TESTING LOW-COST PORTABLE SMARTPHONE ELECTROCARDIOGRAPHS IN THE SCREENING OF PREGNANT WOMEN IN MWINGI WEST AND MWINGI CENTRAL, KITUI COUNTY, KENYA

Putting African Mothers, Newborns and Children First Project – Mwingi West and Mwingi Central, Kitui, Kenya

Reproductive, Maternal, Newborn, Child and Adolescent Health and Nutrition Programme

Amref Health Africa in Kenya

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Sponsoring institution(s)

D-Heart SRL

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ACRONYMS

AIDS	Acquired Immune Deficiency Syndrome
ANC	Antenatal Care
BEmOC	Basic Emergency Obstetric Care
ECG	Electrocardiography
GoK	Government of Kenya
HIV	Human Immunodeficiency Virus
KDHS	Kenya Demographic and Health Survey
KNBS	Kenya National Bureau of Statistics
MCH	Maternal and Child Health
MDGs	Millennium Development Goals
MNCH	Maternal, Newborn and Child Health
MMR	Maternal Mortality Ratio
MOH	Ministry of Health
NGO	Non-Governmental Organizations
NHSSP 11	National Health Sector Strategic Plan
PIH	Pregnancy Induced Hypertension
RMNCAH	Reproductive, Maternal, New-born and Child Health
SPSS	Statistical Package for Social Scientists
SRH	Sexual and Reproductive Health
TFR	Total Fertility Rate
UNFPA	United Nations Population Fund
WHO	World Health Organization

OPERATIONAL DEFINITIONS

Electrocardiography (ECG) is the process of recording the electrical activity of the heart over a period of time using electrodes placed on the skin. These electrodes detect the tiny electrical changes on the skin that arise from the heart muscle's electrophysiological pattern of depolarizing during each heartbeat. It is a very commonly performed cardiology test.

Hypertensive Disorders of Pregnancy has been defined by a number of researchers but in this study the definition by International Society for the Study of Hypertension of Pregnancy (ISSHP), was adopted.

Hypertensive Disorders of Pregnancy: Includes chronic hypertension and pregnancy induced hypertension.

Chronic hypertension: A Diastolic Blood pressure of 90mmHg or more that either predates pregnancy or develops before 20 weeks gestation. A superimposed pregnancy induced hypertension may develop on those with chronic hypertension.

Pregnancy induced hypertension (PIH): Which develops after 20 weeks of gestation. P.I.H is classified:

ABSTRACT

In Kenya, hypertensive disorders complicate 1% of all pregnancies, and its diagnosis still represents a challenge in Kitui County. Cardiological screening services during pregnancy might exert a substantial positive impact because in case of suspicious electrocardiographic findings, the pregnant women can be referred to a tertiary referral hospital for further assessment, in order to ensure a high level care to herself and to the foetus.

D-Heart has partnered with Amref Health Africa Italy and Amref Health Africa in Kenya to pilot the use of low-cost portable smartphone electrocardiographs in the electrocardiographic screening of the pregnant women attending Ante-natal Care services in Mwingi West and Mwingi Central Sub-Counties of Kitui County, Kenya.

Main objectives of this pilot study are: I) Pilot the utility-testing of D-Heart among women attending the Ante-natal Care services at Thaananzau and Nyaani Dispensaries, in Mwingi West and Mwingi Central Sub-Counties; II). Enable referral of patients in need of more specific screening and treatment in Mwingi West and Mwingi Central Sub-Counties; III) Document lessons learnt for the scale up of the low-cost portable smartphone electrocardiographs in electrocardiographic screening of the pregnant women in developing countries.

Findings from this study will provide data on the effectiveness of low cost cardiovascular screening with D-Heart portable electrocardiograph and produce evidences to inform policies on low cost electrocardiographic screening.

