HAPI STAGE 2 – STUDY PROTOCOL

HEAT ADAPTATION FOR PREGNANT WOMEN AND INFANTS (HAPI) - INFLUENCE OF HOUSEHOLD, HEALTH FACILITY AND ENVIRONMENTAL HEAT EXPOSURE ON THE HEALTH OF PREGNANT WOMEN AND NEONATES FOR THE FORMULATION OF INTERVENTION OPPORTUNITIES

Short title: Heat Adaptation for Pregnant women and Infants study

Study Name: HAPI

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1. ABBREVIATIONS AND ACRONYMS

AFFL	Above finished floor level
ANC	Antenatal Clinic
ART	Combination antiretroviral therapy
ARV	Antiretroviral drug
CDW	NHLS Corporate Data Warehouse
CESHHAR	Centre for Sexual Health and HIV Research
CHC	Community Health Center
CoJ	City of Johannesburg
DT	Drybulb Temperature
FGD	Focus Group Discussion
GCM	Global Climate Model
GT	Globe Temperature
HSRC	Human Sciences Research Council
ICF	Informed Consent Form
IDI	In-depth Interview
IPCC	Intergovernmental Panel on Climate Change
IPV	Intimate partner violence
IRB	Institutional Review Board
KII	Key Informant Interview
MIP	Mother-Infant Pair
MNH	Maternal and Neonatal health
MRCZ	Medical Research Council of Zimbabwe
NHLS	National Health Laboratory Services
NICD	National Institute of Communicable Diseases
RH	Relative Humidity
SAWS	South African Weather Service
SFTP	Secure File Transfer Protocol
VPN	Virtual Private Networks

2. LIST OF COLLABORATORS

Institution	Role/s
CESHHAR	Zimbabwe main partner responsible for PI duties in Zimbabwe and implementation of project in Zimbabwe. Site-specific budget management, ethics submissions, workplans, reports, analysis and publications. Site-specific ethics submissions, data analysis and publications
Ministry of Health and Child Care	Collaboration with facility staff to perform the study within these facilities Regular feedback at a National, Provincial, District and Sub-District level Facility managers I Mt Darwin District rural facilities and
Ministry of Public Services, Labor and Social Welfare	Technical support for built environment project design and implementation Participate in review and analysis of data and manuscript development

3. INVESTIGATORS, COLLABORATORS AND ROLES:

Name	Title/affiliation	Role on project
Investigators		
Dr Fortunate Machingura	Director: Climate, Environment and Health CeSHHAR, Zimbabwe	Co-PI (Site-Principal Investigator): Overall direction and management of the project Overall direction and management of the project onsite, in Zimbabwe Protocol development Providing technical input and review Manuscript preparation
Professor Stanley Luchters	Executive Director, CeSHHAR & Prof of Population Health and Environment at LSTM.	Co-PI: Overall direction and management of the project Lead in proposal development and publications associated with project Providing technical input and review Study design and Protocol development Assistance/input on data analysis and manuscript drafting
Mr Tapiwa Nyakabau	Research Manager , Climate, Environment and Health	Research coordination and field oversight: Monitoring of project activities

4. PROTOCOL SUMMARY

Temperatures in Southern Africa are rising twice as fast as the global average, posing significant health risks for maternal and newborn health. Sub-Saharan Africa faces additional challenges due to poverty, inadequate infrastructure, and ecosystem degradation, making vulnerable groups, such as pregnant women in subsistence-farming communities and urban informal settlements, less able to adapt. Social norms and gender inequalities further constrain women's agency and ability to cope with these changes. Studies globally show that heat can lead to adverse outcomes for maternal and neonatal health, including preterm birth, stillbirth, and low birth weight. However, research on heat-related harms in pregnancy in Africa is limited, especially around interventions to reduce these harms. Addressing heat stress requires complex and multi-level solutions, as simple interventions may not be sufficient. Accurate measurement of temperature exposure is essential for understanding health impacts, and this study will employ innovative methods, such as temperature measurements in healthcare facilities and households, to address exposure misclassification. Moreover, little is known about women's perceptions of heat during pregnancy and their current adaptive strategies, despite a growing body of evidence on its adverse health effects.

To develop effective interventions, it's crucial to understand the impacts of heat stress and how individuals and communities respond to it. To understand this complex interplay, we will employ a 2 staged design process-Stage 1 Development of an intervention package and Stage 2 Feasibility testing, intervention optimisation and theory-based evaluation. Stage 2 is preceded by a co-design process involving stakeholders to develop the intervention for testing. This summary outlines the activities conducted in Stage 1, the co-design process, and Stage 2, all of which are integral components of the broader HAPI project (Heat Adaptation for Pregnant Women and Infants).

The overall aim of the HAPI study is to develop co-produced multi-level, multi-component interventions to reduce heat impacts on maternal and newborn health (MNH) in diverse contexts.

The primary objectives of the study are:

- To observe and document the experiences and responses of pregnant women to heat in antenatal clinics and the first stage of labour in maternity settings.
- To track how women's experiences and coping practices relating to heat exposure change over the course of their pregnancies (in community and healthcare settings)
- To document the microclimates and temperature variations that pregnant and postpartum women encounter by measuring personal temperature, temperature in healthcare facilities and in households in addition to weather and satellite data, in relation to activity changes and sleep disturbance.
- To document preferences around intervention attributes among women and key stakeholders and identify potential implementation challenges.
- To capture systems' perspectives on heat exposure in community and healthcare settings, and practical considerations that may influence intervention selection and optimisation through interviews with policymakers, district and facility managers, healthcare workers, and community leaders.
- To model alternative building and nature-based solutions by conducting temperature and humidity monitoring at the participating health facilities and in 20-25 households using digital temperature and humidity sensors positioned in the interior, as well as using downscale weather data and local weather stations.
- To co-design multi-level, multi-component interventions to reduce heat impacts on maternal and newborn health (MNH) in diverse contexts
- To evaluate the effectiveness of multi-level, multi-component interventions to reduce heat impacts on MNH in diverse contexts

Study activities will be conducted at health facilities within the Mt Darwin District including but not limited to the Mt Darwin District Hospital, Chitse Rural Health Care Centre , ans Dotito Rural Health Care Centre, as well as their surrounding communities and households in rural Mount Darwin District Additional facilities may include those located in Mt. Darwin's Natural Region IV and V, characterized by higher temperatures and poorer socio-economic conditions, with the majority of the population belonging to the lowest wealth quintile. The variability in climatic conditions, economic status, and socio-cultural practices across these rural health centres and

their catchment areas will enhance the transferability of the findings.This protocol is specific to activities in Zimbabwe.

In Stage 1 of the project, we will employ a combination of qualitative methods, such as ethnographic observations at maternity facilities covering the antenatal care areas as well as the labour ward, in-depth interviews with 20-25 pregnant women (aged ≥16 years) temperature monitoring which will take place at the women's homes, semi-structured key informant interviews with 15-20 community stakeholders. Additionally, we will conduct personal and household temperature monitoring, and health facility, community and household thermal modelling with performance simulations to complement and enhance the insights gathered through qualitative approaches. Outputs from state 1– the formative study will support the co-design activities of the HAPI project. We will host workshops with relevant stakeholders to co-design a set of interventions to mitigate the impacts of heat on pregnant and postpartum women in Zimbabwe. Data collected in this study will be shared with stakeholders when co-producing interventions. Study results will be disseminated among study participants, local, provincial and national government officials, advocacy groups, and researchers to support policy changes.

In Stage 2 of the study, the thermal measurements will be combined with the qualitative work to inform complex interventions in households and health facilities. Specifically, we will pilot test the selected ad prioritised interventions from the codesign process using action-research and quasi-experimental pre-post intervention study. Action research involves "*Observing-Reflecting-Planning-Acting*" to inform intervention optimisation throughout implementation, in terms of feasibility, acceptability and operational performance. The single-arm quasi-experimental pre-post intervention study will be used to evaluate intervention feasibility, processes, scalability, pilot-effectiveness, and health and social outcomes. In Zimbabwe, we will recruit pregnant women between 26- and 30-weeks' gestation, with follow-up to 3-10 day postpartum, attending antenatal care services at in Mt Darwin District for both the pre- (n=400) and post- (n=400) intervention cohorts, separately (total n=800). A subset of women will be selected from the pre- (n~30) and post- intervention (n~60) cohorts (total n~90), to pilot selected individual and household interventions and community level interventions in the post intervention stage. We

will also administer semi-structured questionnaires to collect data on preferences around intervention attributes, intervention participation and implementation challenges.

This study is funded by the Wellcome Trust (Grant number: 226758/Z/22/Z)

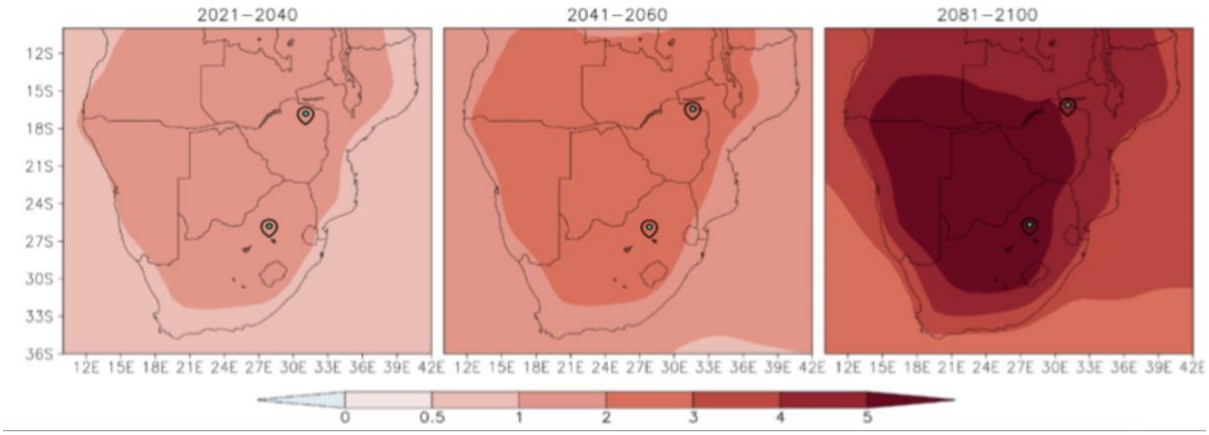
5. INTRODUCTION

5.1. Background

5.1.1. Climate change in Africa

Africa is disproportionately vulnerable to climate change due to strong climate change signals impacting climate systems that are already naturally warm and dry with highly variable rainfall [1]. Southern Africa, in particular, is a climate-change hotspot, with temperatures in the interior rising at about twice the global rate and more frequent heatwaves of unprecedented intensity [2, 3]. In a future with low mitigation efforts, the region is projected to become significantly hotter (Figure 1) and drier, with even more variable rainfall [4-6]. By 2070, it is estimated that without migration, one-third of the Earth's population will reside in areas with annual average temperatures great than 29C, currently only experienced in less than 1% of Earth [7].

Figure 1: Projected temperature changes in Southern Africa, showing relative position of study sites



Footnote: Projected change in average annual temperature as per the ensemble average of 30 different Global Climate Models in the 6th IPCC Assessment Report for the periods 2021-2040 (near-future), 2041-2060 (mid-future) and 2081-2100 (far-future), relative to the baseline (1979-2014), under the low-mitigation scenario on SSP5-8.5 (Shared Socio-economic Pathway 5-8.5). Location markers indicate study sites. The axis shows longitude and latitude.

Projected temperature changes in Southern Africa, showing relative position of study sites

These trends will increase the risk of heat-related mortality and morbidity, especially for vulnerable groups such as pregnant women, neonates, children, the elderly, chronically ill,

socially isolated, outdoor workers, low-income and marginalised communities, and urban residents.

We are still nowhere near the scale and pace of emissions reductions under the Paris Agreement to put us on track toward a 1.5°C world. Between 2030 and 2050, climate change is expected to cause approximately 250 000 additional deaths per year, from malnutrition, malaria, diarrhoea and heat stress [8]. Therefore, implementing adaptation measures is crucial to reduce the loss of lives and burden of disease.

5.1.2. Heat adaptation in Africa

Adaptive capacity is low in southern Africa [9], especially among vulnerable groups. The Intergovernmental Panel on Climate Change (IPCC) defines climate vulnerability as the susceptibility and inability of a system to cope with adverse effects of climate stress, including variability and extremes [9]. The low adaptive capacity in Africa is influenced by existing developmental challenges such as poverty, complex governance and institutional dimensions, inadequate infrastructure and technology, ecosystem degradation, and conflicts [9]. Additionally, there is a strong economic reliance on climate-related activities like agriculture and water-resource sectors. Climate change will aggravate water stress, and negatively impact agricultural production and food security [9]. Our study populations for this study include two vulnerable groups: subsistence-farming communities depend on rain-fed crops and pastures, and communities in urban informal settlements where housing cannot protect against heatwaves and access to cooling is poor [10]. Within these communities, women's adaptive abilities are even more limited as their agency and access to political power are often constrained by structural inequalities and social norms.

5.1.3. Heat impacts on maternal and neonatal health

Review of evidence of heat impacts on maternal and neonatal health (MNH), demonstrates sizable effects on preterm birth [11], stillbirth [11], low birth weight [11], congenital anomalies [12], infant health [13], and a range of other outcomes [14, 15]. While the overall

evidence of heat-related harms in pregnancy is compelling, evidence from Africa is limited. One of our studies, the first time-series analysis in Africa on heat and MNH, showed that rates of maternal hypertensive disorders in Johannesburg were around 1.8-fold higher at an ambient temperature (average daily outdoor air temperature) of 23°C versus 18°C in early pregnancy [16]. We have also demonstrated sizable seasonal patterns in rates of mother-to-child transmission of HIV in Johannesburg and described potential biological-behavioural explanations for these findings [17, 18].

