Effectiveness of Early Child Development Multi-Media Communication on Caregiver and Community Health Worker Behaviors: Evaluation of the Malezi II Program

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Contents

ABSTRACT

Background/Rationale: A recent review on early child development (1) outlines evidence that the parent-child relationship, in particular responsive, sensitive care in the earliest years of life, is critical for all domains of child development, school achievement, and economic productivity in the adult years (2,3). Mass media communication campaigns for public health have also been shown to positively impact a wide range of child survival orientated parental health behaviors (4). Beyond radio campaigns, interventions at a health facility level have demonstrated that video job aids can be effective education tools across a wide range of health topics (5). The Government of Tanzania has shown a commitment to early child development through its policies which recognize that a child's right to quality health and basic social services is important for their survival, development, and protection.

The Conrad N. Hilton Foundation supports the Elizabeth Glaser Pediatric AIDS Foundation to implement a targeted early stimulation program called Malezi (*caring for young children* in Kiswahili) at selected facilities in Tabora region. This program integrates extended early child development (ECD) interventions into reproductive and child health (RCH) and HIV services for young children, adapting the UNICEF Care for Child Development (CCD) curriculum to Tanzania, in collaboration with the Aga Khan Foundation, UNICEF and the Ministry of Health Community Development, Gender, Elderly and Children (MOHCDGEC). A follow-on grant will expand Malezi I coverage of the CCD program implementation and introduce a mass media campaign and video job aids. The addition of radio messaging in Malezi II aims to promote positive perceptions and knowledge of ECD at the community level, and video job aids aim to further support and improve community health worker (CHW) education and counseling skills.

This protocol describes a two-year population-based study to take place in Tanzania evaluating the two Malezi interventions. These include a *minimal intervention package,* composed of radio messaging only **(MR)**, reaching all areas in Tabora, including those where the Malezi I program has not been established and the Malezi II *full intervention package,* composed of radio messaging, the introduction of short video job aids primarily for CHW use, and the Malezi I CCD program (**MRV-CCD**), implemented in Malezi program districts.

Objectives: Specific aims of the research project are to evaluate: 1) the effect of the Malezi II MR intervention on caregiver awareness of children's developmental needs; 2) the extent to which the Malezi II MRV-CCD intervention (radio messaging, video job aids, continued CCD program support) increases caregiver knowledge and practices as compared to a radio campaign alone (MR); and 3) the effect of Malezi II training and video job aids on the quality of CHW counseling support, provided in clinics and homes.

Methods: This study is a two-arm quasi-experimental pre-post evaluation design, comparing two interventions to establish their relative impact on caregiver knowledge and behaviors/practices among a cohort of caregivers of children 0-24 months at enrolment and under three years after a 9-month intervention exposure period. In addition, the quality of counseling support to caregivers, at health facilities and through home visits, will be assessed at baseline and endline in a cohort of CHWs recruited from the MRV-CCD full intervention communities. Caregivers of children age 24 months or less at enrolment (n=1214), and community health workers (n=123) working with selected study facilities will be enrolled in the study. The study will be conducted in catchment communities of selected health facilities in four districts in Tabora region (Nzega, Igunga, Kaliua, Uyui).

Policy Significance: Outcomes from this evaluation will inform decision makers in Tanzania about the feasibility and effectiveness of a health systems-based ECD intervention, augmented by radio communications and/or short video use.

Timeline and approximate budget: Two years (2019-2020); USD 580,000.

LIST OF ACRONYMS AND ABBREVIATIONS

CCD	Care for Child Development package
CHMT	Council Health Management Team
CHW	Community Health Worker
ECD	Early Child Development
EGPAF	Elizabeth Glaser Pediatric AIDS Foundation
EA	Enumeration Area (of the National Bureau of Statistics)
ES	Early Stimulation
HCW	Health Care Worker
LMIC	Low and Middle Income Countries
MOHCDGEC	Ministry of Health, Community Development, Gender, Elderly and Children
MNCH	Maternal Neonatal and Child Health
MR	Malezi II Radio intervention
MRV-CCD	Malezi II Radio, Video, CCD program intervention
NBS	National Bureau of Statistics
NCF	Nurturing Care Framework
NIMR	National Institute of Medical Research (Tanzania)
PMTCT	Prevention of Mother to Child Transmission (of HIV)
PTID	Participant Identification Number
RCH	Reproductive and Child Health
RHMT	Regional Health Management Team
SDG	Sustainable Development Goals
SSA	Sub-Saharan Africa

BACKGROUND

Child development is the "ordered progression of perceptual, motor, cognitive, language, socio-emotional, and self-regulation skills in children" (2). Children should be supported to grow and develop into healthy, productive, moral citizens, who contribute meaningfully to better societies for all. The inclusion of early child development (ECD) among the Sustainable Development Goals (SDG) (6,7) alongside global strategies such as the *'Survive, Thrive, and Transform'* goals of the Global Strategy for Women's, Children's and Adolescent Health, provide the impetus for governments in Africa to deliver interventions which improve the developmental outcomes of children (1,8).

Child development in sub-Saharan Africa

Nowhere is the need to advance child developmental outcomes more acute than in sub-Saharan Africa (SSA). The child population is growing fastest in the poorest nations. Poverty, disease burden, violence and gender inequality are widespread and access to health, education and social justice are limited. SSA bears a disproportionate burden of disease and children face substantial and cumulative threats to their human development and life chances (9).