CHAPTER ONE: INTRODUCTION

1.1 INTRODUCTION

1.1.1 Kitui County

Kitui County is situated in the Eastern region of Kenya bordering Machakos and Makueni counties to the West, Tana River County to the East, Taita Taveta County to the South, and Embu and Tharaka-Nithi Counties to the North. The county is sub-divided into eight sub-counties, namely: Kitui Central, Kitui Rural, Kitui South, Kitui East, Kitui West, Mwingi

Central, Mwingi North, and Mwingi West (Kitui, 2014). The county's population was 1,012,709 according to the Population and Household Census report of 2009 and was projected to grow to 1,108,515 by 2017. The population growth rate of the county at 2.1% is slightly lower than the national rate of 2.6% (KNBS, 2009).

Kitui County has a high poverty index of 63.5% as compared to the national level of 45.9%. This is reflected in the high number of dependants, high number of people in informal employment, poor housing and sanitation (Kitui, 2014). The poor in the County are clustered into certain social categories such as people living with disabilities, female-headed households, unemployed, unskilled and semi-skilled casual workers, HIV/AIDS victims, orphans and widows. The main causes of poverty in the County have been identified as the high population growth rate, high levels of unemployment especially for the youth, food insecurity, a high number of physically challenged persons and high numbers of rural households (Kitui, 2014).

Kitui County's health system is under-developed. There are approximately 255 public health facilities in the County consisting of 15 hospitals (11 public and 4 private), 25 health centres, 185 dispensaries, 44 private clinics and 10 nursing homes (Kitui, 2014). The county has inadequate facilities, low doctor/nurse patient ratios, few operative health facilities, and long distances to health facilities. On average, the distance to the nearest health centre is 10.2km while the doctor to population ratio is 1:22,005 and the nurse to population ratio is 1:1,962. This is against the WHO recommended ratio of 1.10,000 for doctors, and 1:1000 for nurses (Kitui, 2014).

As a result of a myriad of health system challenges, the reproductive, maternal and child health indicators in Kitui County vary between poor and average as summarised in Table 1 below:

Table 1: Status of Key RMNCAH Indicators, Comparing Kitui County and National Average

Indicator	Kitui County	National	Source
Total Fertility Rate (TFR)	3.9	3.9	KDHS 2014
% of women aged 15-19 who have begun child bearing	15%	18%	KDHS 2014
Contraceptive Prevalence Rate (CPR)	57%	58%	KDHS 2014

% of pregnant women receiving ANC from a skilled provider	97.5%	95.5%	KDHS 2014
% of mothers delivering in a health facility	45.6%	61.2%	KDHS 2014
% of mothers delivered by a skilled provider	46.2%	61.8%	KDHS 2014
Fully immunised child coverage	56.8%	74.9%	KDHS 2014
% of children under five who are stunted	45.8%	26%	KDHS 2014

1.1.2 Project Background

Amref Health Africa in Kenya with funding from European Union and Amref Health Africa in Italy (through co-operative agreement (DCI-NSAPVD/2012/307-672) is implementing a five year project (2013-2017) named *"Putting African Mothers, newborn and children first in Kitui County*". The project is implemented in partnership with Ministry of Health (MOH) and Wikivuvwa Development Action (WDA), a local Community Based Organization (CBO). The project addresses social disparities in access, utilisation and outcomes of MNCH, nutrition and family planning services through a health related poverty alleviation initiative. The project is implemented in Mwingi Central and Mwingi West Sub Counties which experience inequitable distribution of national resources, high maternal and child mortality rates, poor infrastructure, low literacy rates, recurrent drought, lack of water and perennial food shortages.

