitsi agho azampasika kwa a komiti a mu chigawa chinu.

Tizamtola mbiri yaumoyo winu na banja linu pakwambilira pa kafukufuku pakugwriritsa ntchito makina asono akusungira uthenga na mbiri ya umoyo winu. Pala miyezi itatu iliyose yamala pa vyaka vwiwiri wakusewezga mukafukufuku uyu azamkwenderani nakuona muvitupa vya wana winu kuti wamanye panji walikusangika na nthenda ya chilaso kweniso ngati pali wanyakhe mwa wana winu wali kutayika/ kufwa.

Pachanya pa ivyo tizamfumbani panji pali munyakhe mwa wana winu ayo wananthenda yakukhwafyana nakusuzgika mukathutiro na kupya. Tizampimaso unandi wa vuchi uheni mwa wana kweniso munyumba izo zichoko za kusankhika mwa mayere mukafukufuku, makina akupimira mvuchi ayo azamyikika kwa mazguwa ghankhonde ndipo tizamchitanso chimozamoza pala yamala miyezi inkhonde na umoza munyengo yakafukufuku uyu.

Tizamwendera nakufufuza nyumba zakusoleka mukafukufuku uyu ivyo vizamtivwira kumanya unandi wa josi uwo wana kweniso wa mama wa kukhwafyana nawo.iyi ndigawo limoza yakuskazirapo mukafukufuku uyu, mungamanya kutola panji kuleka kutola nawo gawo ili, ivi vikukhwafyana yayi nakutola kwinu gawo mukafukufuku wenecho. Wanthu wose azamtola gawo iyi mukafukufuku wakuskazhirapo tizamchita nawo ivi:

Tizamyika kanthu kanyakhe kakuwa ngati pegi pa njowe ya mwana kweniso mama wake kwa kanyengo ka choko kuti tiwone unandi wamvuchi uheni mthupi mwawo, kupima uku kukukhwafyana nakutola ndopa yayi kweniso kulije suzgo lililose. Tizamyika kanthu kanyakhenso ako kazampima mvuchi uheni pa chakuvwala cha mwana nawa nyina kwa madazi awiri kuti tikamanye pala mwakhalanga pafupi namvuchi uheni. Vyakupimira ivi vyose zizamtimbanizga yayi kagwiliro kantchito zinu za dazi nadazi.

Mumanye kuti mukafukufuku uyu wanthu wose wakutola nawo gawo wazampempheka chala kuti wapimike ndopa.

5. Kasi pazamkuwa vyakofya vilivose mukafukufuku uyu?
Panyengo iyi muzamtimbanizgika pachoko mukagwiliro kantchito zinu munyengo yakutola nawo gawo mukafukufuku, chomenechomene pala tizamukhumba kumanya vinthu vinyakhe kufuma kwa imwe kweniso para tizamupima vira taviyowoya. Ndondomeka vyose vyamukafukufuku uyu vya pulikwikwa makola kweninso vyambula kuofya

6. Kasi pali uwemi uli pakutola nawo gawo mukafukufuku uyu?
Nyumba vyonse vyakutola nawo gawo mugulu lakudalirana azampokera mbaula zasono pakwambira kweninso lakuima palekha ku umaliro wakafukufuku uyu, tizamwoneseska kuti mkhwala wakuvwira chilaso akazasangike mu chipatala chapafupi na wose wa kutola gawo. Kweninso wana wonse agho wali mukafukufuku chala wazamvirika na mkhwala uwu mzipatala.

7. Kasi wakuchitiska kafukufuku uyu mbanjani?
Kafukufuku uyu akuyandeska mba sukulu ya college of Medicine, bungwe la Malawi Liverpool Wellcome Trust, Liverpool School of Tropical Medicine, sukulu ya London na Imperial College London.

8. Kasi wazam'manya ndi njani ivyo vizamsangika paumaliro wa kafukufuku uyu?
Tizamsunga vyose mwa chisisi kuma ofesi yithu kwambula kuzunula zina panji chigawa icho mukukhala. Vyose ivyo tizamdumbirana nakusanga vizamyowoyeka na walalawalala, college of medicine, Malawi Liverpool Wellcome Trust na Liverpool School of Tropical medicine pa maungano ayo azamchitika muchigawa chinu kusazgirapo tizampereka vyose vyakusangika vyose ku ungano ukulu wa vyalo vyose ivo vikutola nawo gawo na wakulemba makani. Tizamuoneseska munthowa vyose kumusungirani chisisi chinu.

9. Chingachitika mchivichi para mungasintha maghanoghano yinu?
Mungaleka kutola nawo gawo mukafukufukufuku uyu munyengo iliyose.

Pala mungawa na mafumbo chonde fumbani akwendeska kafukufuku uyu Project Manager Chifundo Ndamala panambala ya foni iyi: **[+265 999 981 409].**

Mafumbo wose akukhwafyana na ufulu wakutolapo gawo mukafukufuku fumbani wapampando wa COMREC. Bungwe iyi ndiyo likewndeska na kuzomereza para mkhwakwenelera kuchita kafukufuku wanthena mungawasanga pa adilesi iyi, COMREC Secretariat, College of Medicine, P/bag 360, Blantyre 3. Tel no: **[+265 111 989 766].**

University of Malawi College of Medicine, Malawi Liverpool Wellcome Trust, University of Liverpool School of Tropical Medicine Information Sheet - Household Level Tumbuka

Ndondomeka na chizomelezgo cha wakupwelera nyumba panji nyina wa wana mnyumba

Mbaula za sono zakuphikira, zakuvwira kupewa chilaso kwa wana awo wandakwaniske vyaka vinkhondi.
M'malawi: kafukufuku ku gulu lakusoleka.

1.Pakwamba
Moto wa mavi ya ng,ombe,viswaswa,khuni na makala ukufumiska josi ilo ndi heni ku moyo withu,ntheula nkhwakuyenelera kuti tisange nthowa za kutchipa kweniso zakugomezgeka izo zingativwira kuchepeska josi na masuzgo yanyakhe ayo yakwiza chifukwa cha nthowa izi. Nthowa yimoza mwa izo nja kugwiriska ntchito mbawula za sono kulekana na nthowa za kuphikira pambalambanda. Mbawula za sono panyakhe zingawa na uwemi ku moyo kweni sono tikumanya yayi. Tikuchita kafukufuku uyu kuti tisange para mbaula izi izo zikuzunulika na zina lakuti Philips zili na uwemi ku moyo chomenechomene kuchepeska nthenda ya chilaso kwa wana.