The scale of the problem is enormous, with 2016 estimates suggesting that among the 249 million children at risk of poor development in all low and middle income countries (LMIC) the SSA region is reported to have the highest prevalence (>60%) of at-risk children. These high risk rates are attributed to a lack of nurturing care, poverty, malnutrition, and socioeconomic disadvantages (10). Compounding this, SSA also carries a disproportionate burden of HIV, accounting for more than 70% of the global burden of infection and AIDS related deaths (11,12).

Strategies for supporting early child development

Child development is known to be influenced by a myriad of biological, environmental and psychosocial risk factors in the parent and the child (9,13). Parental factors could be directly linked to the parent's behavior, cognition and emotions, or indirectly through a variety of familial and contextual stressors associated with parent psychological difficulties, including parenting difficulties, marital conflict, isolation, and poverty. The *Lancet* series of Perinatal Mental Health in 2014, and a similar systematic review of literature from LMIC illustrate that the parent-child relationship and the quality of the parenting environment are particularly influential pathways by which children's development is disturbed (13,14). The *Lancet* series on early child development outlines overwhelming scientific evidence that the parent-child relationship, in particular responsive, sensitive care in the earliest years of life, is critical for all domains of child development and to later school achievement and economic productivity in the adult years (1–3). Importantly, the quality of caregiving and the parent-child relationship has been shown to be modifiable in LMIC (15), making caregiving an important intervention target. There are several examples which have shown successful early life caregiving interventions in SSA settings (6,17–19). A systematic review of interventions with potential to improve child development in LMIC (20) has shown that standardized interventions aimed at supporting child development by providing training to caregivers on early stimulation and responsive care, such as the Care for Child Development (CCD) program, developed by the World Health Organization (WHO) and UNICEF, are successful in a variety of lower resource contexts (6,17) and may be highly suitable, with adaptation for Tanzania.

The Nurturing Care Framework

In conceptualizing implementation approaches by which interventions like CCD could be feasibly delivered, there is a growing understanding, as documented in the 2018 Nurturing Care Framework (21) that the integration of health, nutrition, responsive caregiving, safety and security, and early learning interventions into existing services, is important to maximize scalability (1,3,6,17,20). The use of multiple entry points, beyond the education sector, is critical to broadening the reach and impact of child development interventions. In SSA, the health sector specifically has a particularly important role to play given its regular interface and reach to children and caregivers during the first one thousand days from pregnancy to two years postnatal (6,21,22). How these integrated services will be feasibly implemented and taken to scale within Tanzania needs to be determined.

Globally, there is consensus that in-home support, task shifted to community health workers (CHW) is critical to increasing access (1,23), particularly were resources are low and in the early developmentally sensitive window, when children are less likely to access formal out-of-home support (such as ECD centers, crèches or preschool) (16,23). However, there remains a dearth of successful program examples of public sector led in-home services that integrate ECD with other maternal and child health services in East Africa and rigorous evaluations are needed.

Increasing efficiencies in large-scale delivery of caregiver interventions and mass media interventions

Systematic evidence from LMIC has shown that the more effective child development intervention programs are those with similar characteristics to Malezi I. This includes systematic training for CHWs using a structured and evidence-based curriculum, opportunities for parental practice with children with feedback, and a high frequency of contact (22).

Most mass media campaigns in LMIC have focused on parent behaviors which support child survival. A recent systematic review has shown that these campaigns can positively impact a wide range of child survival oriented parental health behaviors (4). In Africa, given the widespread utilization of radio, these approaches are seen as effective tools for disseminating health information and supporting health-promoting behaviors (24). These range from information on immunizations in Nigeria (25) to sexually transmitted diseases for secondary school students in Tanzania (26). In Tanzania, radio and television “edutainment” soap operas have also been shown to have strong behavioral effects on self-efficacy regarding family planning and use of contraception (27). Studies in Ethiopia found that the availability or possession of a radio was a predictor of insecticide treated nets ownership for malaria prevention, maternal and child health service utilization, and mothers’ knowledge on infant and young child feeding recommendations (28–30). Studies suggest that for media communication interventions to be effective they need to be delivered at sufficient intensity and scale (31).

While caregiver educational interventions using radio, television, video job aids and other digital health interventions have shown some potential, the effects for these information-based, parent-only interventions were relatively small (32). Nonetheless, it is plausible that child development messaging delivered through media outlets, may offer some advantages in increasing caregiver knowledge, and given its substantially lower resource intensity, its contribution warrants investigation in contexts like Tanzania where resources are particularly scarce.

Video job aids to increase quality of care in health workers

It is clear from the child development evidence base that quality is a key variable in determining the success of CHW led interventions (6,16,20). Beyond radio campaigns which aim to increase caregiver knowledge directly, interventions at a health facility level have demonstrated that video job aids can be effective education tools across a wide range of health topics (5). Several studies also point to the acceptability and feasibility of using videos as a communication strategy for health promotion, to reduce the intensity of demands placed on the interventionist, particularly in the context of task sharing. One pilot study in South Africa found that using tablets with teaching videos about HIV, alcohol, nutrition, and breastfeeding helped ease the workload of the health providers and engaged the broader community on topics intended for pregnant mothers and mothers of young children (33). A community-based intervention in Congo that used videos to educate over 60,000 people on Ebola was effective in improving knowledge, attitudes, and behaviors among a population with limited literacy (34). Evidence from radio and video use in Tanzania is limited, although videos have been used as effective training tools for identifying respiratory movements related to pneumonia (35) and educating school children on tapeworm infections (36).