The project endeavors to improve the health status of the County, while promoting improved access to quality Maternal, Newborn and Child Health (MNCH) services and Family Planning (FP). It seeks to contribute towards reversing Kenya's declining health indicators by directly addressing MDGs 4, 5 and 6. It is also meant to contribute to MDG 1 (poverty reduction), MDG 3 (gender equality), also captured under SDG 1 (no poverty) and SDG 5 (gender equality) respectively and contribute to realization of Kenyans Vision 2030. The purpose is to empower communities, CBOs and local partners to address MNCH needs through promoting demand and access to quality FP, SRH, MNCH and Nutrition services. The project's specific objectives are:

1. To promote demand and access to quality RMNCH services

2. To increase high impact nutrition interventions for mothers, newborns and children under five years through preventive and management actions to reduce malnutrition
3. To increase demand and utilization of quality family planning (FP) and Sexual and Reproductive Health (SRH) services;
4. To strengthen the health-care delivery system to provide quality MNCH, nutrition, FP and SRH services

The expected beneficiaries include: 58,795 women of reproductive age, 44,097 children under five years, 45 health workers (nurses and clinical officers), 350 Community Health Volunteers, 14 Community Health Extension Workers (CHEWs), 7 Community Health Committees and 42 teachers at early child development (ECD) centres. In addition the project will have supported 8 CBOs that will in turn sensitize 120,000 men and women, 75,000 young people (*Mwika* forums), 60 village elders and 12 traditional health practitioners on reproductive health rights and Family Planning. Lastly, 120 Family Planning and Sexual Reproductive Health Rights champions and 37 WATSAN management committees will be facilitated to support Reproductive Health and child health interventions. Indirectly, the action is expected to reach 244,988 people in Kitui County, who will be the final beneficiaries of improved access and quality to Maternal, New Born and Child health service, nutrition and family planning.

A midterm evaluation (MTE) commissioned by Amref Health Africa in Kenya was undertaken between 25th April and 16th May 2016 with a purpose of assessing the project's performance. The mid-term evaluation used a mixed-method approach that harnessed the participation of various stakeholders including the beneficiary community, Amref Health Africa in Kenya, County and Sub county health management teams (C/SCHMTs), health service providers in the supported facilities, Wikivuvwa Development Actions (WDA) and other local actors. Data was collected from multiple sources using both quantitative and qualitative methods including literature review, household survey, key informant interviews, focussed group discussions and capacity assessments.

The key findings were as follows:

- The project design and implementation continue to be relevant to the priority needs of the local community and the health system gaps that constrain service delivery. The project has evolved effectively to align with the devolved form of government.
- The capacity of the supported health facilities to provide quality FP, MNCH and nutrition services has improved as a result of project interventions including health worker training, essential medical equipment, renovation of maternity wards and supportive supervision among others.
- The project has engaged with and empowered various community-level structures and civil society organisation. The capacity of the key local partner, Wikivuvwa Development Actions, has improved, both in regards to institutional governance and technical capacity on promotion of FP, SRH, MNCH and nutrition services.
- The project has supported the establishment of 7 community units that were found to be functional. The Community Health Strategy has been effective in influencing utilisation of maternal and child health services in Mwingi West and Mwingi Central.
- The table below presents the project's status against key performance indicators in comparison with baseline (2013) and county and national average (KDHS 2014):

The conclusion was that on the overall the project had evidently contributed to improvement in community awareness of and utilisation of FP/RMNCAH and nutrition services in Mwingi Central and Mwingi West. However, some health system challenges especially shortage of staff and infrastructural gaps continue to pose challenges.

1.1.3 Partnership: D-Heart and Amref Health Africa in Italy and Amref Health Africa in Kenya

Founded in 2015, with office in Genova, D-Heart Srl improves chronic cardiac patients' life by transferring ECG controls on a smartphone. D-Heart was founded by Nicolò Briante and Niccolò Maurizi, two young students of the Borromeo's College in Pavia, Italy.

D-Heart is a social vocation start-up. The D-Heart team has partnerships with several NGOs and in February 2016 went to Senegal where they made a free cardiovascular screening of the population in several villages of the Casamance forest. D-Heart obtained 230,000 euro grant from Vodafone Foundation as the winner of the Think for Social competition in March 2016. D-Heart also won 20,000 at the ComoNext competition for development and BioInItaly Investment Forum 2016 sponsored by Intesa San Paolo. D-Heart was selected among the best Italian healthcare start-up by both Ambrosetti Consulting (Geyser Startup Program) and Cosmofarma Start-Up Village.