2.Mnchifukwa uli mwasoleka
Mukukhala mchigawa icho, kafukufuku uyu M'malawi muno wakuchitikira kweninso chikaya chinu chasoleka kuti chitole nawo gawo?

3.Mnkhwakwenelera kuti nditole nawo gawo?
Mukupempheka kutola nawo galo pekhapekha ngati walalawalala wa chigawa chinu wa zgomerezga kuti chikaya chinu chitole nawo gawo mukafukufuku uyu. Kutola gawo kwinu mungatoleranga wanyinu chala kuti wachita ntheula kuzomera kwinu kuvwira mu kafukufuku uyu panji yayi mauzampereka kalikonse yayi panji kunoleka ivyo mukwenelera kupokera mchigawa chinu kweninso mungakakamizhikanga kutola gawo yayi pala mwaona kuti mnkhwakwenelera chala. Mungasankha kufuma panji kutola gawo mukafukufuku uyu nyengo iliyose iyo imwe mwakhumba nanga uli kwambula kutipa chifukwa icho mwafumira.

4.Chizamchitika mnchivichi para nazgomera kutola nawo gawo mukafukufuku uyu?
Pakwambira tizamkumphalirani gulu iyo chikaya chinu lilimo, pamzamchitika mayere ayo azampatula vikaya ivyo vikutola nawo gawo mumagulu yawiri kugwriritsa ntchito. Mbaula za sono panji kugwiritsa ntchito nthowa ivyo mukaphikiranga nyengo zose. Manyani kuti kusankhika kwa mayere uku kungapangiska yayi panyakhe kusintha mwanthowa iliyose.

Nyumba vyose vya mgulu lakudalirana azampokera mbaula za sono izo muzamgwirisa ntchito m'malo mwa mbaula zakale. Mkhwakwenelera kuti mbaula za sono izi muzamgwirisa ntchito pakuphika vinthu vyose. Nthowa vyose vyakale vikwenera kulekeka. Imoza mwa mbaula khumi (10) izamfufuzika mwapadera panyengo yose yakafukufuku uyu tizamyika kanthu kanyankhe ako ka zamtilongola kuti mbaula zasono izi zikugwilia nchito mukafukufuku uyu. Ku umaliro kwa kufufuza uku kuzamtivwira kumanya umo mbaula izi tingagwirisira ntchito pa umoyo withu wa zuwa na zuwa. Mungaskambizgika umo mungagwiritsira ntchito kakwenelera ka mbaula za sono izi.

Nyumba vyose vya mgulu lakuima palekha zizampempheka kuphika umo akuphikira nyengo vyose, kweni nawo azampasika mbaula zwiri za sono ku umaliro wa kafukufuku. Tizampereka vitupa vya kuchipatala kwa wana awo andakwaniske vyaka vinkhonde munyumba mwinu, pala kwanyengo yasono walije chitupa panyakhe chitupa chakale chakhala pachoko kumala. Tizam'matamo muchitupa ichi chimanyikwiro chakudumba vya kafukufuku uyu ndipo muzampempheka kuwalongola wakusewezga kuchipatala panyengo iyo imwe mwaluta na mwana winu kuchipatala. Panji mwana winu wakukhumbira mvwiri wa mkhwala mukafukufuku. Ivi vizamtivwira kulondezga makola matenda ayo mwana winu angarwala pa nyengo ya mukafukufuku uyu. Nyengo iliyonse iyo mwafuma kukapokera uvwiri kuchipatala, muzampepheka

kumanyiska waku seweza mukafukufuku uyu pa kumanyiska munthu wakuimilira chikaya chinu mukafukufuku pakwimba lamya na maunitsi awo azampasika.

Tizamtola mbiri yaumoyo winu na banja linu pakwambilira pa kafukufuku pakugwriritsa ntchito makina asono akusungira uthenga na mbiri ya umoyo winu. Pala miyezi itatu iliyose yamala pa vyaka vwiwiri wakusewezga mukafukufuku uyu azamkwenderani nakuona muvitupa vya wana winu kuti wamanye panji walikusangika na nthenda ya chilaso kweniso ngati pali wanyakhe mwa wana winu wali kutayika/ kufwa.

Pachanya pa ivo tizamfumbani panji pali munyakhe mwa wana winu ayo wananthenda yakukhwafyana nakusuzgika mukathutiro na kupya. Tizampimaso unandi wa vuchi uheni mwa wana kweniso munyumba izo zichoko za kusankhika mwa mayere mukafukufuku, makina akupimira mvuchi ayo azamyikika kwa mazguwa ghankhonde ndipo tizamchitanso chimozamoza pala yamala miyezi inkhonde na umoza munyengo yakafukufuku uyu.

Tizamwendera nakufufuza nyumba zakusoleka mukafukufuku uyu ivyo vizamtivwira kumanya unandi wa josi uwo wana kweniso wa mama wa kukhwafyana nawo.iyi ndigawo limoza yakuskazirapo mukafukufuku uyu, mungamanya kutola panji kuleka kutola nawo gawo ili, ivi vikukhwafyana yayi nakutola kwinu gawo mukafukufuku wenecho. Wanthu wose azamtola gawo iyi mukafukufuku wakuskazhirapo tizamchita nawo ivi:

Tizamyika kanthu kanyakhe kakuwa ngati pegi pa njowe ya mwana kweniso mama wake kwa kanyengo ka choko kuti tiwone unandi wamvuchi uheni mthupi mwawo, kupima uku kukukhwafyana nakutola ndopa yayi kweniso kulije suzgo lililose. Tizamyika kanthu kanyakhenso ako kazampima mvuchi uheni pa chakuvwala cha mwana nawa nyina kwa madazi awiri kuti tikamanye pala mwakhalanga pafupi namvuchi uheni. Vyakupimira ivi vyose zizamtimbanizga yayi kagwiliro kantchito zinu za dazi nadazi.

Mumanye kuti mukafukufuku uyu wanthu wose wakutola nawo gawo wazampempheka chala kuti wapimike ndopa.