Barriers and facilitators to child development in Tanzania

Tanzania has a high prevalence of children at risk of poor development, with 70% of children being considered at risk according to population-level estimates (10). Despite strong economic growth over the past decade, one-quarter of Tanzanians live in poverty (37). The literacy rate among those aged 15-49 was 63% among women and 66% among men in Tabora, substantially lower than the national estimates of 77% and 83% respectively (38). This is concerning because poverty and lower parental education are known to be associated with poor child development outcomes, most likely through sub-optimal caregiving capacities, limited early stimulation and impoverished educational environments (22). Only 47% of 5-year-old children in Tanzania were enrolled in pre-primary education in 2015, with children from poor households three times less likely to attend school than those in wealthier households (39). Census results for Tabora show little improvement primary school enrolment, only increasing from 52% in 2002 to 56% in 2012 (40).

The Government of Tanzania has shown a commitment to early child development through its policies which recognize that a child's right to quality health and basic social services is important for their survival, development, and protection. There is recognition that meeting such needs at scale is critical for the country's economic and social development. Currently, early child development (ECD) policy language and technical cadres exist in multiple government ministries (education, health, social welfare, and local governments). Government guidelines on early child development now appear in the educational policy in terms of mandatory public pre-primary education from 3 years of age. A draft early child development policy document is also being incorporated into a national child development policy (0-18 years) under the Ministry of Health, Community Development, Gender, Elderly and Children (MoHCDGEC). Furthermore, the Reproductive and Child Health of the Ministry unit issues guidance on early child development with respect to milestones and recommended early stimulation practices for infants/children 0-3 years of age.

Integration of Care for Child Development in the health sector in Tanzania: Boresha Afya and the Malezi I Program

In Tanzania, the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) provides support to both local government authorities and to health facilities having maternal, newborn and child health (MNCH) and/or HIV service delivery platforms. The USAID Boresha Afya program funds EGPAF to provide comprehensive service delivery support and technical assistance to HIV programs in relation to identification, linkage and retention of patients living with HIV, and improving the quality of services. Through this platform in five regions of Tanzania, and through the Malezi II program in Tabora, EGPAF engages with health providers at RCH and prevention of mother-to-child HIV transmission (PMTCT) clinics, HIV clinics, and community health cadres.

The Conrad N. Hilton Foundation supports EGPAF to implement a targeted early stimulation program at selected facilities in Tabora region to integrate extended ECD interventions into reproductive and child health (RCH) and HIV services for young children regardless of their HIV status. During the first phase (2016-17) of the Hilton-supported Malezi I Project (*caring for young children* in Kiswahili), EGPAF adapted and supported implementation of an early child development package into MNCH, PMTCT, and HIV care and treatment services at 47 EGPAF-supported facilities in three districts: Nzega, Igunga, and Tabora Municipal. The Malezi I intervention was adapted from the CCD curriculum in Tanzania by EGPAF in collaboration with Aga Khan Foundation, UNICEF and MOHCDGEC and translated into Kiswahili before being delivered to health care providers. The classroom and field based training was focused on building providers' counseling skills and understanding the concept of responsive caregiving. Specific topics included counseling caregivers on how to identify children's cues and respond to them appropriately; provide a safe and stimulating environment in the home; help caregivers understand if their children are developing well, recommend age appropriate play and communication activities, identify children with disabilities or developmental delays, provide and follow-up on referrals for specialized care as needed, and facilitate CCD group counseling. In addition to training, supervision and mentorship, the Malezi I program provided paper-based monitoring and evaluation (M&E) tools, and job aids from the CCD package to support group and home-based counseling, primarily done by CHWs, although health providers may also lead health education groups at the facility. The full Malezi I CCD intervention package included:

- ECD (CCD-based) knowledge and education/counseling skills training to facility-based and community health providers, including translated CCD-based manual with job aid
- Continuing supportive supervision to Malezi-supported facilities and CHWs
- M&E tools
- Toys (mostly home-made or safe household objects) and play mat for use in facility group sessions and during home visits
- Creative toy building training to support sustainable replenishment of toys for ECD sessions.

The Malezi I intervention was found to be feasible and acceptable as an integrated intervention within routine MNCH/PMTCT services. The internal Malezi I program evaluation, using a pre/post design, found substantial increases in caregiver knowledge and practices as reported through exit and household-based interviews. Knowledge among facility-based health providers and CHWs also increased significantly, and health providers reported increased access to ECD resources.

Given the existing and emerging evidence on potential strategies to better engage communities in supporting health promotion interventions, the Malezi II grant will expand Malezi I coverage of CCD program implementation to nearly double the number of facilities supported, and introduce additional components, specifically, a mass media campaign and video job aids. The addition of video job aids aims to further support and improve CHW education and counseling skills, and the addition of radio messaging aims to promote perceptions and knowledge of ECD, and possibly responsive caregiving behaviors, more broadly at the community level.