D-Heart has partnered with Amref Health Africa Italy and Amref Health Africa in Kenya to pilot the use of low-cost portable smartphone electrocardiographs in the electrocardiographic screening of the pregnant women taking part in the services provided by the Putting African Mothers, Newborns and Children First Project in Mwingi West and Mwingi Central, Kenya.

The partnership agreement (Annex 2) outlines responsibilities of each organization as below:

Responsibilities of Amref Health Africa Italy and Kenya

1. On field utility-testing of D-Heart in the context of the maternal-childhood health programme in Kenya, piloting the intervention in the following two health facilities: for a period of 3 months starting from October, 2016

2. Use of the name 'Amref' as partner during presentations or in documents concerning the project "D-Heart, the portable electrocardiograph for the developing countries".

3. Photographic and multimedia report concerning at least one video and 8-10 pictures for each month of experimentation to describe the activities performed with Amref as a partner.

4. A good referral system in place for patient in need of more specific screening and treatment

Responsibilities of D-Heart SRL:

1. Free supply of 2 electrocardiographic devices and 1 smartphone (iPhone 5) for the testing in the context of the maternal-childhood health programme in Kenya;

1. Free supply of consumable electrodes for the entire duration of the experimentation as agreed previously by Amref;

2. Service of clinical and procedural formation of the local Health Workers that are going to use the devices in their screening activity in July 2016

3. Service of procedural formation of the local Health Workers in relation to the data categorization and sharing;

4. Weekly based service of tele-report of the ECG tracings acquired by the Health Workers during the testing and experimentation period;

5. Scientific and Statistical support before, during and after the experimentation phase provided by D-Heart Team.

The present partnership and collaboration request does not imply any financial involvement by Amref, since all the expenses related to the experimentation would be provided by D-Heart srls.

1.2 PROBLEM STATEMENT

In Kenya, hypertensive disorders complicate 1% of all pregnancies, and they include pre-existing diseases, conditions developed during pregnancy and the postpartum period, congenital or acquired structural abnormalities and arrhythmias (GOK, 2014). During pregnancy enormous changes take place in the cardio vascular system; these have many implications on the management of pregnant women with cardiac disease. These implications must be considered for

appropriate care during the antepartum, intrapartum and postpartum periods (GOK, 2014). In Kitui County, hypertension is listed as the 9th major cause of morbidity in the County, with sedentary lifestyle being listed as a risk factor. Institutional screening for non-communicable diseases in the County is currently taking place in 290 primary care facilities (dispensaries and health centres) and 15 hospitals. The County targets to scale this up to 306 primary care facilities and 20 hospitals (Kitui, 2013). However, cardiovascular screening data for expectant women is not monitored and reported in the County.

Despite evidence on the importance of cardiovascular screening, in many countries including Kenya, early prediction of hypertensive disorders in healthy and initially normotensive pregnant women remains problematic, partly because severe forms such as preeclampsia and eclampsia are etiologically complex and heterogeneous conditions (Abalos, 2014). In many countries, no guidelines exist for an appropriate and cost-effectiveness screening and early detection of hypertensive disorders in the community and there is no uniformity in referral thresholds and assessment procedures (Angeli, *et al.,* 2015).

1.3 JUSTIFICATION

Hypertensive disorders of pregnancy are a major cause of poor outcome, including placental abruption, organ failure, cerebrovascular accident and disseminated intravascular coagulation. These disorders are associated with increased fetal risk of intrauterine growth restriction, intrauterine death and prematurity. Electrocardiography (ECG) recently emerged as a useful tool to evaluate cardiovascular complications during pregnancy. Specifically, left atrial abnormalities detected by standard ECG are associated with a fourfold increased risk of developing hypertensive disorders during pregnancy (Abalos, 2014).