5. Kasi pazamkuwa vyakofya vilivose mukafukufuku uyu?
Panyengo iyi muzamtimbanizgika pachoko mukagwiliro kantchito zinu munyengo yakutola nawo gawo mukafukufuku, chomenechomene pala tizamukhumba kumanya vinthu vinyakhe kufuma

kwa imwe kweniso para tizamupima vira taviyowoya. Ndondomeka vyose vyamukafukufuku uyu vya pulikwikwa makola kweninso vyambula kuofya

6.Kasi pali uwemi uli pakutola nawo gawo mukafukufuku uyu?
Nyumba vyonsevyakutola nawo gawo mugulu lakudalirana azampokera mbaula zasono pakwambira kweninso lakuima palekha ku umaliro wakafukufuku uyu, tizamwoneseska kuti mkhwala wakuvwira chilaso akazasangike mu chipatala chapafupi na wose wa kutola gawo.

7.Kasi wakuchitiska kafukufuku uyu mbanjani?
Kafukufuku uyu akuyandeska mba sukulu ya college of Medicine, bungwe la Malawi Liverpool Wellcome Trust, Liverpool School of Tropical Medicine, sukulu ya London na Imperial College London.

8.Kasi wazam'manya ndi njani ivyo vizamsangika paumaliro wa kafukufuku uyu?
Tizamsunga vyose mwa chisisi kuma ofesi yithu kwambula kuzunula zina panji chigawa icho mukukhala. Vyose ivyo tizamdumbirana nakusanga vizamyowoyeka na walalawalala, college of medicine, Malawi Liverpool Wellcome Trust na Liverpool School of Tropical medicine pa maungano ayo azamchitika muchigawa chinu kusazgirapo tizampereka vyose vyakusangika vyose ku ungano ukulu wa vyalo vyose ivo vikutola nawo gawo na wakulemba makani. Tizamuoneseska munthowa vyose kumusungirani chisisi chinu.

9. Chingachitika mchivichi para mungasintha maghanoghano yinu?
Mungaleka kutola nawo gawo mukafukufukufuku uyu munyengo iliyose.

Pala mungawa na mafumbo, chonde fumbani akwendeska kafukufuku uyu Project Manager Chifundo Ndamala panambala ya foni iyi: **[+265 999 981 409].**

Mafumbo wose akukhwafyana na ufulu wakutolapo gawo mukafukufuku fumbani wapampando wa COMREC. Bungwe iyi ndiyo likewndeska na kuzomereza para mkhwakwenelera kuchita kafukufuku wanthena mungawasanga pa adilesi iyi, COMREC Secretariat, College of Medicine, P/bag 360, Blantyre 3. Tel no: **[+265 111 989 766].**

Appendix C:
Baseline and Follow-up CRFs

CAPS eCRF: BASELINE DATA CAPTURE

1. **[This is an instruction to the fieldworker]**

Collect GPS co-ordinates of household visited

2. **[This is a question for the fieldworker to answer]**

Has consent been obtained for the household to participate in the study?

YES [continue to step 3]
NO [household not eligible – end of data capture.]

[If answer 'no' include free text box to indicate why]

3. **[This is an instruction to the fieldworker]**

Scan the completed consent form.

[Data field will be a digital image]

[Click OK then continue to step 4]

4. **[This is an instruction to the fieldworker]**

Enter or scan the cluster id

[Data field will be a string – need flexibility about format for now. In Chilumba this will be RG-CL]

[Click OK then continue to step 5]

5. **[This is an instruction to the fieldworker]**

Enter or scan the household id

[Data field will be a string – need flexibility about format for now. In Chilumba this will be RG-CL-HSE. May need option to create unique household id]

[Click OK then continue to step 6]

6. **[This is a question for the fieldworker to answer]**

Is this household in the intervention (Philips cookstove) or the control (open fire) group:

Intervention [continue to step 7]

Control [continue to step 8]

7. **[This is an instruction for the field worker]**

Enter or scan the cookstove id for stove #1

[Data field will be a string – need flexibility about format for now]

Enter or scan the cookstove id for stove #2

[Data field will be a string – need flexibility about format for now]

Enter or scan the id for the solar panel

[Data field will be a string – need flexibility about format for now]

[Click OK then continue to step 8]

8. **[This is an instruction to the fieldworker]**

Ask the child's mother or guardianthe following question:

What is your relationship to the children in your household? (may tick more than one box if more than one role applies)

Mother
Father
Brother
Sister
Grandmother
Grandfather
Aunt
Uncle
Cousin
Other (specify)

[If 'Other' ticked then open up free text box to specify]

[Click OK then continue to step 9]

9. **[This is an instruction to the fieldworker]**

Ask the child's mother or guardian the following question:

What fuel is regularly used to cook food at your home? (may tick more than one box)

Electricity
Liquid Petroleum Gas (LPG)/gas
Kerosene/paraffin
Charcoal
Wood
Dung

Crop residues
Other (specify)

[If 'Other' ticked then open up free text box to specify]

[Click OK then continue to step 10]

10. **[This is an instruction to the fieldworker]**

Ask the child's mother or guardian the following question:

During the dry season is most of the cooking at your home done (tick one box)

Outside in a separate structure with a roof only
Outside in a separate structure with walls and a roof
Outside in the open air
Outside on the veranda (khonde)
Inside in a separate room (kitchen)
Inside in a living room

[Only one response allowed]

[Click OK then continue to step 11]

11. **[This is an instruction to the fieldworker]**

Ask the child's mother or guardian the following question:

During the rainy season is most of the cooking at your home done (tick one box)

Outside in a separate structure with a roof only
Outside in a separate structure with walls and a roof
Outside in the open air
Outside on the veranda (khonde)
Inside in a separate room (kitchen)
Inside in a living room

[Only one response allowed]

[Click OK then continue to step 12]

12. **[This is an instruction to the fieldworker]**

Ask the child's mother or guardian the following question:

How many people in your household if any smoke regularly?

[Data field will be a number]

[Click OK then continue to step 13.