The Malezi II program, additional multi-media components, and theory of change model informing the evaluation

The Malezi II grant supports a continuation and expansion of the Malezi I CCD program described earlier, plus two additional interventions related to multi-media communications aimed at improving ECD perceptions, knowledge and responsive caregiver behaviors. These two approaches include a mass media communication strategy using radio messaging and the introduction of short video job aids, along with capacity building training for community health workers in the use of those job aids. This study is designed to evaluate the comparative effectiveness of the two interventions with respect to ECD perceptions, knowledge and responsive caregiving outcomes. In addition, by analyzing differences between baseline and endline within each study group (pre/post design), we will describe the effectiveness of radio messaging alone compared to no radio messaging, and the effectiveness of a fully integrated ECD intervention, including radio messaging, short video job aids and Malezi CCD program support compared to CCD program support without radio and short video support.

The Malezi II *minimal intervention package,* composed of radio messaging only **(MR)**, will reach all areas in Tabora, including those where the Malezi program has not been established. The Malezi II *full intervention package,* composed of radio messaging, the introduction of short video job aids primarily for CHW use, and the Malezi I CCD program (**MRV-CCD**), will be implemented in Malezi program districts, namely, Nzega, Igunga and Tabora Municipal.

The theory of change underlying the Malezi II full intervention package design draws on current evidence for CCD (6,20) and behavior change literature (41). It proposes that a combination of caregiver attitudes and norms (informed by access to information) will influence caregiver intentions to behavior, and ultimately their behaviors. Beyond providing caregivers with information to improve their knowledge, Malezi II supports caregiver capacity to make the desired changes to their caregiving behaviors through group learning (supported by video job aids) and practice and feedback (supported through home visiting).

While caregivers may develop an intention to change through program support, actual behavior change could be limited by a lack of skills (capacity) or not being in an appropriately enabling environment. We hypothesize that the addition of enhanced support from the CHW (short video job aids) and a more enabling environment from their family members and/or community (radio messaging) will lead to behavior change.

The theory of change is summarized in **Figure 1**.

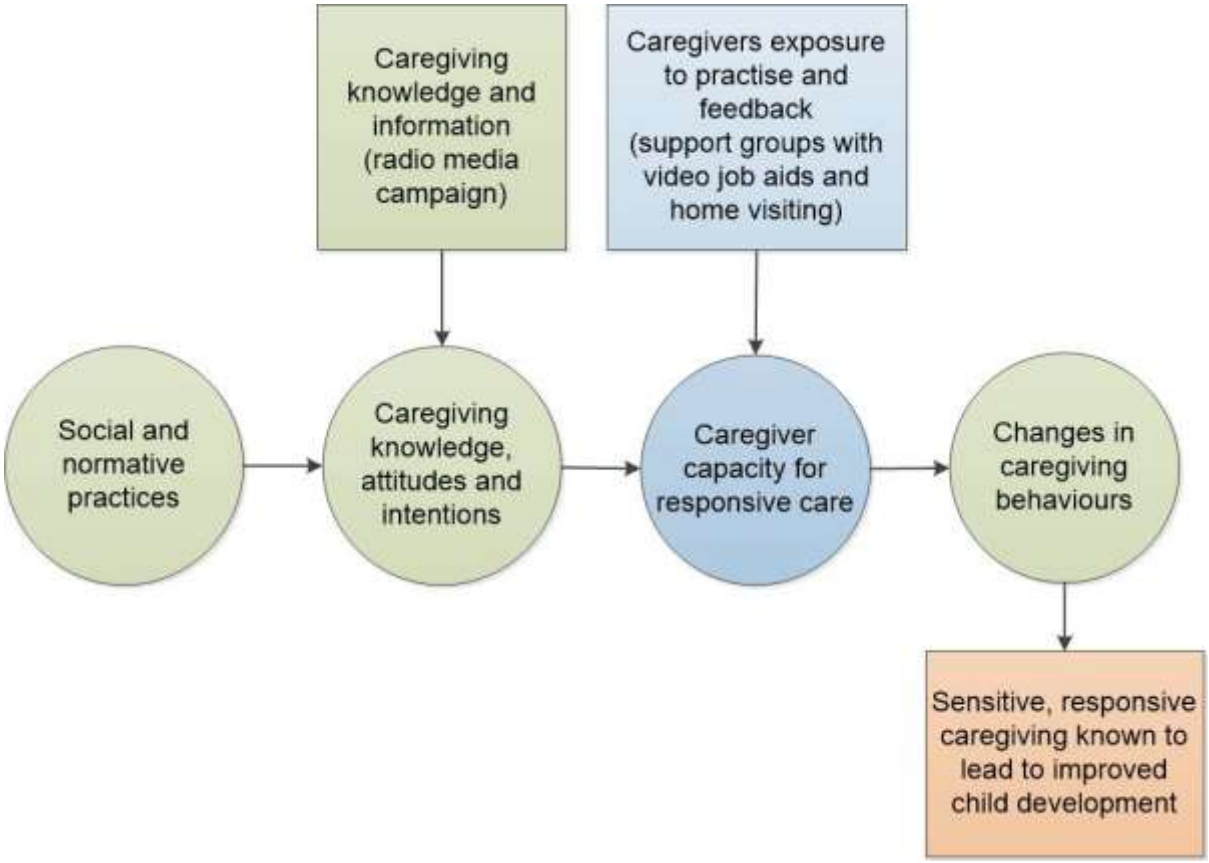

Figure 1. Overview of theory of change

This conceptual model of behavior change underpins the hypothesis that the combined intervention of facility-based ECD resources and messaging from providers, CHW group and individual counseling in the home and facilities, with support from video job aids, and community-targeted mass media radio ECD messaging will have a stronger impact on caregiving behaviors, compared to radio messaging alone. It targets two potential pathways to caregiving behavior change: direct educational messaging to increase knowledge; and opportunities for practice and feedback to increase capacity. However, this augmented Malezi II program model is resource intense. Thus, the research design examines the relative benefits of additional resources to change caregiver behaviors, compared to the benefits of radio messaging alone, which is potentially more efficient and scalable.