Any additional risk for adverse MNH outcomes from heat exposure will have major implications for public health, long-term health, and social and cost implications for affected individuals and communities. Indeed, escalating temperatures owing to climate change threaten to undo the hard-fought gains made by MNH programmes in Africa in recent decades [19]. These gains are fragile: despite much progress, maternal and child mortality in Africa remains the highest worldwide [20]. A modelling paper reported that under the high-emission scenario, heat-related child mortality in Africa may exceed 38,000 per year in 2049 [21]. However, with robust national programmes, built on the foundational knowledge generated through this project and related studies, many of these deaths and other heat-related morbidities could be avoided.

5.1.4. Measuring heat exposure in pregnancy and the early postpartum period

Exposure misclassification is a concern in existing heat-health research. The accurate measurement of temperature exposure is crucial for understanding the potential health impacts of extreme heat, especially for vulnerable populations such as pregnant women. However, conventional methods, which rely on data from weather stations, may not adequately represent the temperature experienced by individuals. Many weather stations are situated near airports or in areas that may not be representative of urban environments. As a result, they may not capture the localized microclimates and temperature variations that people encounter in their day-to-day lives. Further, temperature experienced indoors can also differ significantly from outdoor conditions, further complicating the accurate assessment of

temperature exposure. To mitigate exposure misclassification in heat-health research, we intend to measure temperature in healthcare facilities and in households in addition to weather and satellite data.

Given the evidence of heat impacts on maternal and neonatal health, which can lead to preterm birth, low birth weight, and other adverse outcomes [12-15, 22], monitoring personal temperature exposure using sensors can provide direct information about an individual's health status, including their physiological responses to heat stress [23]. In subsistence-farming communities and urban informal settlements, household temperatures can significantly impact the comfort, health, and overall well-being of inhabitants [24]. To gain insights into the living conditions of the participants and how these conditions might influence their health outcomes in a changing climate, household temperature sensors can be used to continuously monitor the household environment [25-28].

Pregnant women spend time at health facilities during their antepartum visits, labour, delivery and during postpartum visits after delivery. Pregnant women often spend time in long queues within the facility that also extend outside the health facility. The temperature within these facilities can significantly impact the comfort and well-being of pregnant women and their newborn infants [29]. To assess the heat exposure that pregnant women experience in facilities, indoor and outdoor temperature monitoring is necessary to inform facility management strategies to maintain optimal conditions for the study. Given the localized nature of heat stress, district-level monitoring is essential in understanding this public health issue. Heat stress indices, such as apparent temperature or humidity, have been used to assess broader environmental conditions, leveraging meteorological parameters to identify areas of elevated risk [29-35].

In instances of extreme heat events, these conventional methods may not sufficiently represent the immediate environmental conditions. This limitation necessitates innovative approaches to capture transient but impactful climatic events. The concept of a Mobile Biometeorological Station has been proposed and used in similar environmental health studies, emphasizing its utility in gathering time-sensitive, high-resolution data [25, 36-39].

This data, when coupled with the computation of heat stress indices, can provide a more accurate representation of the heat exposure risk.

Collectively, the existing literature underlines the importance of a multi-faceted approach to monitoring heat exposure in the context of maternal and neonatal health. Traditional methods of temperature monitoring at personal, household, and facility levels, together with district-level heat stress indices, provide invaluable insights. However, with the unpredictability of extreme heat events, the integration of dynamic monitoring tools such as a Mobile Biometeorological Station can significantly enhance our understanding of heat stress exposure and its effects on vulnerable populations, like pregnant and postpartum women, thereby informing more effective interventions and mitigation strategies.

5.1.5. Perceptions of heat exposure in pregnancy

Understanding the impact of heat on women in pregnancy and childbirth requires recognition that maternal health is very much a "social and economic phenomenon, not just a clinical and biological issue" [40]. Women's experiences of pregnancy are shaped by multiple and intersecting factors in their environment, from socio-cultural norms, economic inequalities and material constraints to health service access and features of the built environment – all of which mediate the effects of climate change on human health. Research on mothers in rural Uganda has noted the regional diversity of heat impacts on pregnancy and perinatal health, and called for more local studies characterising the place-specific experience of weather and season during pregnancy [41]. Yet very little is known about how people in low-income countries/settings perceive heat, the extent to which they see it as a health threat, and how risk perceptions vary within a population or community.

Importantly, individual vulnerability to heat stress and other adverse health outcomes is not determined by heat exposure alone. Behavioural responses to heat are equally influential in shaping outcomes and these responses, in turn, depend on perceived risk. If people do not feel that they are vulnerable to the dangers of heat, they have little incentive to adopt adaptive behaviours during heatwaves [42]. Studies on heat risk perceptions in the last few

decades have largely focused on populations traditionally considered to be most vulnerable to the effects of extreme heat exposure: the elderly and agricultural and other outdoor workers [43, 44]. Despite a rapidly growing body of evidence on the adverse health outcomes of extreme heat in pregnancy, research on perceptions of heat in pregnancy remains scarce. A qualitative study of low-income female farmworkers' perceptions of heat-related illness during pregnancy in Florida found that women understood the adverse health effects of heat on their pregnancy and on foetal health but had little knowledge of the protective behaviours that could mitigate this risk [45].

Risk awareness and the willingness to engage in protective action requires some knowledge of climate change – but also self-efficacy (confidence in one's ability to perform a certain action) in performing self-protective behaviours [46]. A study among Gambian women farmers found that adaptive strategies had been developed to reduce the effects of heat stress, such as taking regular breaks in the shade and reducing time spent on outdoor work [47]. The women's ability to make these changes, however, were constrained by their socioeconomic and marital status; their knowledge and awareness of heat risks could not compensate for the limited self-efficacy they had to adapt their behaviour. Similarly, qualitative research on pregnant women in rural Kenya carried out by some members of the research team found that local gender norms allowed the women limited autonomy to negotiate a reduction in their workload or recruit extra support during the hot season [48]. Women's ability to do physically demanding labour in the household – considered to be women's 'duty' in this setting – was reduced when pregnant and the temperatures were high: their "maternal energy balance" [41] was threatened, in other words. One theme that this study did not adequately consider was how the women themselves perceived their own and their baby's risk of harm from exposure to extreme heat in pregnancy [41]. More broadly, few studies have explored whether individual- and community-level interventions to mitigate heat risks in low-income settings can increase self-efficacy in heat adaptation behaviours in spite of these patterns of social and gendered vulnerability.

5.1.6. Single interventions to reduce heat stress

Simple and elegant solutions are often explored as quick a solutions to climate change impacts, yet when addressing heat stress exposure more complex and multi-level solutions are required as the efficacy of simple solutions are often limited [49]. As noted by Khosla *et al.* (2022) developing cooling strategies to lower heat stress exposure require personal, technical and cultural interventions [50]. This ultimately requires the integration of multiple disciplines and also co-producing solutions with the end users in question.

5.1.7. Digital building simulations to test and optimize built environment solutions

Digital building simulation plays a crucial role in assessing indoor environment performance and mitigating heat stress exposure in the built environment [27, 51-53]. While it is often undertaken in formal built environments, it is also increasingly used in informal contexts [27, 49]. By utilizing advanced computer modelling and simulation tools, specialists can accurately analyse and optimise various aspects of a building's thermal performance [54]. This process allows them to predict the indoor temperatures, airflow, light quality, and heat retention and to calculate the accumulation of thermal energy within a specific space. From this one can ultimately simulate and quantify heat stress exposure of building users using assumed users' schedules.

One of the significant benefits of digital building simulation is its ability to test different design scenarios under current and future climate conditions [55, 56]. This will help the research team to consider the effectiveness of different heat mitigation strategies as well as their future efficacy under climate change affected conditions. Ultimately, this will lead to significant cost and energy savings in the building industry [54]. Digital simulations also enable the research team to simulate interventions before undertaking them in reality. This allows for both improved communication with community members during co-design processes, as well as more certainty regarding the potential impact of certain strategies.
In conclusion, digital building simulation is a powerful tool that allows professionals to assess indoor environment performance, specifically in addressing heat stress exposure.

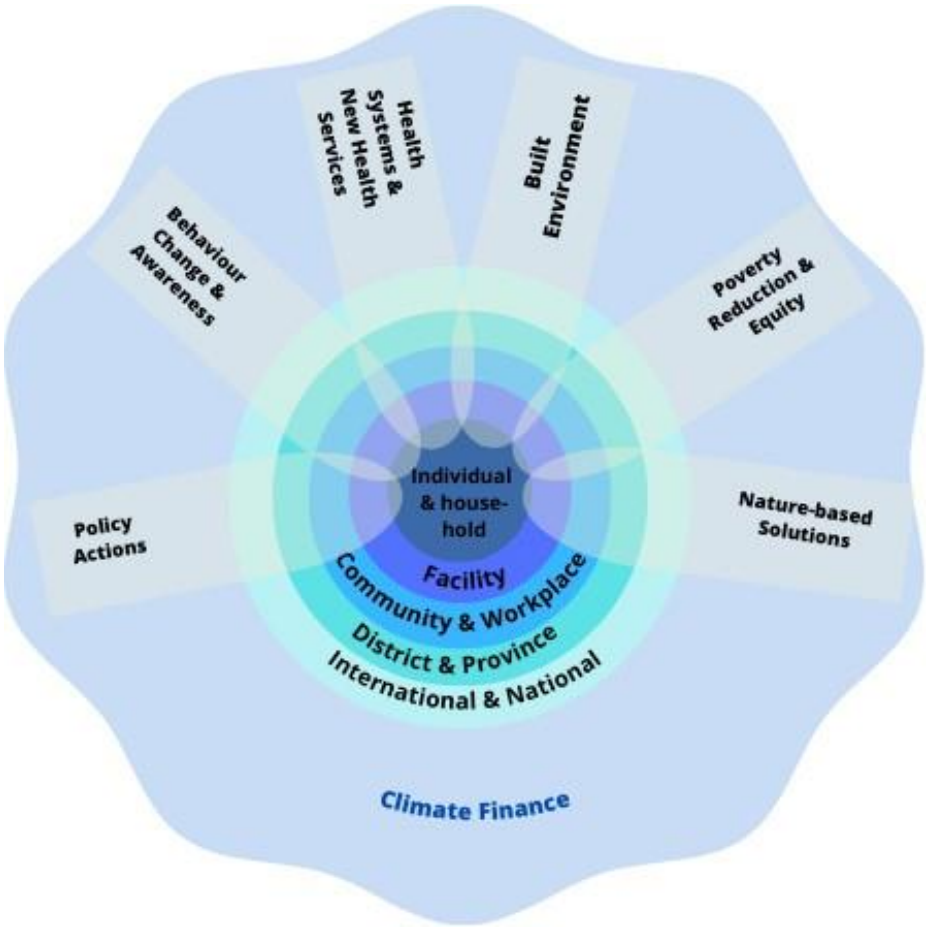
6. JUSTIFICATION FOR THE STUDY

MNH programmes are the cornerstone of health care in most low- and middle-income countries (LMICs) and have benefited from considerable investments in infrastructure and human resources. National programmes on Climate Change and Health may well be nested within MNH programmes – at least initially – as occurred initially with programmes for HIV, vaccines, malaria and malnutrition, for example. The presence of robust MNH platforms, together with evidence from the HAPI study, will be instrumental in convincing climate financers such as the Green Climate Fund [57] that heat-health interventions in LMICs are feasible and require urgent scaled-up financing. Overall, this study will enable us to present detailed data of how heat influences the health of pregnant women and neonates.

A multi-level, multi-component approach is hypothesized to be essential for effective real-world programming and future financing decisions [32, 58]. While simple interventions in Africa are promising [31], the complex vulnerabilities of pregnant individuals to extreme heat [30], inadequate built environments, and low resilience to climate change necessitate a comprehensive approach. The design and implementation of contextually specific and effective climate change adaption measures is essential to reduce the lives lost and burden of disease.

Based on our systematic reviews, field experience, empirical analyses, and a review of the biological mechanisms underlying vulnerability to heat in pregnancy [30], the project team has developed an interventional framework that was described in a recent commentary in a Special Edition of the *International Journal of Obstetrics and Gynaecology* (Figure 2).