13. **[This is an instruction to the fieldworker]**

Ask the child's mother or guardian the following question:
Apart from cooking, are you exposed to any other sources of fire or smoke on a daily or almost every day basis? (check all that apply)

Burning rubbish
Cooking for others/as a business
Making beer
Making bricks
Kerosene lamps
Others
None

[If 'Other' ticked then open up free text box to specify]

[Click OK then continue to step 14]

14. **[This is an instruction to the fieldworker]**

Ask the child's mother or guardian the following question:

What toilet facilities are there?

None
Simple pit latrine
Ventilated Improved Pit (VIP)
Water toilet

[Only one response allowed]

[Click OK then continue to step 15]

15. **[This is an instruction to the fieldworker]**

Ask the child's mother or guardian the following question:

What is the source of water for drinking?**(may tick more than one box)**

Tap to house
Shared communal tap
Bore hole
Covered well
Open well
Lake or river
Other

[Multiple responses allowed.]

[Include text field to specify if 'other']

[Click OK then continue to step 16]

16. **[This is an instruction to the fieldworker]**

Ask the child's mother or guardian the following question:

Does anyone in the household possess the following? **(may tick more than one box)**

Working watch or clock
Working radio
Bank account or bank book
Charcoal iron
Working sewing machine
Mobile phone
Mosquito net
Mattress
Bed
Bicycle
Canoe
Oxcart
Motorbike
Car
None of the above

[Multiple responses allowedunless responses include "None of the above"]

[Click OK then continue to step 17]

17. **[This is an instruction to the fieldworker]**

Ask the child's mother or guardian the following question:

Since this time last year, has there been a time when there was not enough food for the household to have its normal meals? (fewer meals per day, and/or smaller meals, and/or less variety of foods)

Yes
No

[Only one response allowed]

[Click OK then continue to step 18]

18. **[This is an instruction to the fieldworker]**

Ask the child's mother or guardian the following question:

Since this time last year have there been times when the household did not have money to buy bathing soap?

Yes
No

[Only one response allowed]

[Click OK then continue to step 19]

19. **[This is a question for the fieldworker to answer]**

How many children under the age of 4.5 years live in this household?

[Data field will be a number] If the answer is 0, please notify the individual that they will not be eligible to participate in the study. End of data capture.]

[Click OK then continue to step 20]

20. **[This is a question for the fieldworker to answer]**

Will all the children under the age of 4.5 living in this household participate in CAPS?

YES [continue to step 23]
NO [continue to step 21]

[If answer yes then the number of participating children and therefore the number of participants for this household will be the number given at step 19]

21. **[This is a question for the fieldworker to answer]**

How many children under the age of 4.5 living in this household will NOT participate in CAPS?

[Data field will be a number]

[The number of participants for this household is the number given in response to step 19 minus the number given in response to step 21]

[Click OK then continue to step 22]

22. **[This is an instruction to the fieldworker]**

Give the reasons for why each child under the age of 4.5 living in this household will not participate CAPS

[This is a free text box]

[Click OK then continue to step 23]

[Steps 23onwards need to be completed for each child participant. The number of sets of these steps will be determined by the responses to questions 19-21]

23. **[This is an instruction to the fieldworker]**

Enter or scan the participant id

[Data field will be a string – need flexibility about format for now. In Chilumba this will be STID. May need option to create unique participant id]

[Click OK then continue to step 24]

24. [This is an instruction to the fieldworker]

Enter the participant's first and last initials

[format XX]

[Click OK then continue to step 25

25. [This is an instruction to the fieldworker]

Is the participants' date of birth known?

Yes [continue to step 25.1]
No [continue to step 25.2]

25.1. [This is an instruction to the fieldworker]

Enter the participants' date of birth

[format DD/MM/YYYY—confirm it is the date of birth indicated on the health passport]

[Click OK then continue to step 26.]

[Include an eligibility check at this stage – if the age is less than 4.5 years according to date of birth then present message to fieldworker that the child is over the age of 4.5 years and offer option to amend DOB or delete this record]

25.2. [This is an instruction to the fieldworker]

Enter the participants' age in months

[format XX]

[Click OK then continue to step 26.]

[Include an eligibility check at this stage – if the age is less than 4.5 years according to age in months then present message to fieldworker that the child is over the age of 4.5 years and offer option to amend age or delete this record]

26. [This is an instruction to the fieldworker]

Enter the participants' gender

[Dropdown menu with responses male/female—confirm it is the gender indicated on the health passport]

[Click OK then continue to step 27]

27. **Ask the child's mother or guardian the following question:**

Does the participant have a health passport?

YES [continue to step 28]
NO [continue to step 32]

28. **[This is an instruction and question to the fieldworker]**

Review the entries in the health passport over the last 12 months

Has the participant had a diagnosis of pneumonia noted in the health passport during the last 12 months?

YES
NO

[Click OK then continue to step 29]

29. **[This is an instruction to the field worker]**

Is the immunization record page available in the health passport?

YES [continue to step 30]
NO [continue to step 31]

30. **[This is an instruction to the field worker]**

Scan a copy of the child's immunization record from the health passport.

[Click OK then continue to step 30]

31. **[This is a question for the fieldworker to answer]**

Does the health passport have at least 5 blank pages?

YES [continue to step 33]
NO [continue to step 32]

32. **[This is an instruction to the fieldworker]**

Provide the participant with a new health passport

[Click OK then continue to step 33]

33. **[This is an instruction to the fieldworker]**

Insert a CAPS participation sticker into the front of the health passport. Insert a CAPS pneumonia data sticker onto the first blank page of the health passport after the growth chart.

[Click OK then continue to step 34]

34. **[This is an instruction to the field worker]**

Ask the child's mother or guardian the following question:

"Over the last 3 months has this child usually had a cough when he/she doesn't have a cold?"

YES
NO

[Click OK then continue to step 35]

35. **[This is an instruction to the field worker]**

Ask the child's mother or guardian the following question:

"Has this child had wheezing or whistling in his/her chest at any time in the last **3 months**?"

YES
NO

[Click OK then continue to step 36]

36. **[This is an instruction to the field worker]**

Ask the child's mother or guardian the following question:

"During the past 3 months has this child suffered a burn (with a hot object or liquid)?

YES [continue to step 37]
NO [That is the end of the questionnaire for this participant]

[If 'No', the final screen should be a comment box for free text notes]

37. **[This is an instruction to the field worker]**

Ask the child's mother or guardian the following question:

"How serious was the burn?"