STUDY AIMS, OBJECTIVES AND RESEARCH QUESTIONS

Based upon the conceptual model described above, we have articulated research aims to derive specific and measureable objectives. These are presented below in terms of overall aims, specific objectives, and illustrative research questions, corresponding to each aim and objective.

Aims

1. Evaluate the effect of Malezi II radio (MR) messaging on caregiver awareness of children's developmental needs
2. Evaluate the extent to which the Malezi II full intervention (MRV-CCD: radio messaging, video job aids, continued CCD program support) increases caregiver knowledge and

practices as compared to a radio campaign alone (MR), using a quasi-experimental research design
3. Evaluate the effect of Malezi II training and video job aids on the quality of community health care worker counseling support, provided in clinics and home

Objectives

1. To determine caregiver radio listenership patterns at baseline, exposures to the ECD radio messaging nine months' post-intervention, and effect of radio exposure on caregiver ECD perceptions, knowledge and reported parenting practices, using pre-post structured interviews in a cohort of caregivers of children age 0-24 months at baseline, in study communities from each intervention arm.
2. To determine whether the Malezi II full intervention (MRV-CCD) significantly increases caregiver's knowledge and parenting behaviors/practices when compared to radio messaging alone, using a pre-post quasi-experimental evaluation design with structured interviews, in a cohort of caregivers of children age 0-24 months at baseline, in MRV-CCD and MR communities.
3. To determine whether the introduction of short video job aids (training, provision, supportive supervision) to the Malezi II CCD program improves the quality of counseling provided by the CHWs in the clinic and the home, using pre-post observation fidelity checklists for all CHWs working in the MRV-CCD communities.

Secondary Objectives

4. Describe community health worker perspectives with regard to the salience and relevance of the program to their work, barriers and facilitators to implementing the Malezi II program and experiences with use of the short videos as a job aid.
5. Describe caregiver perspectives on the support they receive from community health workers, the expected/perceived role of CHWs in their community, on the short videos, and on ECD services in the health facility.

Research Questions

- To what extent does the Malezi II radio messaging reach caregivers of young children?
- To what extent are caregiver ECD perceptions, knowledge and reported parenting practices changed after introduction of Malezi II radio messaging to their communities?
- Is there a relationship between reported listenership and/or message recall (dose) and caregiver ECD perceptions, knowledge and reported parenting practices?
- To what extent does exposure to the Malezi II full intervention (MRV-CCD: radio messaging, video job aids, continued CCD program support) improve caregiver knowledge and parenting practices?
- Does exposure to the Malezi II full intervention (MRV-CCD) improve caregiver knowledge and parenting practices significantly more than exposure to radio messaging alone (MR)?
- To what extent do the CHWs adhere to the Malezi II training with regard to use of the video job aids, delivery of complete and accurate ECD messages, and general quality of counseling support?
- Do the Malezi II video job aids improve the quality of CHW ECD counseling support given to caregivers in clinic and home settings?

METHODOLOGY

This study is a two-arm quasi-experimental pre-post evaluation design, comparing two interventions to establish their relative impact on caregiver knowledge and behaviors/practices among a cohort of caregivers of children 0-24 months at enrolment (baseline) and under three years after a 9-month

intervention exposure period (endline). In addition, the quality of counseling support to caregivers, at health facilities and through home visits, will be assessed at baseline and endline in a cohort of CHWs recruited from the MRV-CCD full intervention group. Figure 2a provides an overview of the research design for objectives 1 and 2. Figure 2b provides an overview of the research design for objective 3.