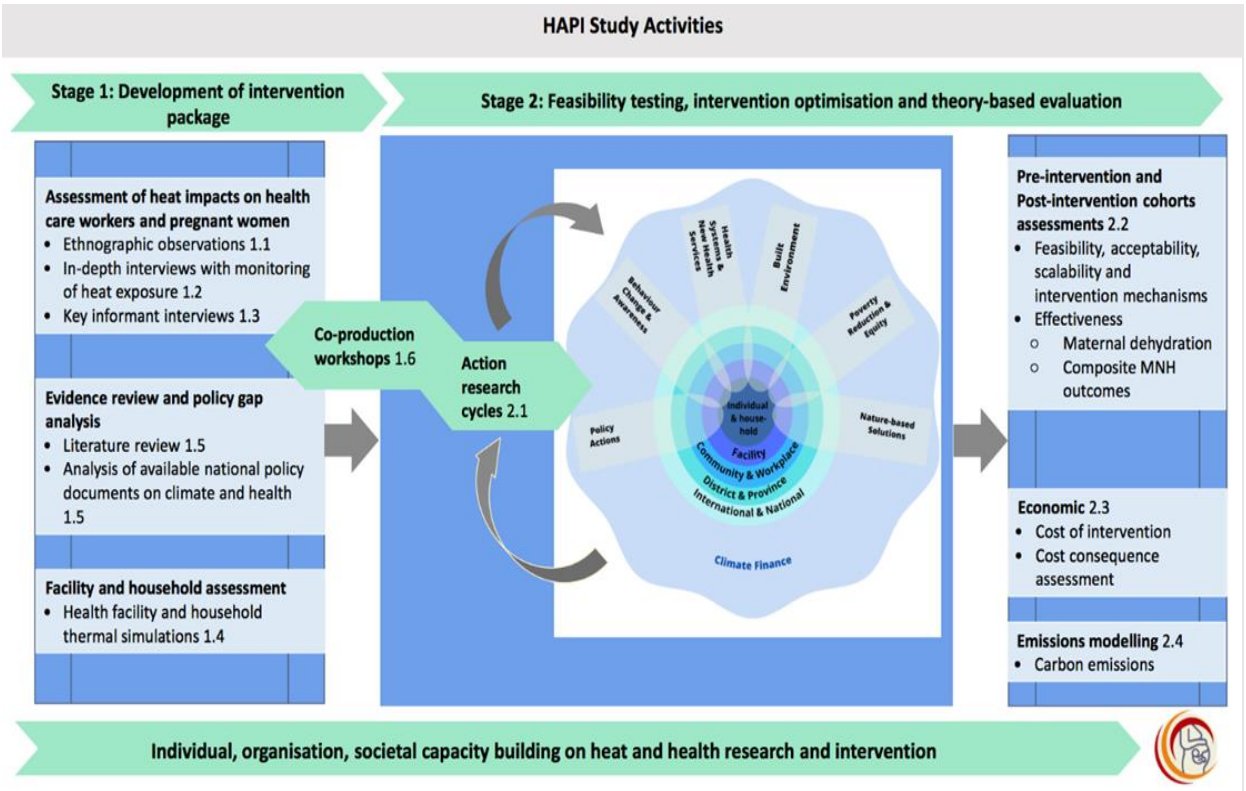
Figure 2: Interventional Framework for the development multi-level, multi-component interventions



The research components outlined in this protocol form part of a larger project: HAPI study (Heat Adaptation for Pregnant women and Infants) (Figure 3). Over 3 years, the study aims to co-produce, and evaluate a multi-level, multi-component intervention to reduce heat impacts on maternal and newborn health in diverse contexts. It also aims to strengthen capacity for research and networking in southern Africa around climate change adaptation interventions. This protocol covers the formative research study components in Stage 1 (1.1-1.6) of the HAPI study activities (Figure 3), to assess the impact of heat on pregnant women through **ethnographic observations** and **serial in-depth interviews**. The research will also include **thermal simulations** of healthcare facilities and households, as well as **personal temperature monitoring** to objectively measure and understand the effects of heat on pregnant women and infants. Overall, this study will enable us to present detailed data of how heat influences

the health of pregnant women and neonates. Additional insights gained from **key informant interviews** with policy makers, district health managers, health facility managers and the heat impacts on healthcare workers will draw on work conducted in another project conducted in the same health district, HIGH Horizons (MRCZ/A/3023)

Figure 3: Framework for the development (Stage 1) and evaluation (Stage 2) of co-produced multi-level, multi-component interventions in the HAPI study, to be completed under this protocol.

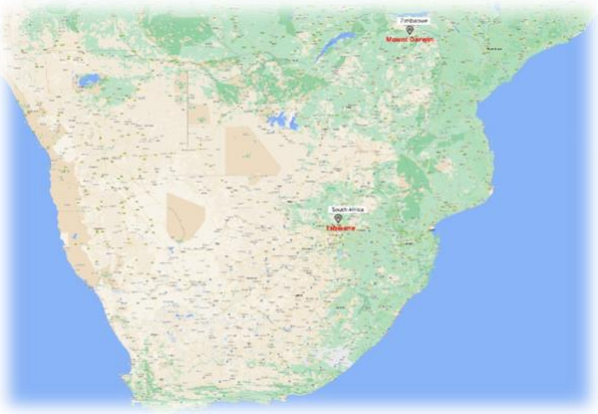


Further, information gathered in this study will be used to establish a baseline for comparison with endline findings in the evaluation of interventions. Data from the formative work conducted thus far will be collated and discussed at co-design workshops. The methodology for the workshops have been added to this version of the HAPI protocol. Evaluation of the effectiveness of co-designed interventions will be conducted in Stage 2 of the HAPI study, is submitted as an amendment to this protocol, and submitted for ethics and other relevant approvals.

Ultimately, we aim to test the Interventional Framework, described in Figure 2, in the HAPI study [59], focusing on the third trimester of pregnancy and childbirth when biological and socio-economic vulnerabilities are highest [30, 59]. The eventual package of interventions will be ***multi-level*** (individual-, household-, community-, facility-, and policy-level), and ***multi-component***, encompassing behaviour change and awareness, health services, built environment and nature- based interventions, together with activities to facilitate policy shifts. Examples of possible interventions are presented in Appendix 01.

The presence of robust MNH platforms, together with evidence from the HAPI study, will be instrumental in convincing climate financers such as the Green Climate Fund [57] that heat-health interventions in LMICs are feasible and require urgent scaled-up financing.

7. OVERALL STUDY SETTINGS



The study site rural Mount Darwin district in Mashonaland Central Province in Zimbabwe (see picture below) – pregnant women have few means of reducing heat exposure during a heatwave, and even drinking water may be scarce [61]. Health facilities, poorly-built brick households and informal housing in urban slums offer little to no protection against heat exposure and are frequently 4-6°C warmer indoors than outdoors [10, 25] In Zimbabwe, primary data collection for Stage 1 of the study will occur at Chitse Clinic, Dotito Rural Health Clinic and Mount Darwin Hospital. Including multiple facilities and contrasting sites allows for assessment of how 'interventions interact with context' [62] within and between sites, and increases the potential transferability of the findings. Primary data collection for Stage 2 of the study will be conducted at Chitse Clinic, Dotito Rural Health Clinic, and Mount Darwin Hospital, and may extend to other rural facilities within the district within the catchment areas of these three primary sites.

7.1. Objectives

- To observe and document the experiences and responses of pregnant women to heat in antenatal clinics and the first stage of labour in maternity settings.
- To track how women's experiences and coping practices relating to heat exposure change over the course of their pregnancies (in community and healthcare settings)
- To document the microclimates and temperature variations that pregnant and postpartum women encounter by measuring personal temperature, temperature in healthcare facilities and in households in addition to weather and satellite data, in relation to activity changes and sleep disturbance.

- To document preferences around intervention attributes among women and key stakeholders and identify potential implementation challenges.
- To capture systems' perspectives on heat exposure in community and healthcare settings, and practical considerations that may influence intervention selection and optimisation through interviews with policymakers, district and facility managers, healthcare workers, and community leaders.
- To model alternative building and nature-based solutions by conducting temperature and humidity monitoring at the participating health facilities and in 20-25 households using digital temperature and humidity sensors positioned in the interior, as well as using downscaled weather data and local weather stations.
- To co-design multi-level, multi-component interventions to reduce heat impacts on maternal and newborn health (MNH) in diverse contexts.
- To evaluate intervention feasibility, processes, scalability, pilot-effectiveness, and health and social outcomes –

8. METHODS

The HAPI intervention is developed over two-stages (see Figure 3). Stage-1 involved formative research, thatl inform the co-design of the complex intervention, while Stage-2 will include refining and evaluating this complex intervention. This protocol describes the project activities for Stage-2. Stage-2 is included as an amendment of the main protocol, after refinement of the methodology and interventions identified from Stage-1. Stage-2 will also leverage data and outputs from the HIGH Horizons project [63], which is implementing selected heat-adaptation interventions for healthcare workers in maternity facilities in Mt Darwin District, and developing an Early Warning System for pregnant women, but has no behavioural or nature-based components, and does not target community settings, households, or policy actors. Funding for interventions and all other project activities will be ring-fenced between HIGH Horizons and HAPI.

The specific activities that were undertaken as formative research under Stage-1 of the protocol were described in detail in separate description not included in this version under the following sub-headings:

1. Sub-Study 1: Ethnographic participant observations
2. Sub-Study 2: In-depth interviews with pregnant women and temperature monitoring
3. Sub-Study 3: Key informant interviews
4. Sub-Study 4: Health facility and household thermal monitoring and performance simulations
5. Sub-Study 5: Co-design multi-level, multi-component interventions to reduce heat impacts on maternal and newborn health

9. STAGE-2: FEASIBILITY, SCALABILITY AND PILOT EFFECTIVENESS TESTING, INTERVENTION OPTIMISATION AND THEORY-BASED EVALUATION

Stage-2 involves evaluation of the complex intervention using three complementary research designs, including a Participatory Action-Research design, a quasi-experimental pre-post intervention design, and a cost-consequence modelling. These three designs will occur concurrently over a period of approximately 17 months. Stage-2 also leverages data and outputs from the HIGH Horizons project [63], which is implementing selected heat-adaptation interventions for healthcare workers in maternity facilities in Mt Darwin District, and developing an Early Warning System for pregnant women, and HCWs but has no behavioural or nature-based components, and does not target community settings, households, or policy actors. Funding for interventions and all other project activities will be ring-fenced between HIGH Horizons and HAPI. Specifically, in Stage 2, we will test the proposed interventions to assess their feasibility, scalability, pilot-effectiveness, and cost-consequence modelling .

Our specific objectives are:

- *Assess Feasibility:* We will determine whether these interventions can be practically implemented and scaled up in the the study site
- *Evaluate Intervention Mechanisms:* We will closely monitor the implementation process to understand how and why these interventions work in these distinct contexts.
- *Pilot effectiveness*: We will implement the complex intervention, focusing on refining and evaluating them throughout the process. This includes assessing their effectiveness in improving maternal and newborn health outcomes, with a specific emphasis on heat adaptation.
- *Cost- consequence*: The cost-consequence modelling in HAPI will evaluate the economic feasibility of community-led heat adaptation and mitigation interventions in Zimbabwe. It will capture both financial costs (e.g., expenditure on goods, services, and volunteer time) and non-financial costs (e.g., donated goods). Using top-down and bottom-up costing approaches, the model will allocate costs to specific activities and sites, informed by comprehensive data including expenditures, time sheets, and M&E

outputs. Additionally, baseline assessments and time-motion studies will ensure accuracy in cost allocation. This modelling will assess the economic impact and sustainability of the intervention, guiding decisions on scaling and resource allocation.

- Stage 2 is critical as it will guide our decisions on scaling these interventions, ensuring they are likely effective and sustainable in reducing heat impacts on MNH in both urban and rural settings

10. STAGE 2 STUDY DESIGN

We will employ three complementary research designs, including Action-research, a quasi-experimental pre-post intervention study, and cost-consequence to evaluate intervention feasibility, processes, scalability, pilot-effectiveness, and health and social outcomes (See Figure 8). The action rsearch will involve two 6 months cycles to further refine and optimise intervention implementation. Intervention refinement will include a co-design process, similar to that undertaken in Stage-1 (described in Section 4.5), but simplified and targeted at specific experts or stakeholders who will reflect on the findings of the action research activities and help decide on intervention refinements, if any.

Figure 4: Study Activities

HAPI project month	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34
Intervention delivery						Implementation of complex intervention											
Action research (Activity 2.1)						Cycle 1: Observe, Reflect, Plan, Act						Cycle 2: Observe, Reflect, Plan, Act					
Quasi-experimental pre-post cohorts (Activity 2.2)	Quasi-experimental study																
Participant enrolment	Pre-intervention												Post-intervention				
Follow-up of enrolled participants	Pre-intervention												Post-intervention				
Cost-consequences (Activity 2.3)												Costing and modelling					

11. QUASI-EXPERIMENTAL PRE-POST INTERVENTION STUDY.

We apply a quasi-experimental pre-post-intervention design to evaluate intervention feasibility, processes, scalability, pilot-effectiveness, and health and social outcomes. In Zimbabwe, 400 women attending antenatal clinics at weeks 26-30 weeks of gestation will be enrolled before and then during intervention (named 'post-intervention cohort') (total n=800), and assessed four-weekly during pregnancy at routine clinic visits, and subsequently at childbirth and postpartum (planned within 72 hours). Semi-structured questionnaires will be administered to collect data on socio-economic status, heat impacts, behaviours related to heat and hydration, access to safe water, heat-resistance of dwellings, indigenous coping strategies, preferences around intervention attributes, intervention rankings, critical uncertainties, costs of service access and intervention participation, and implementation challenges (See appendix 31) We will also conduct biomedical assessments (ultrasound, blood and urine samples), and screening of wellbeing and for mental health conditions. Additional data will be extracted from the patient-held antenatal cards and birth records. Outcomes in the pre-intervention cohort of women will be compared with women in the post-intervention cohort.

11.1.1. Study Setting and population

Pregnant women attending antenatal care at sites in Mt Darwin District facilities between 26-30 weeks gestation, followed up at labour, 72 hours postpartum and where not possible, this visit window will close at 10 days after childbirth.