Light (there is no scar)
Moderate (scar small than a new MK10 coin)
Serious (scar larger than a new MK10 coin)

[Click OK then continue to step 38]

38. **[This is an instruction to the field worker]**

Ask the child's mother or guardian the following question:

How did he/she get burned?

He/she fell in the fire
He/she was burned by a hot object
A container with hot liquid (example water) was spilled
Other

[Include text field to specify if 'other']

[Click OK then that is the end of the questionnaire for this participant.]

[Final screen should be a comment box for free text notes]

CAPS eCRF: FOLLOW UP DATA CAPTURE

1. [This is an instruction to the fieldworker]

Enter or scan the household id

[Data field will be a string – need flexibility about format for now. In Chilumba this will be RG-CL-HSE. The household eCRF will load after entering the household id]

[Click OK then continue to step 2]

2. [This is an instruction to the fieldworker]

Confirm the correct household eCRF has been loaded

[At this step a summary should be presented to the fieldworker showing the household id and a list of the participants' ids, initials and DOBs]

[Click OK then continue to step 3 or Go Back if incorrect household eCRF loaded]

3. [This is a question for the fieldworker to answer]

Is this household in the intervention (Philips cookstove) or the control (open fire) group:

Intervention [continue to step 4]
Control [continue to step 11]

4. [This is an instruction for the field worker]

Enter or scan the cookstove id for stove #1

[Data field will be a string – need flexibility about format for now]

Enter or scan the cookstove id for stove #2

[Data field will be a string – need flexibility about format for now]

5.[This is a question for the fieldworker to answer]

Are Philips cookstoves 1 and 2 working normally?

Cookstove 1

YES [continue to cookstove #2]
NO [continue to step 7]

Cookstove 2

YES [continue to step 6]
NO [continue to step 7]

6. [This is an instruction to the fieldworker]

If the solar panel is present in the household, enter or scan the id for the solar panel.

If the solar panel is not present, ask which household currently has the solar panel and please enter or scan the id before departing the area.

Is the solar panel working normally?
YES
NO
THE PANEL IS UNAVAILABLEq [continue to step 8 and notify the Senior Field Worker]

If the solar panel is unavailable, please indicate why.

[Free text box]

7. [This is an instruction to the fieldworker]

Make arrangements to repair or replace the Philips cookstove or solar panel.

[Click OK then continue to step 8]

8. [This is an instruction to the fieldworker]

Ask the child's mother or guardian the following question:

"Are the Philips cookstoves used for all the households cooking needs?"

YES [continue to step 10]
NO [continue to step 9]

9. [This is an instruction to the fieldworker]

Ask the child's mother or guardian the following question:

"Approximately how much of the household's day to day cooking is done using the Philips cookstoves?"

None (The household does not use the cookstove)
Some (At least one meal, but most of the cooking is still done over an open fire or by ordinary means)
About half (Half of the cooking is done with the advanced cookstove, and half is done over an open fire or by ordinary means)
Most (2-3 meals) (Most of the cooking is done on the advanced cookstove, but some is still done over an open fire or by ordinary means)
All cooking and water boiling is done on the advanced stove

[If the answer is "All" then click OK and continue to step 10]

If s/he does not answer "All", then ask the child's mother or guardian the following question:

Why don't you use the advanced cookstove for all of your cooking?
[check all that apply]

The stoves are too small to use for all of my cooking
My pots do not fit on the stove

The stove is broken or does not work well
I don't know how to use it/I don't feel comfortable using it
I am unable to find fuel
The battery has died
Food doesn't taste the same
I am afraid my child will get burned
Other

[free test box]

[Click OK then continue to step 10]

10. [This is a question for the fieldworker to answer]

Is the household in the SUMS substudy?

YES [continue to step 11]
NO [continue to step 12]

11. [This is an instruction to the fieldworker]

Download the SUMS data onto the study laptop.

[Click OK then continue to step 12]

12. [This is an instruction to the fieldworker]

Are there any children under the age of 4.5 living in this household who need to be added to the eCRF?

YES [continue to step 13]
NO [continue to step 22]

13. [This is an instruction to the fieldworker]

How many children under the age of 4.5 living in this household need to be added to the eCRF?

[Data field will be a number. This number will determine the number of additional participant eCRFs needed and therefore the number of sets of steps 13 to 19]

[Click OK then continue to step 14]

14. [This is an instruction to the fieldworker]

Enter or scan the participant id

[Data field will be a string – need flexibility about format for now. In Chilumba this will be STID. May need option to create unique participant id]

[Click OK then continue to step 15]

15. [This is an instruction to the fieldworker]

Enter the participants' first and last initials

[format XX]

[Click OK then continue to step 16]

16. [This is an instruction to the fieldworker]

Enter the participants' date of birth

[format DD/MM/YYYY]

[Click OK then continue to step 17. Include an eligibility check at this stage – if the age is less than 4.5 years according to date of birth then present message to fieldworker that the child is over the age of 4.5 years and offer option to amend DOB or delete this record]

17. [This is an instruction to the fieldworker]

Enter the participants' gender

[Dropdown menu with responses male/female]

[Click OK then continue to step 18]

18. [This is a question for the fieldworker to answer]

Has the participant got a health passport with at least 5 blank pages?

YES [continue to step 20]
NO [continue to step 19]

19. [This is an instruction to the fieldworker]

Provide the participant with a new health passport

[Click OK then continue to step 20]

20. **[This is an instruction to the fieldworker]**

Insert a CAPS participation sticker onto the front cover of the new health passport. Place a CAPS pneumonia sticker onto the first blank page after the growth chart in the center of the health passport

[Click OK then that is the end of the questionnaire for this participant]

21.[This is an instruction to the fieldworker]

Select the participant

[provide menu with a list of all the participants in the household and options to 'SELECT', or mark as unavailable 'NOT POSSIBLE TO COLLECT DATA TODAY']

[Click SELECT and continue to step 23 or click 'NOT POSSIBLE TO COLLECT DATA TODAY' and continue to step 22. All participants in the household should have data entered

under 'SELECT' or 'NOT POSSIBLE TO COLLECT DATA TODAY' before the household visit is concluded with the exception of any participants added to the eCRF at this visit]

22. [This is an instruction to the fieldworker]

If it is not possible to collect data from the participant today record the reason using the drop-down menu:

Temporary issue [If ticked then open up free text box to give reason and ask fieldworker to make a further appointment to conduct this visit]
Permanent issue [If ticked then open up free text box to give reason. If the participant has died a verbal autopsy should be arranged if the family are agreeable on a separate occasion. This participants' eCRF should then be saved and no longer editable]

[Click OK then that is the end of the data entry for this participant for this study visit]

23. [This is a question for the fieldworker to answer]

Has the participant got their health passport?