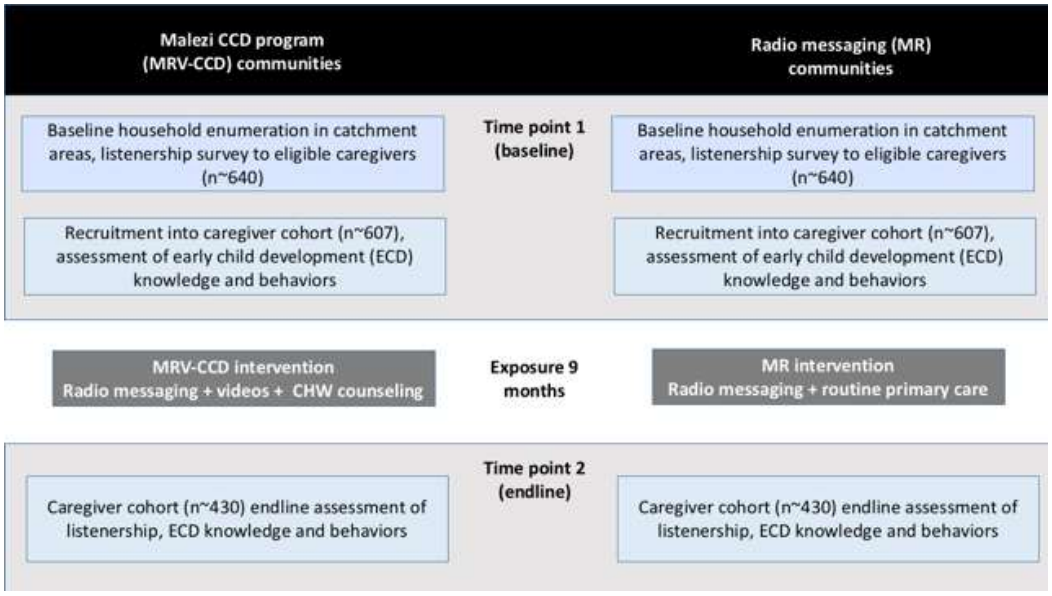

Figure 2a. Research design overview – community component

The study includes enumeration of all households in probability selected geographical units (national census enumeration areas) in catchment villages of selected health facilities, about 12-16 per intervention group. All households with resident caregivers of children 0-24 months of age will be eligible for recruitment into the caregiver cohort. Data collection includes two stages of recruitment/participation at baseline, whereby an eligible caregiver will complete a radio listenership survey during the household enumeration exercise, and will then be recruited into the caregiver cohort at a separate visit. Those consenting to the caregiver cohort will complete a detailed home-based caregiver survey at baseline and the same people will complete the listenership and caregiver surveys at endline. Table 1 provides an overview summary of data gathering activities.

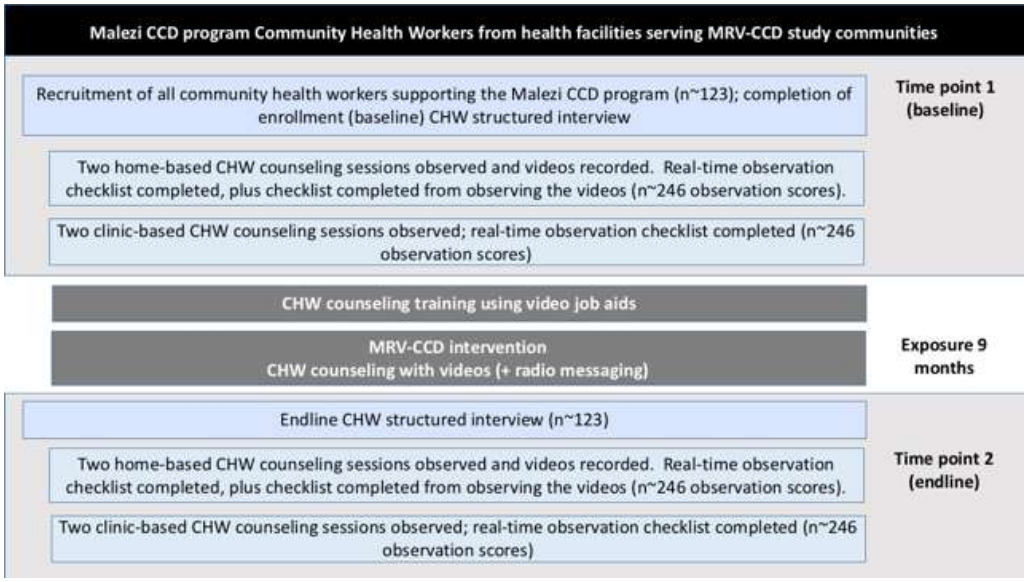

Figure 2b. Research design overview – community health worker component

Table 1. Data gathering activities

Abbreviated Objective	(1) Caregiver radio listenership patterns, exposures, and effect on caregiver ECD perceptions, knowledge and reported parenting practices nine months post-intervention	(2) Effect of Malezi II full intervention (MRV-CCD) on caregiver's knowledge and parenting behaviors/practices compared to MR intervention	(3) Effect of short video job aids on the quality of counseling provided by the CHW in the clinic and the home (4) CHW perspectives and experiences with use of the short videos as a job aid (5) Caregiver perspectives and experiences with CHWs, short videos, and ECD services in the health facility.
Design	Two-arm pre/post intervention cohort(s) design About 30 health facility catchment communities (1) 12-16 facilities – MR intervention (radio messaging only) (2) 12-16 facilities – MRV-CCD augmented intervention (radio, video job aids, CCD package)		Pre/post cohort, intervention MRV-CCD group only 12-16 health facility catchment communities selected for the Malezi II evaluation study in MRV-CCD group Qualitative component with CHW FGDs and caregiver IDIs
Study Activities	▪ Baseline enumeration of households to identify eligible caregivers and administer listenership survey (1-2 months, baseline) ▪ Recruitment into caregiver cohort, and baseline survey administration in the home (2-3 months, baseline) ▪ Conduct CHW training to use short videos (1 month) ▪ Intervention exposure: short video use and radio messaging (9 months) ▪ Caregiver cohort endline data collection (2-3 months)		▪ Recruitment into CHW cohort, baseline questionnaire ▪ Observations conducted in clinic and home (2-3 months, baseline) ▪ Conduct CHW training to use short videos (1 month) ▪ Intervention exposure: short video use (9 months) ▪ FGDs with subset of CHW and IDIs with caregivers during period of intervention exposure ▪ CHW endline data collection (2-3 months)