11.1.2. Inclusion and exclusion criteria

11.1.3. Inclusion criteria

- Pregnant, between 26-30 weeks' gestation
- 16 years and older at the time of consent
- Intending to give birth in Mt Darwin District health facilities
- Not experiencing serious complications of pregnancy that have required hospitalisation
- Willing and able to provide written consent to participate in the study.

11.1.4. Exclusion criteria

- Women in the pre-intervention cohort will be excluded from the post-intervention quasi experimental cohort.

11.1.5. Sample Size

For the purposes of determining the required sample size, the primary pilot-effectiveness outcome is mild-moderate hypovolemic maternal dehydration during labour (urine specific gravity >1.015, measured by handheld optical refractometer, Sper Scientific portable clinical refractometer 300005 or similar). This reflects both hydration practices, and heat exposure (fluid loss through perspiration). We calculated the sample size to provide sufficient power for country-specific analyses; a pooling across countries may not be possible due to heterogeneity in intervention package and effectiveness. With about 800 women and 15% attrition, we will have >95% power to detect a 15% difference in the proportion of women with primary outcome between the pre- and post-intervention cohorts. In the before cohort, based on a literature review, we estimated 30-60% of women will have mild-moderate dehydration during labour (level varying by ambient temperature and season).

11.1.6. Participant sampling

Pre- and post-intervention cohorts: Consecutive eligible women in Mt Darwin District health facilities will be approached for recruitment. Consecutive recruitment minimises selection biases. We will enrol at least 5-10 women per day, with each cohort including up to 400 women (up to 400 pre-intervention and up to 400 post-intervention). Duration of total planned follow up time is about 2-4 months for each woman, assuming that most women complete pregnancy at around 40 weeks gestation. Routine clinical follow-up visits at antenatal clinic are generally at 20-, 26-, 30-, 34-, 36-, 38-, and 40-weeks during pregnancy (+/- 7 days), then during the first stage of labor, and again postpartum within 72 hours postpartum (window closes 10 days after delivery). Pre- and post-intervention cohort recruitment is spaced around 9-12 months apart and timed to coincide with the hot season.

11.1.7. Recruitment and enrolment

Pre- and Post-Intervention Cohorts: The study team will collaborate with facility staff to identify pregnant women attending ANC services between 20 and 28 weeks of gestation who meet the eligibility criteria. These women will be invited to enroll in the study at 26–30 weeks of gestation. HCWs will assist the study team in determining the suitability of women attending the facility for ANC services on recruitment days. Facility HCWs will also be invited to participate as co-researchers. They will seek permission from eligible women to allow either the HCW (if their schedule permits) or a member of the study team to approach them regarding the study.

If the women agree, recruiters or HCWs will meet with them in a private room within the facility, either after their ANC visit or while they await another service. During this meeting, the recruiters will verify eligibility, provide a brief overview of the study, and gauge their interest in participation. The contact and basic demographic details (name, surname, age, and area of residence) of interested women will be documented in a screening log.

Pregnant women who meet the eligibility criteria and express an interest in participating will be provided with a study-specific information sheet (Appendix 22 and Appendix 23), either individually or in a group setting. The informed consent process will ensure participants have a clear understanding of the study procedures and will include private discussions to address any questions before obtaining signed consent. The comprehensive informed consent process is detailed in Section 11.1.

Once consent is obtained, a participant enrollment log will be completed for each participant. Each participant will then be assigned a unique participant ID, which will serve as their identifier on all study-related materials.

11.1.8. Remuneration

Women will be re-imbursed USD10 per study visit attended, for her time, effort and inconvenience during the study visit. Remuneration will be provided at the end of each interview in cash.

11.1.9. Data collection

Data collection will occur at enrolment (26-30 weeks), and at a 4-week antenatal care follow-up visit visit , at childbirth and within 72 hours postpartum. These visits coincide with the MoHCC Basic Antenatal Care Visit Schedule for pregnant women . Informed consent will be conducted on the day of enrolment, following procedures described above and in further detail in Section 31. Contact details including telephone numbers, alternate telephone numbers and home address will be collected and logged separately from the database that captures study information

The first interview will take place during the summer months (between November 2024 - February 2025) with follow-up interviews conducted over the remainder of the hotter season, as per the schedule below(figure 9). Ideally pre-intervention cohort visits will be conducted from November 2024 to May 2025 and post-intervention cohort visits will be conducted from November 2025 to May 2026.

All interviews will be carried out by a research staff member and HCWs trained in conducting interviews and collecting study biomarkers**.** Enrolment semi-structured questionnaires will be interviewer-administered via CAPI (*computer assisted personal interviewing*) using a study tablet computer to collect data variables such as demographics, socioeconomics, housing type, water and electricity access, heat-related knowledge, current impacts of heat, behaviors related to heat and hydration, housing characteristics, and knowledge and use of indigenous coping strategies. Follow-up visit interviewer-administered questionnaires will be shorter and focus on heat-related knowledge, current impacts of heat, behaviors related to heat and hydration, use of indigenous coping strategies, access to safe water with post-intervention

postpartum questionnaires also including questions on preferences around intervention attributes, intervention rankings, critical uncertainties, costs of service access and intervention participation, implementation challenges, and reflections on the process of participating in this study . Questionnaires and interviews will be conducted in the language of participants' choice (but restricted to languages spoken fluently by the interviewers in our team).

The results of any routine ultrasound if available and blood tests that have been done will be extracted from the Maternity Case Record (MCR). Additional data will be extracted from the patient-held antenatal cards and birth records, including antenatal visit dates; delivery date; information to determine gestational age; prior pregnancy history; use of medication and substances; comorbid conditions; laboratory and point-of-care test results; vaccine history; anthropometry; ultrasonography findings; maternal and newborn complications during labour and delivery; newborn clinical features; and congenital anomalies. Where necessary, data missing from the MCR may be supplemented with data captured from the birth register.

We will conduct urine specific gravity measurements at enrolment and follow-up visits. Screening for wellbeing (WHO-5 or EQ5, or similar) and for mental health (PSS-7 or EQDL-5 or similar) conditions will also be conducted.

Figure 5: Study procedures and data collected as part of the quasi-experimental pre-post intervention study (N=800 women: 400 in pre-intervention, 400 in post-intervention

	Pre-intervention bio-behavioural study procedures (N=800)				Post-intervention bio-behavioural study procedures (N=800)		
Study procedure	Enrolment in antenatal clinic (24-28 weeks gestation)	Labour ward admission	Postpartum (<72 hours after childbirth)		Enrolment in antenatal clinic (24-28 weeks gestation)	Labour ward admission	Postpartum (<72 hours after childbirth)
Informed consent	X				X		
Contact details	X				X		
Questionnaire for women							
- Socioeconomics and risk factors	X				X		
- Housing type and water access	X				X		
- Birth plans and preparedness	X				X		
- Heat-related knowledge	X		X		X		X
- Heat-protective behaviours	X		X		X		X
- Hydration practices	X	X	X		X	X	X
- Wellbeing (ONS wellbeing assessment)	X		X		X		X
- Birth experience			X				X
- Self-reported exposure to the intervention							X
- Acceptability of intervention							X
Temperature monitoring							
- Intermittent skin temperature monitoring		X	X			X	X
- Continuous temperature monitoring (wearable devices in subset of women only)	X	X	X		X	X	X
- Continuous indoor temperature monitoring in dwellings and facilities	X	X	X		X	X	X
- Weather station and remote sensing	X	X	X		X	X	X
Pregnancy and birth records of women							
- Clinical outcomes in women (composite)^		X	X			X	X
- Clinical outcomes in newborns (composite)^			X				X
Biological urine sample							
- Urine specific gravity assessment (primary outcome)	X	X	X		X	X	X

- Maternal composite clinical outcomes: 1 or more of the following obstetric emergencies, emergency Caesarean section, pre-eclampsia/eclampsia, antepartum or postpartum haemorrhage, sepsis.
- Newborn composite clinical outcomes, 1 or more of the following: stillbirth, preterm birth, low birth weight, APGAR score ≤6, neonatal admission

11.1.10. Timelines .

Table 1: Example scheduling and Timelines for the pre post interventions

Study Design	**Pre-intervention *(end 20 April 2025)***					**Action Research Cycle *(start 1 June 2025 – 31 May 2026)***	**Post Intervention (start *15 Jan – end 25 May 2026)***				
Study Procedure	26-30 weeks Enrolment (15-17 January 2025)	30-34 weeks (12-16 February 2025)	34-38 weeks (12-16 March 2025)	38 – 42 weeks Labor Ward Admission 16 March - 20 May 2025	Postpartum (<72 hours) 25 May 2025	HAPI Intervention and codesign Start 1 June - 2025-	26-30 weeks Enrolment (15-17 Jan 2026)	30-34 weeks (12-16 Feb 2026)	34-38 weeks (12-16 March 2026)	38 – 42 weeks Labor Ward Admission 16 March - 20 May 2026	Postpartum (<72 hours) 25 May 2026
Informed consent	X	-	-	-	-	[redacted]	X	-	-	-	-
Contact details	X	-	-	-	-		X	-	-	-	-

**Questionnaire for women: **											
- Socioeconomics and risk factors	X	X	-	-	-		X	X	-	-	-
- Housing type and water access	X	-	-	-	-		X	-	-	-	-
- Birth plans and preparedness	X	-	-	-	-		X	-	-	-	-
- Heat-related knowledge	X	X	X	-	X		X	X	X	-	-
- Heat-protective behaviors	X	X	X	-	X		X	X	X	-	-
- Hydration practices	X	X	X	X	X		X	X	X	-	-
- Well-being and mental health assessment	X	X	X	-	X		X	X	X	-	-
- Birth experience	-	-	-		X		-	-	-		X
- Self-reported exposure to intervention	-	-	-				-	-	-		

- Acceptability of intervention	-	-	-	-			-	-	-	-	
**Temperature monitoring: **											
- Intermittent skin temperature (Handheld Infrared Skin Thermometer on forehead)	X	X	X	X	X		X	X	X	X	X
- Indoor temperature monitoring in dwellings and facilities	X	X	X	X	X		X	X	X	X	X
- Weather station and remote sensing	X	X	X	X	X		X	X	X	X	X
**Pregnancy and birth records of women: **											
- Clinical outcomes in women (composite)	-	-	-	X	X		-	-	-	X	X

- Clinical outcomes in newborns (Composite)	-	-	-	-	X		-	-	-	-	X
**Biological urine sample: **											
- Urine specific gravity assessment	X	X	X	X	X		X	X	X	X	X

If the last participant is recruited on 30 January 2025 at 26 weeks , they are likely to give birth by 20 May 2025. Thus the last possible date for recruitment is 30 January2025

12. INTERVENTION IMPLEMENTATION AND ACTION-RESEARCH RESEARCH

12.1.1. The action research approach

On concludion the pre intervention survey decribed in Section 5.1.2 above, we will implement and refine the *intervention* through cycles of action research. The cyclical approach to intervention implementation and refinement involves “Observing-Reflecting-Planning-Acting” to inform intervention optimisation, throughout implementation, in terms of feasibility, acceptability and operational performance. Two cycles of action-research will be conducted over the 12-months of intervention implementation. Cycles involve:

i. Observing real-time implementation obstacles, interplays between interventions and context, unanticipated events, and progressively-optimised thermal and cost-consequence simulations based on actual field experience. Observations will also be drawn from ongoing ethnographic observations, the perspectives of field staff, process indicators, and interviews. This initial phase will last 2-3 months.
ii. Refinement of interventions and programme theory will occur over 1-2 months through a repeat of the co-production processes described in Activity 4.6, where stakeholders will reflect on the findings of the ‘’Observing’’ phase and decide on intervention refinements.
iii. Planning delivery of the refined intervention and securing necessary approvals.
iv. Acting to implement the refined interventions.

The cycle is then repeated, allowing for community-, facility-, and site-specific interventions, whilemaintaining fidelity to the overall intervention approach

12.1.2. Intervention implementation through action research

A set of interventions have been selected based on an interim analysis of outputs from the co-design workshops, which involved a high-level examination of the data from the Stage 1 activities to facilitate timely and actionable insights. Following the co-design workshops described in stage 1 sub-study 5, an internal peer review process was conducted among the study team, which included reflecting on the findings from the workshop and ultimately led to the refining, defining, and harmonizing of the proposed heat adaptation-mitigation interventions.

Table 2: Summary of main heat adaptation-mitigation intervention components which have been selected through the co-design process in Zimbabwe

	Behavioral	Built Env	Nature
Individual	1) Personal Cooling Kits 2) Traditional Water-Cooling Systems 3) The Mother Heat Alert EWS 4) The Mass Media Radio Messaging		
Household	1) Partner Support and Family Support for Heat Stress Adaptation	2) Cool Roofs	
Community	1) Heat Champions 2) Watering hole hubs on adaptation & resilience for managing extreme heat risks - WARMER Model 3) Men's behaviour change model 4) Women's Self-Help Groups (SHGs 5) CHIEDZA – Chief-led Heat Intervention for Engagement, Dendemara-dialogue, & ZviAction		6) Commu planting
Facility	1) ANC Heat Health Talks 2) Waste Segregation 3) Hydration stations 4) The Water Buddie System 5) LED Heat Messaging Displays 6) Energy efficient refrigerants and refrigerators	7) Ceiling Installation and Repairs in Maternity and Postpartum Wards 8) Energy-Efficient Lighting 9) Solar Power Systems 10) Water Storage Tanks	11) Facility T Planting
Policy			
TOTAL	**16**	**5**	**2**

Interventions at the facility level will be implemented at Mt Darwin Distict Hospital, Dotito and chitse health facilities. Household and community level interventions will be optimised in the catchment areas of these facilities. An estimated 50 households will be selected for continuous temperature monitoring in the dwellings where any built environment modifications will be implemented and monitiored.