YES [continue to step 24]
NO [continue to step 25]

24. [This is a question for the fieldworker to answer]

Has the health passport got at least 5 blank pages?

YES [continue to step 29]
NO [continue to step 28]

25. [This is an instruction to the fieldworker]

Record the reason why the participant does not have their health passport

Temporarily unavailable [continue to step 26]
Permanently unavailable [continue to step 27]

26. [This is an instruction to the fieldworker]

Make a further appointment to conduct this study visit.

[Click OK then that is the end of the data entry for this participant for this visit]

27. [This is an instruction to the fieldworker]

Provide the participant with a new health passport

[Click OK then continue to step 36]

28. [This is an instruction to the fieldworker]

Provide the participant with a new health passport

[Click OK then continue to step 29]

29. [This is an instruction to the fieldworker]

Scan the health passport starting with the page with the CAPS sticker relating to the last visit up to and including the latest entry. If there are no entries after the CAPS sticker just scan the CAPS sticker relating to the last visit.

[Click OK then continue to step 30]

30. [This is a question for the fieldworker to answer]

Has the participant had a diagnosis of pneumonia noted in the health passport since the last study visit?

YES [continue to step 31]
NO [continue to step 45]

31.[This is a question for the fieldworker to answer]

Was the diagnosis of pneumonia noted in the health passport recorded as

Very severe
Severe
Not severe
Severity not recorded/unable to determine

[Click OK then continue to step 32]

32.[This is a question for the fieldworker to answer]

Was the participant treated as an inpatient or outpatient?

Inpatient [continue to step 33]
Outpatient [continue to step 34]

33.[This is a question for the fieldworker to answer]

How many days was the patient in hospital for including the day of admission and discharge?

[data field will be a number]

[Click OK then continue to step 34]

34. [This is an instruction to the field worker]

Scan the CAPS pneumonia data sticker. Record the following information from the CAPS pneumonia sticker

Did the child have a cough?

YES
NO
NOT RECORDED

[Click OK then continue to step 35]

35. [This is an instruction to the field worker]

Did the child have difficulty breathing?

YES
NO
NOT RECORDED

[Click OK then continue to step 36]

36. [This is an instruction to the field worker]

Did the child have fast breathing?

YES
NO
NOT RECORDED

[Click OK then continue to step 37]

37. [This is an instruction to the field worker]

Did the child have chest indrawing?

YES
NO
NOT RECORDED

[Click OK then continue to step 38]

38. [This is an instruction to the field worker]

Did the child have stridor?

YES
NO
NOT RECORDED

[Click OK then continue to step 39]

39. [This is an instruction to the field worker]

What was the respiratory rate?

[data field will be a number]

[Click OK then continue to step 40]

40. [This is an instruction to the field worker]

What was the temperature?

[data field will be a number]

[Click OK then continue to step 41]

41. [This is an instruction to the field worker]

Were there any Danger Signs?

YES
NO
NOT RECORDED

[Click OK then continue to step 42]

42. [This is an instruction to the field worker]

Scan the page of the Health Passport with the results of the Xray if available. Please record the results of the X ray.

[text box]

[Click OK then continue to step 43]

43. [This is an instruction to the field worker]

What was the result of pulse oximetry?

[data field will be a number]

[Click OK then continue to step 44]

44. [This is an instruction to the field worker]

What was the result of the malaria test?

POSITIVE
NEGATIVE
NOT DONE/NOT RECORDED

[Click OK then continue to step 45]

45. [This is an instruction to the field worker]

Ask the child's mother or guardian the following question:

"Over the last 3 months has this child usually had a cough when he/she doesn't have a cold?"

YES
NO

[Click OK then continue to step 46]

46. [This is an instruction to the field worker]

Ask the child's mother or guardian the following question:

“Has this child had wheezing or whistling in his/her chest at any time in the last 3 months?”

YES
NO

[Click OK then continue to step 47]

47. [This is an instruction to the field worker]

Ask the child’s mother or guardian the following question:

“During the past 3 months has this child suffered a burn (with a hot object or liquid)?

YES [continue to step 48]
NO [continue to step 50]

48. [This is an instruction to the field worker]

Ask the child’s mother or guardian the following question:

“How serious was the burn?”

Light (there is no scar)
Moderate (scar small than a new MK10 coin)
Serious (single scar larger than a new MK10 coin, or multiple small scars whose total area is greater than a new MK10 coin)

[Click OK then continue to step 49]

49. [This is an instruction to the field worker]

Ask the child’s mother or guardian the following question:

How did he/she get burned?

He/she fell in the fire
He/she was burned by a hot object
A container with hot liquid (example water) was spilled
Other

Include text field to specify if ‘other’

[Click OK then continue to step 50**]**

50. [This is a question for the fieldworker to answer]

Have there been any adverse events (such as any other injury from the cookstove or the solar panel use)related to cooking since the last study visit?

YES [continue to step 51]
NO [continue to step 54]

51. [This is an instruction to the fieldworker]

Describe the adverse events in the text box

[Data will be a free text box]

[Click OK then continue to step 52]

52. [This is a question for the fieldworker to answer]

Were any of the adverse events serious (death, life-threatening, hospitalization, disability or incapacity, congenital anomaly)?

YES [continue to step 53]
NO [continue to step 54]

53. [This is an instruction to the fieldworker]

Report any adverse event to the Project Manager within 24 hours. Report any serious adverse event to the Project Manager immediately.

[Click OK then continue to step 54**]**

54. [This is a question for the fieldworker to answer]

Is the child still under the age of 5?

YES [continue to step 56]
NO [continue to step 55**]**

55.[This is an instruction to the fieldworker]

The child has now completed their participation in CAPS. Thank the participant and his/her mother/guardian

[Click OK then that is the end of the questionnaire for this participant.]