In the last few years, some clinical studies tested the combinations of different risk markers to develop multivariable models for the prediction of hypertensive disorders during pregnancy. The use of multiple markers in a screening approach may reflect different aspects of the hypertensive disease process and increases the specificity and sensitivity of the screening (Angeli, *et al.* 2011). Various systematic reviews have generated evidence that combining new screening tests with risk markers will provide the sensitivities and likelihood ratios required for prediction of

hypertensive disorders in pregnancy enhancing the ability of clinicians to detect subgroups of pregnant women at increased risk.

One of the objectives of the Kitui County Health Strategic Plan 2013/2014 – 2017/2018 is to halt, and reverse increasing burden of Non communicable conditions. In order to achieve this objective, scaling up screening of non-communicable diseases including diabetes and hypertension, has been indicated as a priority action (Kitui, 2013). Cardiological screening services during pregnancy might exert a substantial positive impact in the pregnant women, especially in low to medium income regions such as Kitui County. In such regions, the prevalence of hypertension and Peri-Partum cardiomiopathy justifies electrocardiographic screening strategy in the pregnant. For instance, in case of suspicious electrocardiographic findings, the pregnant women can be referred to a tertiary referral hospital for further assessment, in order to ensure a high level care to herself and to the foetus (D-heart, 2016).

1.3.1 Significance of the Study

Findings from this pilot study will provide evidence on the effectiveness of the low cost electrocardiographs for electrocardiographic screening of pregnant women, and inform policy and programming on strategies for electrocardiographic screening of pregnant women and management of hypertension during pregnancy.

CHAPTER TWO: LITERATURE REVIEW

2.1 Review of Literature

2.1.1 Maternal Health

Maternal and newborn conditions account for a substantial part of the health gap between the developed and developing countries. Globally, there were an estimated 289,000 maternal deaths in 2013, a decline of 45% from 1990. The Sub-Saharan Africa region alone accounted for 62%

(179,000) of global deaths, followed by Southern Asia at 24% (69,000). The MMR in developing regions (230 countries) was 14 times higher than in developed regions (16 countries) with Sub-Saharan Africa having the highest regional MMR (510/100,000 live births) (WHO, 2014). Approximately 1000 women die each day worldwide from pregnancy related causes, 99% of them in developing countries and more than 50% in Sub-Saharan Africa (WHO, 2014).

Maternal mortality levels in Kenya have remained unacceptably high at 362 maternal deaths per 100,000 live births, (with some regions reporting MMRs of over 1000 /100000 live births) (KNBS, 2015). The most common causes of maternal morbidity and mortality are seven main categories of direct and indirect causes: Eclampsia compounded by hypertensive disorders, abortion, embolism, obstetric hemorrhage, hypertensive disorders, pregnancy-related sepsis, other direct causes, and indirect causes. Indirect causes, which include deaths due to conditions such as malaria, HIV/AIDS and cardiac diseases, account for about one-fifth of maternal deaths (Balabanova, *et al.* 2011).

1.3.2 Hypertensive Disorders and Cardiovascular Screening

Hypertensive disorders of pregnancy (HDP) account for nearly 18% of all maternal deaths worldwide, with an estimated 62,000 to 77,000 deaths per year (Angeli, *et al.,* 2015). HDP fall into four categories: chronic (pre-existing) hypertension, gestational hypertension or pregnancy-induced hypertension (PIH), pre-eclampsia/eclampsia and pre-eclampsia superimposed on chronic hypertension.3 (Eclampsia document). Data on the incidence of HDP are scarce, as shown in a recently published systematic review, where just 74 studies from 40 countries reported the incidence of pre-eclampsia and eclampsia, only seven of these with data on national coverage.