12.1.3. Study Setting and population

The intervention implementation will happen in Mt Darwin Distict, Dototo and Chitse health fcailities and their catchment areas.

12.1.4. Inclusion and exclusion criteria

12.1.5. Inclusion criteria

- Residing in Mt Darwin District communical areas around the Mt Darwin District Hospital,, Chitse Health centre and Dotito Health centre
- HCWs working from Mt Darwin District Hospital,, Chitse Health centre and Dotito Health centre
- Willing and able to provide verbal consent to participate in the community action research
- Policy makers operating or with influence in Mt Darwin District
- Willing to allow study team to apply household level interventions
- Household head permission to allow study team to apply household level interventions

12.1.6. Exclusion criteria

- Those not living in the actchment areas of Mt Darwin District, Chitse and Dotito Health fcailities
- HCWs not working operating from Mt Darwin District Hospital,, Chitse Health centre and Dotito Health centre
- Unable to provide verbal conent
- Unwilling for household level interventions to be implemented
- Household head refusal to have interventions implemented in home (for action research participants)

12.1.7. Sampling and Sample Size

All community members are eligible and all HCWs are eligible if with Mt Darwin, Dotito and chitse facilities and catchment areas**.**

12.1.8. Intervention implementation procedures

This project employs action research cycles to implement and refine heat adaptation interventions across the catchment areas of Mt. Darwin District Hospital, Dotito, and Chitse rural health centers. These interventions will target individual, community, facility, and policy levels, creating a multi-tiered framework to address heat-related health risks. At the community level, interventions will include radio campaigns delivering heat-related health messages, traditional chief-led adaptation festivals to revive nature-revering practices, community woodland management to promote cooling and resource sustainability, and facility-level measures to enhance healthcare delivery under extreme heat conditions. Specific household-level interventions will be assessed first among a purposively selected group ranging from 10 up to about 50 pregnant women, thrir partner or their households depending on the nature of the intervention to ensure targeted, data-driven optimization. Selection criteria will include maternal age categories (16–24 years and >25 years), housing type, and geographic distribution across the communal areas of Chitse, Dotito, and Pfura within Mt. Darwin District.

Informed consent will be obtained using a two-step process. First, telephonic permission will be sought, followed by written consent from the household head, unless the pregnant woman herself is the head of the household. If the household head is unavailable, they may nominate a proxy to provide written consent. In cases where consent is withheld, the household and the pregnant woman will not be enrolled in the study. For consenting households, researchers will implement targeted interventions, including the installation of continuous temperature monitoring sensors, distribution of personal cooling kits (containing items such as portable fans and umbrellas), and modifications to the built environment, such as roof painting or thatching. Participants will also receive guidance on the optimal use of the built environment, including strategies for effective ventilation, shading, and scheduling work during cooler periods. Pregnant women in these households will also be exposed to heat early warning systems through messages delivered by trained community heat champions/village health workers, who will act as trusted messengers to promote behavioral changes and preparedness for heat events.

We will conduct continuous, real-time ethnographic observations across sites and surrounding areas. Social scientists will embed within sites, fully immersing themselves in the lives of the

participants exposed to the interventions in the three sites including the 50 households . They will observe and document any real-time interactions, behaviours, and the contextual factors that influence the intervention. The social scientists will maintain reflexive journals to document their observations, thoughts, pictures and reflections. Each scientist will consolidate their observations into thick descriptions submitted every two months

For pregnant women in the consenting households, data collection will encompass physiological, behavioral, and environmental indicators of heat exposure. We will administer a semi-structured questionnaire that will be conducted through the cohort follow-up, at enrolment and at 6 months participants will have a brief interviewer-administered questionnaire seeking additional information on the adaptation interventions. This will include questions relating to the acceptability, usability, usefulness and effectiveness of interventions (Appendix 34).

Field perspectives will be gathered through IDIs and FGDs using structured topic guides see table below. In alignment with the ARC approach and its citizen science principles, field staff will include individuals actively engaged at the frontlines of intervention implementation across households, community, health system, and policy sectors. For each round of data collection, 15 purposively selected participants, comprising 5 women, 5 household representatives, and 5 key informants, will participate in interviews. In addition, 4 FGDs will be conducted with women, household representatives, and community and policy stakeholders at the end of both ARCs. In total, the study will conduct 10 IDIs with women and households, 5 KIIs and 4 FGDs involving women, households, policy and community stakeholders. Health system data will leverage the HIGH horizons data. Women participating in the study will include those directly involved in ARC Household representatives will consist of men and other key decision-makers from households engaged with the intervnetion. Stakeholders will encompass community decision-makers as well as sub-national and national policy-level actors who participated in the co-design workshops in stage 1. These discussions aim to identify and address implementation challenges, explore contextual barriers to intervention success, and capture practical insights from those directly involved in the intervention process. This approach will ensure a comprehensive understanding of the factors influencing intervention delivery, engagement, and optimization.

Table 3: Summary of Data Collection Methods to capture field perspetives

CRITERIA	IDIS WOMEN AND HOUSEHOLDS	FGDS WOMEN, HOUSEHOLDS, POLICY AND COMMUNITY STAKEHOLDERS	KIIS
Purposive Sampling	- Age, role in community, parity, marital status, education, socioeconomic status - husbands, fathers-in-law	- Pregnant/postpartum women, caregivers, - husbands, fathers-in-law, - community leaders managers, decision-makers at local, district, and provincial levels	- Role, years in position, decision-making authority, influence
Inclusion Criteria	- Aged ≥ 16 years - currently participating in AR1 and or AR2 - Direct engagement with the intervention	- Aged ≥ 16 years - Direct impact by or involvement in the intervention in AR1 and AR2 -	- Aged ≥ 18 years - Direct involvement in health policy related to the intervention - Extensive experience in policymaking at provincial or national levels
Exclusion Criteria	- Lack of direct involvement in the intervention - Insufficient experience in relevant community roles	- Individuals not directly impacted by or involved in the intervention - Lack of representation from key subgroups	- No direct role in codesign - Limited experience in health policy
	Field perspectives – IDI guide (Appendix 38)	Field perspectives – FGD guide (Appendix 40	Field perspectives – KII guide (Appendix 39)
Topic Guide Questions	- Can you describe your experiences with any heat adaptation interventions? - What are the main barriers or facilitators in the uptake of these interventions?	- Can you describe your experiences with any heat adaptation interventions? - What are the main barriers or facilitators in the uptake of these interventions? - How has the intervention	- Can you describe your experiences with any heat adaptation interventions? - What are the main barriers or facilitators in the uptake of these interventions?

	- How has the intervention affected your daily activities and experience of health (mental, social, cognitive) -Can you describe youyr experiences with heat in pregnancy, labour, soon after delivery and when breastfeeding (as relavant for participant) -what could make the experiences better ? - What costs have you incurred (time, money, resources) in accessing or adapting to these interventions? - How could the intervention be improved for you? (cost, acceptability, feasibility)	affected your daily activities and experience of health (mental, social, cognitive) -Can you describe youyr experiences with heat in pregnancy, labour, soon after delivery and when breastfeeding (as relavant for participant) -what could make the experiences better ? - What costs have you incurred (time, money, resources) in accessing or adapting to these interventions? - How could the intervention be improved for you? (cost, acceptability, feasibility)	- How has the intervention affected your daily activities and experience of health (mental, social, cognitive) - What costs have you incurred (time, money, resources) in accessing or adapting to these interventions? - How could the intervention be improved for you? (cost, acceptability, feasibility)

In addition to journaling ethnographic observations and field perspectives, we will employ the Context Tracker {Busza, 2024 #521} to systematically monitor and document the critical contextual factors shaping the development, implementation, and optimization of the HAPI intervention. the Context Tracker, a versatile data collection tool tailored to systematically document contextual factors influencing intervention delivery and participant engagement across multiple study sites will be used to track the implementation context. This tool will track micro-level factors, such as individual and household influences on intervention uptake; meso-level factors, including community and health system facilitators and barriers; and macro-level factors, such as political, economic, and structural determinants in the Mt. Darwin

District. A trained social scientist will collect data through a combination of routine program statistics, structured observations, and qualitative methods. By mapping five key domains—physical, social, economic, political, and organizational—across the three analytical levels (micro, meso, macro), the Context Tracker will allow us to systematically identify and compare facilitators and barriers to implementation, monitor variations in engagement among pregnant and postpartum women, and examine how the intervention's theoretical mechanisms of action are triggered or inhibited in distinct settings. The Context Tracker will be applied in ARC1 and ARC2 to capture temporal changes and ensure the intervention is responsive to evolving local dynamics. It standardizes data collection by applying evidence-based domains consistently across sites, while remaining adaptable to capture unique, site-specific factors. Designed for both in-person and remote use, it will monitor changes over time, addressing dynamic challenges such as heat waves, floods etc..

12.1.9. Remuneration

Participating households will have the attending women reimbursed USD10 per study visit attended, for her time, effort and inconvenience during study visits, and inconvenience of study staff collecting temperature monitoring data periodically from her home (data collection from the home do not count as study visits). Remuneration will be provided at the end of each study-specific visit USD10 in cash

13. SUB-STUDY 4: HEALTH FACILITY & HOUSEHOLD THERMAL MONITORING & PERFORMANCE SIMULATIONS

Temperature and humidity will be measured at 15-minute intervals, at the participating health facility and in 20-25 households using digital temperature and humidity sensors on inside walls and adjacent outdoor structures. This will be supported by downscaled climate model data form satellites, for both present day and projected future climatologies, as well as data from local weather stations, where available. Temperatures will be monitored at 15-minute intervals using digital loggers. Indoor temperature data will be used to verify digital-thermal simulations (EnergyPlus simulation engine), and to model and test alternative building and nature-based solutions. This will allow the research team to undertake factor screening and thereby determine the optimum integration of thermal modulation measures in the built environment.

Indoor temperature monitors will be installed within 2-3 days of enrolment. Detailed information on the set-up and use of indoor temperature monitoring is provided in section **Error! Reference source not found.**. Briefly, for indoor temperature and relative humidity (rh) measurements, the Onset Hobo MX1101 CC will be used and the MX1104, will be used to provide data on globe temperature (GT), a critical factor in understanding the heat stress level experienced. Appendix 11 details the specifications of the above-mentioned devices. Within 5 days of the last study visit, the last set of temperature readings will be downloaded, and indoor temperature monitors will be removed from the home.

Participants from selected households will be provided with heat diaries to record daily experiences of heat exposure. Women's own record-keeping of heat experiences on a simple Heat Record Form (Appendix 10) will be used to document their experiences of heat between study visits. Urine specific gravity (USG) samples will be collected from the same women in the 30-50 households to assess hydration status, while skin temperature will be measured to monitor physiological responses to heat. Anthropometric measures, repeated USG samples, and skin temperature readings will be collected every two-months throughout the first six-month of the intervention period ahead of intervention optimisation codesign meetings from

the same women . For women who deliver during this period, qualitative data on labor and birth experiences will also be captured to understand experinces of heat stress on maternal and neonatal outcomes through field pesrspectives documented through IDIs and FGDs

13.1.1.1. Indoor environment monitoring of households and health facility

Briefly, the monitoring of the indoor environment of the labour ward, postnatal recovery room and antenatal clinic at the health facilities and households will involve the installation of an array of sensors which will continuously monitor the Drybulb temperature (DT), Relative Humidity (RH) and Globe temperatures (GT) in and around the labour ward, postnatal recovery room and antenatal clinic at the health facilities, while only DT and RH will be monitored in households. The sites will be visited on a monthly basis to download the data collected from the sensors (via bluetooth) and the collected data will be uploaded to a secure central data repository

13.1.1.2. Indoor environment monitoring of health facility

In the health facility the indoor environment monitoring sensors will be installed by suitably trained research assistants. The research assistants will include both trained community health workers who are community members in the study area and a senior architectural technologist. The specific sensors and the positioning of installation is described in Table 1 below.

Table 4: List of sensors and devices that will be installed in and around the facility, detailing position of installation

Measure	Sensor or device with similar specification	Installation position
Drybulb Temperature (DT)	Onset Hobo MX1101	Installed on the Southern and Northern wall between 1000 - 1800mm above finished floor level (affl). Sensors to be installed out of direct sunlight.
Relative Humidity (RH)		

Globe Temperature (GT)	Onset Hobo MX1104	Installed in the center of each room at a height of 2100 affl.
Outdoor weather station: Ambient temperature (DT) Relative Humidity (RH) Solar radiation (PAR) Wind speed and direction	Hp2551ca-wireless-weather-station, or similar	Installed in open space outside the health facility (near-community). Installed between 1000 and 1800 affl. Sensors to be installed in direct sunlight with no overshadowing.

Drybulb temperatures, relative humidity, and globe temperatures will be continuously monitored in the facility using an Onset Hobo MX1101 and Onset Hobo MX1104 sensors. The sensors monitor the indoor temperature at 15-minute intervals and store the data on their onboard memory. The sensors are battery powered with accuracy of ±0.21°C from 0° to 50°C for temperatures and ±2% from 20% to 80% for relative humidity.