Final screen should be a comment box for free text notes. This participant's eCRF should then be saved and no longer editable**]**

56. **[This is an instruction to the fieldworker]**

Insert a CAPS participation sticker to indicate which visit has been conducted today. Confirm that there are 2 available columns for writing on the CAPS pneumonia sticker. If not, replace the CAPS pneumonia sticker on the first blank page after the previous CAPS pneumonia sticker.

[Click OK then that is the end of the questionnaire for this participant.]

[Final screen should be a comment box for free text notes]

An advanced cook stove intervention to prevent pneumonia in children under 5 years old in Malawi: a cluster randomized controlled trial.

Cluster Consent Form: English Version 2.3

Name of village head man_____

Address_____

1. Have you read or listened to the village information sheet (v.2.3: 06/12/13)?	Yes / No
2. Have you had the opportunity to ask questions?	Yes / No
3. Have your questions been answered, and do you feel that you have enough information about this study?	Yes / No
4. Do you understand that your subjects are free to withdraw from the study at any time without giving a reason and without any penalties?	Yes / No
5. Do you understand that data collected during the study may be looked at by individuals from Liverpool School of Tropical Medicine and regulatory authorities? Information you provide which is needed for analysis outside Malawi will be anonymised.	Yes / No
6. Do you agree for your village and subjects to take part in the study?	Yes / No

If you have answered 'yes' to questions 1-6, please sign the form, or place a thumbprint below, which means that you voluntarily agree for your village and subjects to participate in the study.

I voluntarily agree to enter this study.

Signature_____Date_____

Witness to consent if participant unable to sign their name

(name in capitals)_____

Signature_____Date_____

Investigator obtaining consent (name in capitals)_____

Signature_____Date_____

An advanced cook stove intervention to prevent pneumonia in children under 5 years old in Malawi: a cluster randomized controlled trial.

Household Consent form: English version 2.3

Name of participants:

1. _____
2. _____
3. _____
4. _____

Address_____

1. Have you read or listened to the patient information sheet (v.2.3: 06/12/13)?	Yes /No
2. Have you had the opportunity to ask questions?	Yes /No
3. Have your questions been answered, and do you feel that you have had enough information about this study?	Yes / No
4. Do you understand that you are free to withdraw from the study at any time without giving a reason and without any penalties?	Yes /No
5. Do you understand that data collected during the study may be looked at by individuals from Liverpool School of Tropical Medicine and regulatory authorities? Information you provide which is needed for analysis outside Malawi will be anonymised.	Yes / No
5. Do you agree to undergo the optional personal monitoring? You can still take part in the trial if you say no.	Yes / No

If you have answered 'yes' to questions 1-5 and 'yes' or 'no' to question 6, please sign the form, or place a thumbprint below, which means that you voluntarily agree to enter the study.

I voluntarily agree to enter this study.

Signature_____Date_____

Witness to consent if participant unable to sign their name

(name in capitals)_____

Signature_____Date_____

Investigator obtaining consent (name in capitals)_____

Signature_____Date_____

An advanced cook stove intervention to prevent pneumonia in children under 5 years old in Malawi: a Cluster randomized controlled trial.

Cluster Consent form: Chichewa version 2.3

Dzina la mfumu_____

Kochokera/Adilesi_____

1.	Kodi Mwawelenga kapena mwamva za pasamba la olowanawo Kafukufuku lofotokoza za kafukufukuyi (v.2.3: 06/12/13)?	Eya / Ayi
2.	Kodi Mwapatsidwa mpata ofunsa mafuso?	Eya / Ayi
3.	Kodi mafunso anu ayankhidwa ndipo mukuona kuti mwaziwitsidwa mokwanira pa zakafukufukuyi ?	Eya / Ayi
4.	Kodi mukumvesa kuti anthu a mmudzi mwanu ali omasuka kutuluka Mukafukufukuyu nthawi ina ili yonse popanda kupeleka chifukwachinachilichonse ndipo sazalandira chilango chilichonse?	Eya / Ayi
5.	Kodi mukumvesa kuti zonse zomwe zizatengedwe pa nthawi ya kafukufukuyu Zikaonedwa ndi anthu ochokera ku Liverpool School of Tropical Medicine ndi a mabungwe oyang'anira kafukufuku? Zonse zomwe anthu anu azanene zizafunika kuunikidwa bwino kunja kwa dziko la Malawi, zizakonzedwaso Mwachinsinsi kuti opelekayo asazaziwike**.**	Eya / Ayi
6.	Mukuvomera kuti anthu atenge nao gawo mukafukufukuyu?	Eya / Ayi

Ngati mwayankha kuti "Eya" mafunso 1-5 ndi "Eya" kapena "Ayi" ku funso number 6, chonde sainani pa tsambali, Kapena ikani chidindo cha chala chachikulu cha kudzanja pansipa kusonyeza kuti mwalola kuti anthu a mmudzi mwanu alowe nawo mu kafukufukuyu mosakakamizidwa.

Ndapeleka chilolezo choti anthu a mmudzi mwanga alowe nawo mu kafukufukuyu mosakakamizidwa.

Saini_____Tsiku_____

Mboni ya olowa mu kafukufukuyu ngati mwini wake saziwa kulemba

(lembani zilembo zikuluzikulu)_____

Saini_____Tsiku_____

Otenga chilolezo (lembani zilembo zikuluzikulu)_____

Saini_____Tsiku_____

An advanced cook stove intervention to prevent pneumonia in children under 5 years old in Malawi: a cluster randomized controlled trial.