For every woman who dies, it is estimated that 20 others suffer severe morbidity or disability.5 The proportion of women surviving severe maternal complications (also called ‘near-miss’ cases) has been proposed as a useful gauge for the evaluation of the quality of maternal health care and its determinants, with the potential to complement the information obtained from the reviews of maternal deaths (Audibert, 2005).

A study carried out by the World Health Organization (WHO) developed and tested standard definitions of maternal near miss based on markers of organ dysfunction (i.e. survivors of organ dysfunction during pregnancy, childbirth or postpartum are classified as maternal near-miss cases). The World Health Organization Multi-country Survey on Maternal and Newborn Health (WHOMCS) characterised the severe maternal, perinatal and neonatal morbidity taking place in a worldwide network of health facilities using this approach (Abalos, *et al.* 2013). The study indicated that overall, 8542 (2.73%) women suffered from hypertensive disorders. Incidences of pre-eclampsia, eclampsia and chronic hypertension were 2.16%, 0.28% and 0.29%, respectively. Maternal near-miss cases were eight times more frequent in women with pre-eclampsia, and increased to up to 60 times more frequent in women with eclampsia, when compared with women without these conditions. In eclampsia, most of these potentially life-threatening conditions involved the central nervous system: coma or loss of consciousness lasting 12 hours or more; metabolic coma (loss of consciousness and the presence of glucose and ketoacids in the urine); stroke; or status epilepticus, uncontrollable fits or total paralysis. The study showed that Kenya's incidence of chronic hypertension, pre-eclampsia and eclampsia was 0.10%, 1.97%, and 0.32% respectively (Abalos, *et al.* 2013).

The study concluded that prompt recognition of hypertensive disorders in pregnancy, and treatment with the timely administration of blood products are crucial in the management of such life-threatening complications. The excessive mortality in relation to maternal near-miss cases found by the WHO in some settings may reflect inappropriate recognition of these indicators or inadequate or delayed management of associated complications. An accurate diagnosis and assessment of these clinical, laboratory and management indicators is essential for the development of specific plans for antenatal interventions and for the management of the delivery and postpartum periods, including prompt and appropriate referral to third-level facilities (Abalos, *et al.* 2013).

2.2 RESEARCH OBJECTIVES

2.2.1 Broad Objective:

To test the use of low-cost portable smartphone electrocardiographs in the electrocardiographic screening of the pregnant women attending Ante-natal Care services in Mwingi West and Mwingi Central Sub-Counties of Kitui County, Kenya

2.2.2 Specific Objectives:

a. Pilot the utility-testing of D-Heart among women attending the Ante-natal Care services at Thaananzau and Nyaani Dispensaries, in Mwingi West and Mwingi Central Sub-Counties through a cost effective analysis and user experience surveys.

b. Provide ECG report to all the women attending the studies during their visit at the dispensaries and Enable correct referral of patients in need of more specific screening and treatment in Mwingi West and Mwingi Central Sub-Counties

c. Correctly define the improvable points of the D-Heart screening procedure for the scale up of the low-cost portable smartphone electrocardiographs in electrocardiographic screening of the pregnant women in developing countries.

CHAPTER THREE: METHODOLOGY
3 METHODOLOGY

3.1.1 Study Area

The study will be carried out in Kitui County, which is is situated in the Eastern region of Kenya bordering Machakos and Makueni counties to the West, Tana River County to the East, Taita Taveta County to the South, and Embu and Tharaka-Nithi Counties to the North. The county is sub-divided into eight sub-counties, namely: Kitui Central, Kitui Rural, Kitui South, Kitui East, Kitui West, Mwingi Central, Mwingi North, and Mwingi West (Kitui, 2014). The county's population was 1,012,709 according to the Population and Household Census report of 2009 and was projected to grow to 1,108,515 by 2017. The population growth rate of the county at 2.1% is slightly lower than the national rate of 2.6% (KNBS, 2009).