The sensor will be installed using a temporary wire bracket that is hooked to the top of the existing corrugated iron walls of the household. For households with brick walls, the installation of bracket will be adjusted so as not to damage the wall. The house wall will not be damaged in any way and the bracket will be adjusted to the specific conditions. A single sensor will be installed in the bedroom/sleeping area (of the research participant) or lounge of each household; depending on the preference of the participant and household head. The research assistant will confirm the position of the sensor with the homeowner and research participant prior to installation. The selected sensors will not disrupt the research participants visually nor will they emit any sounds.

Data will be collected from the facility-based sensors on a monthly basis, using a bluetooth enabled data download application on a mobile device or computer. The relevant facility

manager at the health facility will be informed well in advance about the impending data collection date and their availability will be confirmed.

The devices have downloading ranges of 30m (line of sight), so the research assistants will be required to visit the health facility and the specific room to download the data. The data download will take a maximum of 60 seconds per sensor, researchers will not spend more than 8 minutes per room to download the data. The temperature data will be linked to a predetermined sensor number. The data downloaded from the sensors will be uploaded to a secure central digital repository housed at CeSHHAR See section 9 for the data handling, storage and data management protocol.

13.1.1.3. Indoor environment monitoring of households

In the selected households the indoor environment monitoring sensors will be installed by suitably trained research assistants during, or within 2 days of, the first IDI. The specific sensor and installation thereof is described in Table 2 below.

Table 5: Sensor that will be installed in the household, detailing position of installation

Measure	Sensor	Installation position
Drybulb Temperature (DT)	Onset Hobo MX1101	Installed on the Southern and Northern wall between 1000 -1800mm affl. Sensors to be installed out of direct sunlight.
Relative Humidity (RH)		

Drybulb temperature and relative humidity measures will be continuously monitored in the households using an ONSET HOBO MX1101 sensor. The sensors continuously monitor the indoor temperature at 15-minute intervals and store the data on the onboard memory. The sensors are battery powered and have an accuracy of ±0.21°C from 0° to 50°C for temperatures and ±2% from 20% to 80% for relative humidity. The sensor displays the room temperature and humidity so this can be seen by household members should they be

interested. They will not make any sounds, unless programmed to warn residents of temperature thresholds being crossed – this feature will be disabled to reduce disturbance to household members.

The sensor will be installed using a temporary wire bracket that is hooked to the top of the existing corrugated iron walls of the household. For households with brick walls, the installation of bracket will be adjusted so as not to damage the wall. The house wall will not be damaged in any way and the bracket will be adjusted to the specific conditions. A single sensor will be installed in the bedroom/sleeping area (of the research participant) or lounge of each household; depending on the preference of the participant and household head. The research assistant will confirm the position of the sensor with the homeowner and research participant prior to installation. The selected sensors will not disrupt the research participants visually nor will they emit any sounds.

Data will be collected from the indoor household sensors monthly, using a bluetooth enabled data download application on a mobile device or computer. Homeowners will be informed well in advance about the data collection date and their availability will be confirmed. Research assistants will not enter a home unaccompanied by the homeowner or research participant and will also visit the households to download the data in groups of two.

The sensors have a downloading range of 30m (line of sight), so the research assistants will be required to enter the homes to download the data. The data download will take a maximum of 60 seconds per sensor, researchers should not spend more than 5 minutes at a household to download the data. The temperature data will be linked to a predetermined sensor number. The downloaded data will then be uploaded to a secure central digital repository housed at CeSHHAR. See section 9 for the data handling, storage and data management protocol.

14. CO-DESIGN WORKSHOPS

14.1.1. Study Design

We propose up to 60 participants in total constituted by pregnant and postpartum women, household heads, community leaders, health workers, health facility managers, sub-national and national stakeholders. We believe this sample size of n=60 will allow for inclusivity and diversity of perspectives to ensure that the refined intervention package address multiple dimensions of the issue. By fostering collaboration and a shared understanding of heat-related challenges, stakeholders will generate context-specific solutions tailored to the unique needs of each intervention level and component. Through active knowledge exchange and the blending of cross-disciplinary insights, these workshops promote innovative and practical strategies for enhancing resilience to heat across all levels of society.

14.1.2. Participant Sampling

We will invite participants including pregnant and postpartum women, household heads, community leaders, health workers and health officials at subnational and national level to participate in a co-design workshop to discuss and refine interventions that have been implemented. Potential participants will be approached individually or in groups, where possible, and the study will be explained to them. Those who express interest in joining the co-design workshop will have the informed consent form read to them and the form will be signed on the day of the workshop (Appendix 30). This information sheet will include information on the co-design process that will take place and the participants role in this process. The detailed informed consent process is described in Section 31.

– *IndividualHousehold Level:* At the household level, we will invite women and household heads who participated in AR1 and AR2 to the codesign workshop to provide input on the ongoing interventions implemented in AR1 and AR2 for further refinement. To ensure a rich diversity of perspectives, we will ensure to have representation from people of diverse socio-economic status, ethnic background, and age. Women and household heads will be separated into two groups to manage and minimise power dynamics.

- *Community level:* We will invite a subset of community leaders who participated in the first co-design workshop to also provide input on all of the selected interventions also for the refinement of the implemented interventions.
- *Health systems and policy Level:* We will invite a sub-set of health officials and other stakeholders who also participated in the first co-design workshop, including health workers, district health officers, local and national government officials, and representatives from local non-governmental organizations (NGOs). We will ensure that all geographical areas represented by our study sites are included, thereby capturing the heterogeneity of the region.

All results will be categorised and incorporated into a framework and summarised in a table similar to Table below.

Proposed Framework of themes and results from optimisation of the intervention

Domain	Heat Adaptation interventions identified					
	Behaviour changes and awareness	Health systems and services	Modifications to the built environment	Nature based interventions	Policy action	Poverty reduction and equity
Individual (pregnant and postpartum women and their newborns)						
Health workers						
Household						
Community						
& Health Facility						
Health systems						
Policy and outside environment						

(subnational and national levels)						

15. COST CONSEQUENCE ANALYSIS

The cost-consequence modelling will assess the economic feasibility of implementing the multi-level and multicomponent community-led heat adaptation and mitigation interventions in Zimbabwe. This modelling aims to capture both direct financial costs (expenditure on goods, services, and volunteer time) and non-financial costs (donated goods or volunteer time).

15.1.1. Prospective costing study

The prospective nature of HAPI provides an opportunity for us to examine costs over time as it is not limited by the short nature of most studies. This will allow us to track changes in the cost structure over time, examining the variation as the interventions evolve. We will assess the cost implications of rolling out the intervention in the community and monitor the evolution of the programme.

i) Specifically, we will assess:
   a. the changing cost structure of heat adaptation and mitigation with intervention roll-out.
   b. Cost variation with programme evolution and scale.

15.1.2. Top down costing approach.

This approach will utilise comprehensive data (e.g., expenditures, time sheets, M&E reports) to allocate intervention expenditures to sites and then to activities. The costs will be categorised by activity and input type, focusing on capturing total costs, especially start-up and recurrent capital expenditures, and applying a 3% annual discount rate. Specifically, we will assess:

   a. Comprehensive access to data (expenditures, time sheets, M&E etc) to facilitate allocation of intervention expenditures to sites and then to activities

b. Costs will be disaggregated and categorised by activities and input type.
    i. Start-up capital and recurrent costs
c. Approach captures total cost better though less precise for disaggregating costs at the activity level.
d. First allocating out specific expenditures that could be clearly tracked to sites, then by M&E outputs such as training, persons reached, distances etc
e. All expenses prior to AR1 will be treated as start-up costs and together with capital costs annualised at 3% discount rate

15.1.3. Bottom up costing

Supplementing the top-down approach, a more granular bottom-up cost analysis will be conducted, particularly at the site level. A bottom up approach will supplement costing (more site level data collection) to ensure robustness of cost allocation. This will include formative baseline assessments in HAPI and HH in three sites, interviews with HCWs, stakeholders, and researchers, and time-motion studies to observe the cost allocation in real-time. Specifically, we will assess:

a. Formative baseline in HAPI and HH in 3 sites
b. Includes interviews with HCW, Stakeholders, Research staff, Stakeholders listed in AR1 and AR2 interview guides above
c. Time and motion analysis

15.1.4. Cost data analysis

All data from these processes will be entered and analysed using Microsoft Excel to ensure accurate data interpretation and reporting.

Our approach helps to determine the true economic impact and sustainability of the interventions, ensuring that the financial, human, and material resources are appropriately accounted for. The study will then inform decisions on scaling the intervention in other areas. In terms of the timeline and methods, we aim to complete the process efficiently within stage 2 of implementation. This approach guarantees that the economic analysis is directly tied to the operational needs and the scaling potential of the heat adaptation strategies

16. STUDY-RELATED FORMS

Forms that will be used in the implementation of the evaluation include:

- Pre-intervention cohort: Participant Information sheet and informed consent form (Appendix 22)
- Post-intervention cohort: Participant Information sheet and informed consent form (Appendix 23)
- AR1: Household head telephonic permission (Appendix 24)
- AR1: Household head written consent (Appendix 25)
- AR1: Participant Information sheet and informed consent form (Appendix 26)
- AR2: Household head telephonic permission (Appendix 27)
- AR2: Household head written consent (Appendix 28)
- AR2: Participant Information sheet and informed consent form (Appendix 29)
- Co-Design: Participant Information sheet and informed consent form (Appendix 30)
- Pre- and post-intervention cohort: Baseline Questionnaire (Appendix 31)
- Pre- and post-intervention cohort: Follow-up Questionnaire (Appendix 32)
- Pre- and post-intervention cohort: Postpartum Questionnaire (Appendix 33)
- AR1 and AR2: Questionnaire (Appendix 34)
- ARI and AR2: Context Tracker (Appendix 35)
- AR1 and AR2: Monthly Researcher journal (Appendix 36)
- AR1 and AR2: Microsoft Excel costing spreadsheet (Appendix 37)
- AR2: Field perspectives IDI guide (Appendix 38)
- AR2: Field perspectives KII guide (Appendix 39)
- AR2: Field perspectives FGD guide (Appendix 40)

17. QUALITY CONTROL AND QUALITY ASSURANCE

All staff involved in data collection will receive thorough training on the data collection methods and procedures that they will be involved in. This will help to ensure that interviews are conducted consistently, and temperature monitoring data are collected consistently and accurately at all times.

Various administrative forms will be used to track the collection of data and ensure timely follow-up with the participants and scheduling of interviews (e.g. Recruitment and Enrolment logs; Data tracking log).

18. DATA HANDLING AND ANALYSIS

18.1.1. Data Entry, Editing and Management

The data collected will be directly uploaded to the central REDCap database housed at CeSHHAR and may also be shared with Wits RHI. This will ensure that post editing will be limited as well as traceable. A log of all electronic database corrections will be retained via the REDCap database manager.

18.1.2. Data Analysis

Evaluation of complex interventions involves consideration of a wide range of outcomes. For purposes of sample size, the primary pilot-effectiveness outcome is mild-moderate hypovolemic maternal dehydration during labour (urine specific gravity >1.015, measured by handheld optical refractometer, Sper Scientific portable clinical refractometer 300005). This reflects hydration practices, and heat exposure (fluid loss through perspiration). Secondary outcomes include process indicators for interventions, heat strain, mental wellbeing, composite maternal-clinical outcomes (obstetric emergencies, emergency Caesarean section, pre-eclampsia/eclampsia, antepartum or postpartum haemorrhage, and sepsis) and composite infant clinical-outcomes (preterm birth, low birth weight, APGAR score ≤6, and neonatal admission). Household temperatures will be used to determine effectiveness of household level interventions.

Baseline survey data will be analysed descriptively using percentages and presented in tables and will be included in reports and publications as such. Survey baseline and follow-up data will be compared using Student's t test, Mann-Whitney U test and chi-square, as applicable. Analyses will be presented overall, and by site, facility, and pre-specified population sub-groups (to identify high-risk groups). Binomial multivariable regression will compute risk differences between pre- and post-measures in the primary outcome, controlling for multi-hazard factors and changes in climate exposures over time, with fixed-effect clusters. If size or direction of effectiveness differs markedly between facilities, or sites then analysis may be restricted to facility- or site-level.

18.1.3. Bias

Reporting bias may occur if participants view heat exposure as a nuisance, rather than a health hazard, and under-report clinically-relevant symptoms. To minimise this bias, we will sensitise the communities and begin all activities by giving some background about heat-health risk

19. DATA MANAGEMENT PLAN FOR ALL SUB-STUDIES

CeSHHAR Zimbabwe will be the data coordinating centre. This unit is headed by an experienced data manager. Data will be cleaned, entered, analysed and safely stored there and data maybe shared with Wits RHI in line with project data management guidelines.

Data management and security standards will be equivalent for routine programme data and data collection in pre and post surveys, though there will be significant differences in the way data are collected. For pre and post experimental serves, data will be collected using CAPI with assistance from a trained social scientist. Data validity checks will be built into the CAPI platform. In the field, data will be backed up daily into “cloud storage”. Laptop computers on which any data may be stored will be kept in locked storage at all times. In the field, consent forms are kept in locked trunks and returned to the CESHHAR within 5 days of collating them. Field teams will download data into a password protected database accessible only to the Research manager and named PI, on a central computer. This will be backed up daily. The consent forms are kept separately from survey data. In Harare consent forms will be stored in a locked room at CeSHHAR offices.