Household Consent form: Chichewa version 2.3

Mayina a atenga mbali:

1. _____
2. _____
3. _____
4. _____

Kochokera/Adilesi_____

1. Kodi Mwawelenga kapena mwamva zapa tsamba la olowa nawo kafukufuku lofotokoza za kafukufukuyi (v.2.3: 06/12/13)?	Eya / Ayi
2. Kodi Mwapatsidwa mpata ofunsa mafuso?	Eya / Ayi
3. Kodi mafunso anu ayankhidwa ndipo mukuona kuti mwaziwitsidwa mokwanira paza kafukufukuyi ?	Eya / Ayi
4. Kodi mukumvesa kuti ndinu omasuka kutuluka mukafukufukuyu nthawi ina ili yonse popanda kupeleka chifukwa chinachilichonse ndipo simuzalandira chilango chilichonse?	Eya / Ayi
5. Kodi mukumvesa kuti zonse zomwe zizatengedwe nthawi ya kafukufuku Zikaonedwa ndi anthu ochokera ku Liverpool School of Tropical Medicine ndi a mabungwe oyang'anira kafukufuku? Zonse zomwe Muzanene zizafunika kuunikidwa bwino kunja kwa dziko la Malawi, zizakonzedwaso Mwachinsinsi kuti opelekayo asazaziwike.	Eya / Ayi
6. Mukuvomera kutenga nawo gawo paza makina omwe azayikidwe pankhomo panu komanso pathupi lanu. Mukhonza kupitilira mukafukufuku ngakhale mutanena kuti ayi.	Eya / Ayi

Ngati mwayankha kuti "Eya" mafunso 1-5 ndi "Eya" kapena "Ayi" ku funso number 6, chonde sainani pa tsambali, Kapena ikani chidindo pansipa kusonyeza kuti mwalowa nawo mu kafukufukuyu mosakakamizidwa.

Ndavomera kulowa nawi mu kafukufukuyu mosakakamizidwa.

Saini_____Tsiku_____

Mboni ya olowa mu kafukufukuyu ngati mwini wake saziwa kulemba

(lembani zilembo zikuluzikulu)_____

Saini_____Tsiku_____

Otenga chilolezo (lembani zilembo zikuluzikulu)_____

Saini_____Tsiku_____

An advanced cook stove intervention to prevent pneumonia in children under 5 years old in Malawi: a Cluster randomized controlled trial.

Cluster Consent form: Tumbuka version 2.3

Dzina la mwini chikaya_____

Kwakufumira/keyala _____

1.	Kasi mwawerenga panji mwapulika vyalembeka umu vya wakunjiranagho mukafukufuku uyu? (v.2.3: 06/12/13)	Enya / Yayi
2.	Kasi mwapika mpata wakufumba mafumbo?	Enya / Yayi
3.	Kasi mafumbo yinu gha zgoleka nthena mukuona kuti mwamanyiskika chomene zamukafukufuku uyu?	Enya / Yayi
4.	Kasi mwapulikiska kuti ndimwe wakumasuka kufuma mukafukufuku Nyengo yiliyose kwambula kupereka chifukwa chilichose kwambula kupokera chilango?	Enya / Yayi
5.	Kasi mwapulikiska kuti vyose ivyo vyatoreka nyengo ya kafukufuku vyamuoneka na Liverpool School of Topical Medicine na mabungwe yakwendeska vya kafukufuku vyose ivyo muzakuyowoya vizamkhumbika kuunukidwa makora kuwalo kwa chalo Malawi, ndipo vizamunozgeka mwa chisisi kwambula kumanya uyo wapereka?	Enya / Yayi
6.	Mukuzomerezga kuti wanthu winu watole nawo gawo mukafukufuku uyu?	Enya / Yayi

Pala mwazgola kuti Enya mafumbo 1-5 ndi “Enya” panji “Yayi” ku fumbo la 6, chonde sainani panyakhe wikani chidindo cha chiguhno chakumalyero pasi apa kuoneska kuti mwanjira nawo mukafukufuku uyu kwambula kukakamizgika

Ndazgomera kunjira nawo mukafukufuku kwambula kukakamizgika.

Sayini_____Dazi/Zuwa la lero_____

Kaboni wauyo wanjira mukafukufuku pala mwenecho wakumanya yayi kulemba

(Mulembe vilembo vikulu vikulu)_____

Sayini_____Dazi/Zuwa la lero_____

Wakutola chizomerezgo (mulembe vilembo vikuluvikulu)_____

Sayini_____Dazi/Zuwa la lero_____

An advanced cook stove intervention to prevent pneumonia in children under 5 years old in Malawi: a Cluster randomized controlled trial.

Household Consent form: Tumbuka version 2.3

Mazina yakutolapo gawo:

1. _____
2. _____
3. _____
4. _____

Kwakufumira/keyala_____

1.	Kasi mwawerenga panji mwapulika vyalembeka umu vya wakunjiranagho mukafukufuku uyu? (v.2.3: 06/12/13)	Enya / Yayi
2.	Kasi mwapika mpata wakufumba mafumbo?	Enya / Yayi
3.	Kasi mafumbo yinu gha zgoleka nthena mukuona kuti mwamanyiskika chomene zamukafukufuku uyu ?	Enya / Yayi
4.	Kasi mwapulikiska kuti ndimwe wakumasuka kufuma mukafukufuku nyengo yiliyose kwambula kupereka chifukwa chilichose kwambula kupokera chilango?	Enya / Yayi
5.	Kasi mwapulikiska kuti vyose ivyo vyatoreka nyengo ya kafukufuku vyamuoneka na Liverpool School of Topical Medicine na mabungwe yakwendeska vya kafukufuku vyose ivyo muzakuyowoyavizamkhumbika kuunukidwa makora kuwalo kwa chalo Malawi, ndipo vizamunozgeka mwa chisisi kwambula kumanya uyo wapereka?	Enya / Yayi
6.	Mukuzgomera kutola gawo pa za makina agha omwe azammyikika panyumba pinu kweninso pa imwenso? Mungalutinzga kukhala mukafufukufu panji mwazhgola kuti yayi.	Enya / Yayi

Pala mwazgola kuti Enya mafumbo 1-5 ndi “Enya” panji “Yayi” ku fumbo la 6, chonde sainani panyakhe wikani chidindo cha chiguhno chakumalyero pasi apa kuoneska kuti mwanjira nawo mukafukufuku uyu kwambula kukakamizgika.

Ndazgomera kunjira nawo mukafukufuku kwambula kukakamizgika.

Sayini_____Dazi/Zuwa la lero _____

Kaboni wauyo wanjira mukafukufuku pala mwenecho wakumanya yayi kulemba

(Mulembe vilembo vikulu vikulu)_____

Sayini_____Dazi/Zuwa la lero_____

Wakutola chizomerezgo (mulembo vilembo vikuluvikulu)_____

Siyini_____Dazi/Ziwa la lero_____

Conflicts of interest

The study investigators have no conflicts of interest to declare.