The pilot study will target women of reproductive age (15 – 49 years). Specifically, the study will target expectant mothers attending Ante-natal Care services in Mwingi West and Mwingi Central, Kitui County.

3.1.2 Study Design

This pilot study will utilize a case report study design. Quantitative data will be collected on demographic data, anamnesis and ECG reading for expectant mothers attending Ante-natal Care services in Mwingi West and Mwingi Central, Kitui County.

3.2 SAMPLE SIZE DETERMINATION

The target population for the study is expectant women attending Ante-natal Care services in Mwingi West and Mwingi Central Sub-Counties. The sampling frame consist of the seven facilities covered under the Amref 'Putting African Mothers, Newborns and Children First' Project. Purposive sampling of two health facilities has been be undertaken, based on the D-heart and Amref partnership that stipulated two health facilities for a three-month pilot phase. The criteria for selection of the two facilities are outlined here-in and include: availability of electricity (power) connection for charging the devices, presence of health care worker, large coverage population to enable attainment of adequate case reports. In this case, Nyaani Dispensary in Mwingi Central and Thaananzau Dispensary in Mwingi West were sampled.

In determining the sample size, the estimated population was considered, estimated population of expectant women as per the KDHS 2014, as well as indicator on percentage of 4 ANC visits by women in the two Sub-Counties as per the Amref Mwingi Project's mid-term evaluation conducted in 2016. This is illustrated in table 2 below:

Table 2: Sampling size determination

Sub-county	Health Facilities supported by the Amref Project	Estimated population	Presence of Electricity/Power	Estimated population of Expectant women (3.9% fertility rate) (KNBS, 2015)	Women Attending 4 Ante-natal Care Visits (68%) (Amref, 2016)
Mwingi Central	Enziu	6551	No	255	173
	Yumbu	2526	Yes	98	66
	Nyaani	6301	Yes	245	166
Mwingi West	Kavuvuani	4897	No	190	129
	Thaana Nzau	5203	Yes	202	137
	Kakululo	6396	No	249	241
	Nzauni	5809	No	226	219

3.2.1 Sampling Technique

Census technique will be utilized to sample study respondents. All expectant mothers who will attend Ante-natal care clinic at Nyaani and Thaananzau dispensaries for three months from October, 2016 – December, 2016 will be sampled for the study.

3.2.2 Inclusion and Exclusion Criteria

Inclusion Criteria

All women of reproductive age obtaining Ante-natal clinic services at the sampled dispensaries will be included in the study.

Exclusion Criteria

All men and children will be excluded from the study. All women of reproductive age not accessing Ante-natal care services at the two sampled dispensaries will be excluded

3.3 DATA COLLECTION

Quantitative data will be collected during this pilot study. Data will include socio-demographic characteristics as well as data on anamnesis and ECG reading. In case of suspicious electrocardiographic findings, the pregnant women will be referred to the Mwingi Sub-County Referral hospital for further assessment, in order to ensure a high level care for the mother and to the foetus.

3.3.1 Training, Pre-testing and Quality Control

The tool developed and approved will be pre-tested at Yumbu dispensary, which is not within the study sites but meets all criteria similar to the sampled sites. The pre-testing will be aimed at checking appropriateness of the questions in answering the study questions on electrocardiographic screening of women.

The health care workers will thereafter be trained by D-heart and the Principle Investigator and Co-Investigators. This will be done in collaboration with the Sub-County Health Management Teams. The training will cover basic technique on the use of the electrocardiograph devices and will take three days.