For programme data, one hard-copy file linking participants’ names with ID numbers, and contact/locator information will be maintained by the Research Manager and stored in a secure locked cabinet separate from participant data. Other hard-copy data will be stored separately in participant files and locked in a file cabinet located in a secure room accessible only to key study personnel. Participants will be asked to provide written informed consent for participation in the surveys and qualitative interviews. Specific data aspects are presented n subsections below:

20. DATA MANAGEMENT

Our data management plan includes the following key principles:

- Each participant will have a unique participant identification number. All hard copies of patient identifying data will be stored in a locked cabinet. Electronic versions of transcripts and original audio-recordings will be stored on a secure SharePoint site on our institutional server, which is secure and protected by two-level authentication.
- All of the data will be analysed electronically.
- Data will be fully anonymised or pseudonymised in reporting of the research findings, for example, when participant quotes are used.
- When storing a copy of the data on local machines is required (e.g., for qualitative analysis), the data will be password protected and de-identified.
- Access to data will be restricted to a limited number of study staff that have appropriate training to manage data.
- When sharing data with external transcribers, if required, they will not be sent by email but transferred safely using encryption or secure tools like Filesender or similar.
- The study will adhere to the Wellcome Trust regulations on data sharing.
- Many scientific journals now expect that datasets from the study being reported on are made accessible to readers, and some mandate this as a condition of publication. Access to the data collected in this study will be partly restricted - i.e., the dataset will be shared only upon written application to the study PI. More detailed aspects of data sharing are discussed in the section 5.3 of the protocol.
- Data will be shared between investigators at the two study sites.
- Data ownership will remain with the country teams in which the data was collected.

21. RECORD RETENTION AND DISPOSAL

- All paper-based research documents will be securely stored in a lockable steel cabinet in the research filing room. The keys will be held in a locked drawer within the project manager's office, ensuring restricted access.
- Upon the completion of the HAPI project, all paper files will be transferred to a fire- and water-resistant cabinet. These documents will be retained for a period of at least 5 years post study completion, in line with standard research protocols.
- Paper questionnaires will be stored for a period of five years from the time the final results of the study are published.
- The de-identified routinely collected participant level data and the questionnaire data, which may include information on socio-economic status, heat impacts, behaviours related to heat and hydration, and access to safe water, will be retained by CeSHHAR for at least 5 years post study completion.
- Qualitative data, including interview transcripts, audio files and observational notes, will be retained for a period of at least 10 years following the completion of the HAPI project. Secure disposal of these materials will be conducted in a manner that ensures participant confidentiality, such as secure digital deletion.
- Study data may be shared with relevant stakeholders, including the Climate-Health Africa Network for Collaboration and Engagement (CHANCE), as requested. CHANCE aims to bring policymakers, researchers and other stakeholders in East and Southern Africa to develop evidenced-based policies on climate change and health and support access to climate financing.
- Disposal of printed materials will be conducted in a manner that ensures the information is rendered unreadable, such as shredding, to maintain the confidentiality of the study participants and the integrity of the research process.

22. DATA ACCESS AND RELEASE

- In line with the Wellcome Trust's policy on data, software, and materials management and sharing, CeSHHAR is committed to maximizing the availability of research data with as few restrictions as possible (Wellcome 2017). Therefore, de-identified datasets from the HAPI project will be made publicly available upon publication of the final planned manuscript. These datasets will be placed in public repositories in machine-readable formats, ensuring that the data supporting the conclusions of peer-reviewed scientific research publications are freely available
- Datasets created for public release will contain a general description of the HAPI project, including data collection procedures. Where appropriate, a codebook with variable names and descriptions will also be included to facilitate understanding and use of the data.
- Access to the de-identified data generated from the HAPI project will be primarily restricted to the research team at CeSHHAR . The research team will have access to the data for the purpose of data analysis, interpretation, and publication of results
- De-identified qualitative data will be made available to other researchers upon reasonable request, following the publication of the primary study findings. Access to raw qualitative data may be limited due to the need to protect participant confidentiality.
- Data may also be shared with other stakeholders as per established data sharing agreements. Any such data sharing will be conducted in a manner that respects the privacy of the study participants and the integrity of the research process.
- Wellcome Trust also expects all users of research data, software, and materials to cite the source, and to abide by the terms and conditions under which they were accessed. The Trust recognizes and values a range of research outputs in assessing the track record of researchers, and this will be considered as a critical part of the end-of-grant reporting process (Wellcome 2017

23. DATA TRANSFER

- Quantitative data collected during the HAPI project, will be digitized and stored in a secure, encrypted database managed by CeSHHAR. The database will be managed using ODK/RedCap, a secure web application for building and managing online surveys and databases, widely used in health research.
- Data Transfer Agreements will be drawn up and signed prior to the transfer of any data between sites or to external partners.
- Data transfer between the research sites in Zimbabwe, and between the field and the central office, will be conducted through secure, encrypted channels to ensure data integrity and confidentiality. Secure File Transfer Protocol (SFTP) or Virtual Private Networks (VPN) are examples of secure channels often used in health research for data transfer. This includes data collected from questionnaires and field notes, audio notes and transcriptions from interviews and observations.
- All data generated from the HAPI project, will be de-identified to protect the privacy of the study participants. The final study databases will not include patient names, medical record numbers, or any other individually identifiable information.
- Any transfer of de-identified qualitative data will be conducted using secure, encrypted channels, such as SFTP or VPN. Transcripts and other qualitative data files will be deidentified prior to transfer to protect participant confidentiality.
- In the case of cross-site transfer of knowledge, specifically around novel qualitative methods and cost-consequences work, secure data transfer protocols will be followed to ensure that the information is shared effectively and securely.
- Data transfer to stakeholders will be conducted in accordance with agreed protocols and data sharing agreements, ensuring that all transfers comply with relevant data protection regulations in Zimbabwe.

24. DATA OWNERSHIP

The de-identified health data will be owned by CeSHHAR and MoHCC. As the primary institutions managing the project, they will have joint ownership over the data, subject to any data sharing agreements that may be established with other stakeholders. • In the case of publications or presentations resulting from the HAPI project, MoHCC and CeSHHAR will be acknowledged as the primary data owners. Co-authors and collaborators will be acknowledged as per their contributions to the project, in accordance with standard academic practice.

25. DATA SAFETY AND MONITORING

25.1.1. Response to New or Unexpected Findings or to Changes in Study Environment

- From the onset of the HAPI project, we will consider appropriate future uses for the study data and design the consent processes to accommodate this, as per the Wellcome Trust guidelines.
- We have a separate question on the informed consent form that requests use of the participants' anonymized study data for (re-)-analysis in studies done for purposes other than this study, and beyond the end of the study. If participants do not agree for their data to be used in other studies, they will still be permitted to join the study.
- The principal investigator confirms that the HAPI team will seek appropriate informed consent from study participants for the use of any potentially commercially exploitable results from the study.
- If there are any concerns raised regarding the participant records, QC, QA and data verification as described, an urgent meeting will be called with key study personnel to discuss the implications of these findings on ongoing study implementation. Key personnel in this instance will include representatives from all participating institutions. Minutes from this meeting will be kept on record and available for inspection on request by ethics committees, funders or other clinical bodies. The problems will be clearly stated, and a corrective and preventative plan developed for each, with follow up within a month to ensure that the error has not recurred and that the corrective and preventative plans are in place.

- Trends which might warrant changes to the study protocol, particularly related to protection of study participants, will be referred to the Wellcome Trust and MRCZ for review.
- We do not anticipate that there will be significant changes to patient care guidelines during the study period that may affect the study, however if these occur, changes to the protocol may need to be made. These will be discussed within the study team and with the Wellcome Trust and a study amendment will be submitted for both Wellcome Trust and MRCZ for approval

25.1.2. Identifying, Managing and Reporting Adverse Events

Adverse events related to study activities may include accidental disclosure of sensitive information which could lead to stigmatizing or discriminatory actions. Other adverse events could involve loss of data, for example, due to theft of the tablet/computer. Any adverse events will be reported by the project staff to the study coordinator who will report directly to the principal investigators. Any adverse events will be reported to the respective IRBs within 2 days of the adverse event occurring. Details of the adverse event will be documented and information on outcomes and resolution of the event will be sought and updated in the study records. All staff will be trained to handle participant distress and will have access to referral pathways (Appendix 20).

25.1.3. Handling of unanticipated events

Possible unanticipated problems that might occur during the conduct of this study include breach of confidentiality, inclusion of ineligible subjects or a breach in study procedures. Staff involved with this project will be trained to prevent these situations and regular monitoring of study activities will be conducted to identify any irregularities. In the event that any project materials or equipment (tablets, paper forms, etc.) are lost or stolen, or a breach of protocol occurs, study staff will immediately inform the PI who will then contact the Wellcome Trust. Information will be obtained regarding the loss or breach occurring, and as to whether any materials containing identifying information were included. A written statement of the events surrounding the loss of confidential data will be submitted to the PI within two business days.

The respective IRBs will be notified by email within 2 business days of becoming aware of the incident and the appropriate forms will be filed by the PI. Appropriate changes to the protocol will be implemented if necessary.

25.1.4. Emergency Care by study staff

- If any participant is identified to be acutely ill by the study staff, the participant will be accompanied by study staff to the relevant service point to receive appropriate acute care.
- In case of emergency, study staff will immediately assist the participant with contacting emergency services if at the participant's home, or accompany the participant to the emergency department if at the facility.
- The PI will be notified of the clinical emergency telephonically and provide further guidance, if required.
- When a participant is considered unsafe in their physical environment, case-by-case decisions and referrals to appropriate care will be made, in consultation with the participant.

26. PROJECT REVIEW AND REPORTING

- Staff directly involved in conducting the study will meet on a weekly basis with the PI to discuss progress and any potential challenges.
- On a monthly basis, full team meetings with all co-investigators will be held in person or by conference call to discuss study progress, challenges, QA/QC and any trends requiring addressing or further training.
- Per Wellcome Trust guidelines, written progress reports will be submitted annually, and a final project report will be submitted to Wellcome Trust and MRCZ upon completion of implementation and analysis. Interim updates will be provided through conference calls and meetings, as needed, with key stakeholders.
- Annual progress reports will be prepared for CeSHHAR management and Wellcome Trust.

27. STUDY MONITORING

Regular on-site internal monitoring will be performed by the PI or designee to protect the participants by ensuring that the study is proceeding according to study protocols and GCP requirements.

The study sponsor may conduct monitoring or auditing of study activities to ensure the scientific integrity of the study and to ensure the rights and protection of study participants. Monitoring or auditing may be performed by means of on-site visits to the study site, electronic remote monitoring or through other communications such as telephone calls or written correspondence. The visits will be scheduled at mutually agreeable times, and the frequency of visits will be at the discretion of the sponsor. During the visit, any study-related materials except identifying information of the participants may be reviewed and the Investigator along with study staff should be available for discussion of findings.

The study may also be subject to inspection by regulatory authorities (national or foreign) as well as the IECs/IRBs to review compliance and regulatory requirements.

28. LIMITATIONS OF THE STUDY

- This study is not designed to be nationally representative or representative of all health facilities in Mt Darwin District. Results may not be generalizable to other settings.
- Due to the fact that all interviews must take place during the warmer months, following pregnant women from early in their pregnancy is not feasible. This limits the amount of information that can be gathered from exposures pre-conception, at conception and in the first and second trimesters. In addition, longer term effects of heat exposures on infants cannot be quantified in this study.
- Although participants will be instructed not to share the activity trackers or personal temperature monitors with others, adherence will be self-reported with no feasible method for independent verification. This uncertainty could potentially introduce a source of bias or inaccuracies in the data collected.

- There is also the potential for recall bias when women in the IDI sub-study are interviewed about their experiences as there are considerable time gaps between interviews. We do however try to mitigate this as much as possible by having them complete a Participant Heat Record form.
- Women who enrol in the IDI sub-study maybe different than those who do not resulting in a potential self-selection bias. Purposive selective recruitment may introduce a selection bias.

29. TRAINING

All the study staff including the sub-investigators, project managers, study coordinators, nurses, social scientists, field workers/community health workers and the data collection team will be trained on the protocol using materials such as PowerPoint presentations and role plays, and will each receive a copy of the protocol. Training for research staff will be conducted during the period of study set-up while awaiting feedback and approvals from the respective ethical approval bodies. All training will be captured in a training log and only trained staff will be permitted to work on the study.

Training will include the following**:**

- Full protocol for all study staff
- Good Clinical Practice and Ethics training
- Informed consent procedures for all participants
- Questionnaire administration for interviewer-administered questionnaires
- Conducting participant observations
- Conducting serial In-depth Interviews
- Conducting Key Informant Interviews
- Collecting data from personal temperature monitors and activity trackers
- Collecting data from indoor and outdoor temperature monitors
- Collecting data from the Mobile Weather Station
- Data entry using REDCap
- Data management (including quality control and quality assurance)

- Distress Referral protocols (Appendix 20)
- All study SOPs

The training topics covered for different staff cadres will be tailored to their specific role in the study, as some of the content areas may not be relevant to their work.

All study staff will hold current certification in GCP and acceptable ethics certificates. During training, GCP and ethical practice will be reinforced for all cadres of staff and all phases of study implementation.

30. ETHICAL CONSIDERATIONS

The study protocol will be sent for ethical review to the Research council of Zimbabwe and the Medical Research council of Zimbabwe. Should any amendments to study activities be required, these will not be implemented prior to receipt of the required approval(s), except where necessary to eliminate apparent immediate hazards to study participants. The ethics committees will be updated yearly on the study progress, if a serious adverse event occurs, or as required by the ethics committee.