Abbreviated Objective	(1) Caregiver radio listenership patterns, exposures, and effect on caregiver ECD perceptions, knowledge and reported parenting practices nine months post-intervention	(2) Effect of Malezi II full intervention (MRV-CCD) on caregiver's knowledge and parenting behaviors/practices compared to MR intervention	(3) Effect of short video job aids on the quality of counseling provided by the CHW in the clinic and the home (4) CHW perspectives and experiences with use of the short videos as a job aid (5) Caregiver perspectives and experiences with CHWs, short videos, and ECD services in the health facility.
Data sources / methods	**Enumeration/enrolment questionnaire:** ▪ Background / SES ▪ Listenership survey (dose) ▪ Basic caregiver knowledge/attitudes/practices (awareness of developmental needs) Administered by data collectors at enumeration and endline in community	**Caregiver questionnaire:** ▪ In-depth caregiver capacity and psychosocial status (stress, anxiety, depression, IQ) ▪ Parenting attitudes (discipline), practices (borrow RISE, MICS, other) ▪ CHW exposure ▪ Video exposure and listenership at endline Administered by research associates in home (by appointment after enumeration)	**CHW questionnaire:** ▪ Background/SES ▪ CHW practices, attitudes and capacity (IQ) ▪ Psychosocial status (anxiety, depression) ▪ Listenership survey ▪ Use of and attitudes toward videos at endline **CHW observation checklists:** ▪ Checklist for home (2 visits at baseline; 2 visits at endline) ▪ Checklist for clinic (2 assessments at baseline and 2 at endline) Completed by research associates in home and clinic **FGDs/IDIs using qualitative guides**

Intervention Description

In all study districts, study participants will receive services according to the national standard of primary under-5 health care. This encompasses MNCH/PMTCT clinical care, routine immunizations, and identification and referral of health and development problems to the district hospital, and if necessary, referral to the regional level (secondary) or a zonal hospital (tertiary). In addition, national guidelines authorize community cadres to support primary health care messaging, patient and community education and mobilization to seek health services, and individual referrals from community to facility, largely issued during home visiting of pregnant women, mothers of young children (under 5), and HIV-positive individuals. Community cadre guidelines for MNCH-trained community health workers stipulate that pregnant women should receive four visits, mothers of children under one year should receive seven visits, and mothers of children 1-4 should receive quarterly home visits. A designated MNCH health provider at facility will supervise CHWs assigned to that facility, and is expected to provide periodic mentoring support to the CHWs and to hold monthly meetings at the health facility where CHWs compile and submit monthly reports, share experiences, and challenges.

In addition to this national standard of care, two interventions will be delivered as part of this evaluation (Table 2). The first intervention introduces ECD radio messaging in Tabora, targeting radio stations that are most likely to reach communities in all study areas (Nzega, Igunga, Kaliua, Uyui). The second intervention introduces short video job aids and training of CHWs in use of those job aids during individual counseling of caregivers at home visits and group counseling of caregivers in facilities, in addition to the radio messaging component. Furthermore, this second intervention package will also be implemented in areas where the Malezi I CCD program was established in 2016, and have received continuous support and monitoring since then from the Malezi program team in collaboration with local government authorities as part of routine supportive supervision to health services.

The radio messaging in both intervention groups, and the short videos in the second intervention group (only) will be introduced after the baseline assessment of the caregiver cohort. The exposure period for the two interventions, as described in Table 2, will be for nine months, followed by the endline assessment of caregivers.

Table 2. Description of intervention packages in two study arms

Intervention group	Description and expected exposure (dose)
Malezi II minimum package **Radio (MR)**	**Radio messaging spots** Dose: Up to 35-40 different messages, 3 stations aired on (2 regional, 1 national), about 10 times per day; 7 days per week airing frequency; 9 months duration of exposure ▪ Caregiver exposure to radio messaging during 9-month period: currently unknown, but estimated at 50% of caregivers hearing about 7 messages/week.
Malezi II full package **Radio, Video Job Aids, CCD program (MRV-CCD)**	**Radio messaging spots** ▪ Same as MR group

MRV-CCD	**Short video ECD job aids (with training)** Five short ECD mobile films (videos) of 3-5 minutes each will feature a mixture of real-life testimonies and scripted interactions between health workers and caregivers, and demonstrations of caregivers stimulating their young child. Each video will show a range of age-appropriate ECD practices that encourage child development (play; communication; positive caregiver-child interaction; safe/stimulating environment; positive discipline), illustrating skills and providing knowledge. All videos will have some cross-cutting content, emphasizing the general benefits of ECD activities during the early years, and one video will be devoted exclusively to cross-cutting parental guidance on developmental milestones and benefits of applying ECD practices. Four videos will target specific age groups (0-5, 6-11, 12-23, >=24 months). Caregiver exposure to group counseling at clinic is estimated to be 2-4 sessions in a 9-month period Caregiver exposure to individual counseling at home is estimated to be 3-6 sessions in a 9-month period
MRV-CCD	**Malezi I CCD program established (2016-17), with continuing technical and M&E supervision** ▪ ECD (CCD-based) knowledge and education/counseling skills training (4 days didactic and practice) to facility-based and community health providers, including translated CCD-based manual with job aid ▪ M&E tools and refresher training ▪ Continuing joint quarterly supportive supervision to Malezi-supported facilities and CHWs with government health authorities ▪ Creative toy building training to support sustainable replenishment of toys for ECD sessions ▪ Toys (mostly home-made or safe household objects) and play mat for use in facility group sessions and home visits ▪ Materials for CHW work in facilities and homes: o CCD participants' manual o CCD counseling card or new developed Flipbook which is a pictorial modified CCD counseling card o A bag of age appropriate play materials

The methodologies of each intervention arm have been tested independently (although not in a combined package) in high income countries and in some LMIC, showing varying degrees of effectiveness in changing caregiving behaviors (16). This research is therefore not an efficacy study, but instead tests the real world effectiveness of the additional value added from multi-media interventions. The Malezi Radio (MR) intervention group will assess the effectiveness of a *mass media communications strategy* targeting caregivers in communities, without having built the capacity of the health care system to reinforce ECD messaging and responsive caregiving skills. The Malezi Radio, Video and CCD (MRV-CCD) intervention group will assess the effectiveness of *adding mass media communication and CHW-capacity to use short ECD video job aids* in the context of a health care system with an established CCD program.