To ensure data quality, the investigating team will be providing weekly technical support to the two facilities' health workers throughout the three month period, to ensure consistency in screening, data collection, and management of clients. In case of suspicious electrocardiographic findings, the pregnant women can be referred to the Mwingi Sub-County Referral hospital for further assessment, in order to ensure a high level care to herself and to the foetus

3.3.2 Data Management

Data will be managed as outlined in the partnership between D-heart and Amref. This includes:

- Photographic and multimedia report concerning at least one video and 8-10 pictures for each month of experimentation to describe the activities performed with Amref as a partner

- Weekly based service of tele-report of the ECG tracings acquired by the Health Workers during the testing and experimentation period. Feedback will be given the Health Workers on a weekly basis

3.4 ETHICAL CONSIDERATIONS

3.4.1 Confidentiality and Protection of participants

Information protection and confidentiality will be ensured through:

- Health workers will be trained on confidentiality of information, and in collaboration with the principal investigator (PI) will ensure that only authorized personnel have access to all materials and data collected and that any data disposal is done correctly through shredding.
- All information and data (both raw and cleaned) that will not be disposed but will be handed over to Amref Health Africa in Kenya Research office for appropriate storage as per ethical practice

Participants' protection and confidentiality will be ensured through:

- Participants will have to consent appropriately before information is obtained from them
- All personnel engaged in the pilot study will sign a confidentiality agreement form to ensure that participants' information is safeguarded.
- Conducting the screening and interviews in a private setting
- The report generated will not contain any participant's names or identifying information
- Under no circumstances will any identifying information on individual participants be made public.

3.4.2 Informed Consent

Prior to participation in the study, all participants will provide their written consent. A consent form for use in this process has been appended herein and contains direction for consent. Participants will be taken through the purpose of the study, its objectives and the methodology, and how the information from the evaluation will be used.

3.4.3 Risks and benefits

The risks associated with participation in the study are minimal and are limited to potential loss of privacy and breach of confidentiality. To minimize these risks, access to all information in

hard and soft versions will be granted to only authorized personnel. There will be no direct benefits to participants for participating in the study. However, through participation, participants will be contributing towards improving management of cardiovascular illnesses among pregnant women in Kenya and the information will assist in informing other similar programs.

3.4.4 Dissemination of Results

It is envisaged that the information collected will provide information about the effectiveness of the low cost electrocardiographs for electrocardiographic screening of pregnant women, and inform policy and programming on strategies for electrocardiographic screening of pregnant women and management of hypertension during pregnancy.

The findings of this three-month pilot study will be disseminated to key stakeholders including the Sub-County and County Health Management Team. Additionally, the two organizations intends to develop publications and scientific presentations for sharing in national and international forums.

3.4.5 Limitations the Study

In case of suspicious electrocardiographic findings, the pregnant women can only be referred to the Mwingi Sub-County Referral hospital for further assessment, in order to ensure a high level care to herself and to the foetus. Management and treatment of the condition will not be included in this study and training of health workers.

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MANAGEMENT AND ORGANIZATION OF THE STUDY

Researcher	**Key Qualifications**	**Key Role**
Evalin Karijo	Public Health Specialist; Global Executive MBA in Health Leadership and Management	Principle Investigator
Dr Niccole Maurizi	Medical Specialist	Technical Support in Data Management and Analysis
Roberta Rughetti	Research Specialist	Technical Support in Data Management and Analysis
Samuel Okumu	Public Health Specialist	Co-investigator; literature

Research Team (More information is available in attached CVs)

Table 3: Team Management

		review, data management
Peter Ofware	Social Scientist	Co-investigator; Technical Support

Task /Activity	Months in Weeks						Output
	Sept	Oct	Nov	Dec	Jan	Feb	
Protocol development							Research Protocol
Submission to ESRC							Research Protocol

TIME SCHEDULE AND ACTIVITIES

Table 4: Time Schedule and Activities

Revision of protocol and Approval by ESRC Training of health care workers							Health care workers trained on electrocardiographic screening
Screening and data collection							Data collected
Data submission and reporting							Data collected
Sharing findings with D-Heart and stakeholders							Information shared

ANNEXES

Annex 1: Data Collection Tool

AMREF DHEART
DATA COLLECTION S

Annex 2: D-heart and Amref Partnership Agreement

Partnership
Agreement D-Heart-A