All staff will have appropriate ethics training that meets the in-country or ethics committee requirements, as well as necessary protocol training and required qualifications prior to conducting study procedures.

Safety of participants will be closely monitored. Should any adverse events be noted, participants will be referred for local standard of care, if required. We anticipate minimal risk to participants associated with participation in the study.

31. INFORMED CONSENT PROCESS

Written informed consent will be obtained from pregnant women as well as the health workers, depending on the specific sub-study. Informed consent will be obtained using forms specifically developed for the study. These forms will be developed in English, translated into

Shona. Informed consent will include information on who is carrying out the study, the study purpose, how the findings will be used, what is being asked of participants, risks and benefits of participation, the possibility to opt-out at any time, and who to contact for more information, or if there are any concerns.

The participants will be offered a copy of their signed consent form for their own record. This document contains the contact information for the principal investigator should the participant have complaints or concerns related to the study.

A certified translator will translate the English version of all the Informed consent forms to Chishona. After the potential participant indicates that they may be interested in participating in the study they will be informed of languages that the Informed consent forms are available in and be asked to select which language they prefer.

After the potential participant indicates that she may be interested in participating in the study, we will ask the participant if they are able to read, as well as their language preference for written documents. If they are able to read the participant will be given the informed consent form (ICF) to read in the language of their choice. If they are unable to read, study staff will explain the information sheet and consent form to them verbally, in a language of their choice. Eligible women will be given the option to take the ICF home to discuss with family members prior to joining the study. We will ask permission to call the potential participant telephonically to follow up whether she is interested in study participation.

Completion of the ICF may occur at the same time as the date of enrolment, at the health facility (or other suitably chosen space). The staff member conducting the informed consent process will read through the entire ICF and discuss each section with the potential participant in their chosen language which they understand to ensure that they are able to read the ICF. All aspects of the study will be explained as part of the informed consent process: purpose of the study, study procedures, study visits, questionnaire administration, interviews to be conducted in their homes (or other suitably chosen space), personal and household temperature monitoring, risks and benefits of participation, approximate length of each study

interview and corresponding remuneration for time spent at each study interview ($10 for the enrolment study visit, and $10 for subsequent visits)

Participants will also be made aware that as part of the study, they may receive SMS (short message service) messages for appointment reminders. Study staff visiting the home will use a branded car but the car will simply say “CeSHHAR”. Staff will have identifiable clothing and name tags so that they can easily be identified by participants. When the household is visited, study staff will be accompanied by trusted community health workers. They will ask for the participant by name at the household. Once the participant is comfortable with the study staff member, the community health worker will leave. Staff will insist on a private space for the interview within the house, or if that is not possible, will offer the participant another place of her choice.

For codesign, completion of the ICF will occur either prior to the co-design workshop or on the day of the workshop. The staff member conducting the informed consent process will read through the entire ICF and discuss each section with the potential participant in their chosen language which they understand to ensure that they are able to read the ICF. All aspects of the study will be explained as part of the informed consent process.

For stage 2, completetion o the iCF will occur prior to enrolment or at enrolment for the pre or post intervention study at the health facility during a woman’s ANC visit. Women agreeing to have temperature sensors installed at theit homesteads will sign an additional consent form.

An Informed Consent Checklist (Appendix 18) will be completed for each informed consent signed. Upon completion of the ICF process, the original ICF form will be filed in the study regulatory folder, and a copy will be made for the participant when the staff member returns to the study office. The participant copy will be provided to the participant (in a sealed envelope) when a staff member next visits the home to collect temperature monitoring data – within 10 days of completing the ICF. Should the participant decide that she does not want to keep the copy, the copy will be kept with the original in the Regulatory file and her decision will be noted on the Informed Consent Checklist (Appendix 18).

Participants who are illiterate

If the person who is going to sign consent is illiterate, they will be asked to bring a literate friend or family member (of their choice) with them to the consent discussion. If this is not possible, another impartial witness will be found (e.g. a staff member not involved in the study).

If the participant is able to write her name, then she will complete the signature page of the informed Consent Form as described above.

Participants who are semi-literate or illiterate and unable to write their name, will be asked to indicate their consent with a thumbprint and with a witness, who will also sign to certify that the study procedures were explained to the participant, and she agreed to the participation voluntarily.

She will also make her mark (thumbprint) on each page of the consent form in the bottom right-hand corner as well as on the signature line of the signature page.

The date line should remain blank for an illiterate participant (i.e., study staff should not write in the date for the participant). The date the consent process is performed and the fact that the participant is illiterate will be documented on the Informed Consent Checklist (Appendix 18).

32. PARTICIPATION OF VULNERABLE POPULATIONS

The study includes vulnerable populations, who may require specific safeguards or considerations during the study. Vulnerable groups include pregnant women, migrant pregnant women, and remote-rural communities (in the Zimbabwe study sites only). They are all groups at high- risk for heat-related conditions - allows us to understand how their experiences of heat exposure differ from those of other women (Chersich et al. 2020). Both Wits RHI and CeSHHAR are reproductive health research institutes and have a long track record in rights-based approaches, initiatives to reduce ‘’unconscious bias’’ among staff, and ensuring diversity in study populations. Specific efforts to retain under-served groups may include home visits by field staff and fortnightly telephonic contact. Staff will implement the study distress protocols or assist with linkage of women with services where required.

33. RISKS AND BENEFITS

Risks associated with study participation have been listed below, as well as the plans which the study will put into place in order to mitigate this risk and protect study participants.

1) *Risk of potentially augmented stress among women who have experienced a complicated childbirth or adverse perinatal events*

   In instances where a participant in the serial IDIs has experienced a miscarriage or stillbirth, her wellbeing is of the utmost concern. We will make contact with such participants when appropriate and offer our condolences and support. We will also offer the participants the option of continuing with the study once they are ready to do so, as some might find it helpful to have a neutral and sympathetic person to talk to. It would be valuable for the research team to get the participant's reflections on whether they connect the miscarriage or stillbirth to heat in any way. However, there will be no coercion or pressure on the participant to take part in their final, postpartum interview. If such interviews are held, then the Interviewer will only ask questions related to health and heat among postpartum women.

2) *Risk of vulnerability to theft with wearables*

   We are aware that women who wear an activity tracker on their wrist may become a potential target for criminals. We will consult with pregnant women and our Community Advisory Boards prior to study commencement about these risks and exclude these devices from the study if there are substantive concern

3) *Risk of breach of confidentiality*

   A private space for recruitment, questionnaire administration, data collection and in-depth interviews will be used by all study staff. All staff will be trained in GCP and confidentiality of patient information will be emphasised throughout staff training. Study staff will protect participant confidentiality through the use of participant identification numbers in place of the participants' name and by limiting access to participants' data and secure storage thereof. All data collected from participants including transcripts, fieldnotes and biomedical data will be stored in a secure server with access granted only to project staff directly involved in the study. Data will be collected into a secured, password-protected database (e.g. REDCap), using a participant identifying number. The link between the participant identifying number,

and name and date of birth, will be kept in a separate password-protected database. All information will be de-identified for analysis.

Data shared on public access platforms will be de-identified and adhere to the Wellcome Trust's policies for data accessibility and sharing [79].

Interviews will be audio-recorded and transcribed in full, with all identifying information removed from the transcripts, aside from gender, age, population group and facility name. Audio-recordings and transcripts will be stored in a secure folder and saved to the CeSHHAR SharePoint server with password-restricted access limited to the investigators and other study staff, and stored separately from other participant records such as informed consent forms that may identify individuals. After the study has concluded, audio-recordings will be destroyed in accordance with the time specifications mandated by the Medical Research Council of Zimbabwe, and the Wellcome Trust guidelines, whichever is longer.

There are several potential benefits to study participation, both for women and for their children. These include:

1) *Ability to track one's own heat exposure and activity*

   Pregnant women participating in the study will be able to track their personal temperature exposure as well as their activity levels using the FitBit wearable device.

2) *Acquisition of an activity tracker*

   Upon study completion, women will be allowed to keep the FitBit device, at no cost to themselves. The device will be delinked from all study-related tracking mechanisms at the conclusion of the study. If the woman has a compatible smartphone, the study team will assist her with linking her wearable device to her smartphone.

3) *Increased awareness of heat risks*

   Through exposure to the study, participants may gain an increased awareness of the impact of heat exposure on the health of pregnant women and their infants. For pregnant women, this knowledge can empower them to take proactive measures to protect themselves and their babies from potential adverse effects. Moreover, at the community and facility level, the increased awareness may spark constructive dialogue and the consideration of strategies to safeguard the well-being of pregnant and

postpartum women. This collective awareness will not only help to lay the groundwork for our entry into the second Stage of the project but may also lead to community-driven initiatives tailored to address the challenges posed by high temperatures.

34. CONFIDENTIALITY

All study data will be entered into an electronic study database and interview transcripts will be saved on the CeSHHAR secure SharePoint. Paper records will be maintained in a double-locked room at the CeSHHAR office. All electronic files will be encrypted and access restricted to study investigators. All study tablets, computers, flash drives, external hard drives and web-based servers containing electronic databases will be encrypted and password protected. Standard non-legal confidentiality agreements will be signed by all CeSHHAR (Appendix 19).

35. ALTERNATIVES TO PARTICIPATION

Participation in the study is completely voluntary. All potential participants approached for participation will be informed of the voluntary nature of their participation. Pregnant women who are potential participants will also be informed that they will receive their normal standard of care at the facility regardless of their decision to participate in the study. Health workers who are potential participants will also be informed that their employment and current duties remain unaffected regardless of their decision to participate in the study.

36. CONFLICTS OF INTEREST

The study team will manage any conflicts of interest to ensure credibility and mitigate bias. Members of the study team will certify that they have no affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) related to the subject matter and will sign the CeSHHAR Conflict of Interest Statement prior to the initiation of the study

If conflicts of interest are discovered among members of the study team, that may affect the integrity or credibility of the study, actions will be taken to resolve the conflict of interest. Specific actions will be determined by the nature of the conflict and the timing of when it is discovered. The actions taken may include but are not limited to:

- Removal of the individual with the conflict of interest from participating in study activities;
- Revising the role of the individual with the conflict of interest so the relationship is no longer relevant/no longer presents a conflict; and
- Assessment of the individuals' contribution to study activities for bias prior to delivery of final research outputs.

37. AUDIENCE AND STAKEHOLDER PARTICIPATION

We consulted widely in developing this proposal. Firstly, we engaged with local Community Advisory Boards to identify key needs and interventional priorities and consulted highly-influential civil society groups. Secondly, we consulted the Ministry of Health and Child Care, who gave detailed inputs and expressed strong support for the study, including as named study collaborators. Thirdly, we presented the HAPI interventional approach to research and policy representatives from 10 African countries at the combined CHANCE and WHO Clim-Health Africa meeting in August 2022 in Botswana. At the meeting, CeSHHAR conducted a formal Research and Policy Prioritization Workshop using CHNRI methods with 54 leading policy makers, researchers, funder representatives, and national and international NGOs. The top-three ranked research priority areas on heat and health were: capacity building, health promotion and health services. The top-ranked policy need was "Guidelines on building climate-resilient and environmentally-sustainable health facilities". Our project directly addresses each top-ranked priority. As members of the CHANCE network CeSHHAR will continue high-level stakeholder involvement throughout the project.

38. DISSEMINATION AND REPORTING

We anticipate the following outputs from this research:

- Publication of findings from the 4 sub-studies

- Data gathered through formative work on qualitative enquiry and digital simulations that will inform co-design of interventions for Stage-2 of the study.
- Media messages, targeting diverse groups.

Output metadata and documentation

Metadata include data dictionaries and data descriptors such as names of principal investigators, funding sources, protocols, sample and sampling procedures, temporal and geographic coverage of data, look-up tables, technical information (e.g., file formats), interviewer guides and coding instruments.

Outputs availability

Manuscripts will be published in open-access journals. Data and code generated as part of the publication output will be saved in open-access repositories, such as Github, Figshare or Zenodo, on project websites, as per Wellcome Trust Guidelines [Wellcome 2017].

Discoverability and access to outputs

We will use DataCite or similar platforms, which automatically assigns Digital Object Identifiers, enhancing output linking, citation and tracking. We will develop data-access Standard Operating Procedures for responsible access granting mechanisms and publicise these on the Wellcome Open Research platform. Open database licences such as Creative Commons and Open Source Initiative will promote data access. Outputs will be accessed at conferences, press statements, and community and policy-maker meetings.

Possible restrictions and data storage considerations

Restrictions to data management and sharing are guided by national legislation (Data Protection Act in Zimbabwe). Data will be stored on a secure cloud-server and participant-identifiers stored separately, linked through Unique Participant IDs. Only de-identified data will be shared.

39. STUDY TIMELINE FOR ALL HAPI STAGES

Temperatures																			
Project years	1												2						
Project months (starting 1 March 2023)	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18-24	
HAPI STAGE-1: Formative Research																			
Protocol, consent forms and data collection tools development																			
Ethics and regulatory approvals																			
Stakeholder engagement																			
SOP development																			
Staff recruitment																			
Equipment purchase																			
Staff training																			
Sub-study 1: Ethnographic observations																			
Sub-study 2: In-depth interviews and monitoring heat exposure of pregnant women and health workers																			
Sub-study 3: Key informant interviews																			
Sub-study 4: Health facilities and household thermal simulation modeling																			
Data analysis																			
Report preparation																			
Manuscript preparation and publication																			

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41. LIST OF APPENDICES

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