Location

The research study will be implemented in four selected districts of Tabora region. Recruitment of MRV-CCD intervention participants will take place in Malezi health facility catchment areas of Nzega and Igunga districts, while recruitment of the MR intervention participants will be done in districts outside of the Malezi program areas, Kaliua and Uyui districts.

Figure 3. Tabora Region and Districts

The Tabora region is home to a predominantly rural (87%) population, located centrally among 31 regions in Tanzania. Most economic activity in Tabora is agricultural (40). In Tanzania, about 8 in 10 adults are literate (77% of women and 83% of men), with about half having completed primary education, and 23% of women and 28% men having secondary or higher education (38). Currently, there is no school enrollment disparity between girls and boys. The Malezi project is implemented in three of Tabora's seven districts: Nzega, Igunga and Tabora Municipal.

Study Population

There are two populations in this study: Caregivers and community health workers. A caregiver is defined as someone who lives in the household, is recognized by others in the family/community as the child's parent or guardian, and is responsible for the child's eating and sleeping on most days of the week.

Eligibility criteria for caregivers are:

- Caregiver to a child aged 0-24 months (the *index child*) at time of recruitment
- Resident in enumerated household and intending to remain resident in the same village/community for at least one year*
- Willingness to be home-visited by a CHW
- Age 18 years or older
- Able to understand and willing to provide informed consent

* Only one caregiver per household will be eligible to participate. In case there is more than one present at the time of enumeration, the caregiver of the youngest child will be selected.

Exclusion criteria for caregivers are:

- Index child has an anomaly (congenital) or other disability identifiable at recruitment
- Caregiver impairment of hearing, sight or speaking
- Working as a CHW or medical provider

In the Tanzanian setting, CHWs are defined as "female and /or male individuals chosen by the community and trained to address health issues of individuals and communities in their respective localities, working in close relationship with health facilities." CHWs work on a volunteer basis, receiving a small stipend for their efforts, and are supervised by a facility-based health provider.

Eligibility criteria for CHWs are:

- Assigned to a Malezi II study health facility/catchment community
- Working as a Malezi II project CHW (i.e. attended Malezi (I or II) training, or capacitated for Malezi II project through on-job training and mentoring)
- Able to understand and willing to provide consent

There are no exclusion criteria for CHWs.

Sample Size Calculations

The outcome parameters used for sample size calculations for objectives 1 and 2 are estimated from the Malezi I program evaluation baseline data (before introduction of CCD program), comparable to what we would expect in the MR intervention group, who have not been exposed to any CCD intervention. From 24-29% of caregivers reported having a local or shop toy in the home, 22% reported singing to the child in the past month, and 7-13% reported reading or writing with the child in the past week.

Objective 1: To determine caregiver radio listenership patterns at baseline, and exposures to the ECD radio messaging nine months' post-intervention, and effect of radio exposure on caregiver ECD perceptions, knowledge and reported parenting practices, using pre-post surveys in a cohort of caregivers of children 0-24 months of age at baseline, in study communities from each intervention arm.

A sample size of 593 enrolled in the MR intervention group will provide 80% to detect a 5% or greater change from baseline (10%) to endline (15%) in the MR intervention group, taking into account 15% LTFU, design effect of 1.2, and estimated correlation of 0.4 between respondents at baseline and endline (Table 3). This sample size will provide even greater power to detect a 10% difference if baseline estimates are higher than 10%.

Table 3. Sample size estimation* parameters, MR group, caregiver cohort, pre-post

	Prevalence of key outcome			Power	Sample size	Adjusted Sample size (15% LTFU, DE 1.2)
Arm	**Baseline**	**Endline**	**Expected Change**			
MR (Malezi radio)	10%	15%	5%	80%	420	593
	20%	30%	10%	99%	419	592
	25%	35%	10%	98%	411	580

*STATA 14 paired proportions large-sample McNemar's test at 5% level significance.

Objective 2: To determine whether the Malezi II full intervention (MRV-CCD) significantly increases caregiver's knowledge and parenting behaviors/practices when compared to radio messaging alone, using a pre-post quasi-experimental evaluation design in a cohort of caregivers of children 0-24 months of age at baseline, in MRV-CCD and MR communities.

The change between baseline and endline in the Malezi I evaluation for the above-mentioned indicators ranged from 10-30% after introduction of the Malezi I CCD program. With the introduction of radio messaging only, we estimate a 5-10% effect size, and about a 20-30% effect size in the full intervention (MRV-CCD) group (Table 4).

We estimate that a sample size of n=430 caregivers per intervention group will provide 90% power to detect a 15% "difference-in-differences" between the MR and MRV-CCD intervention groups at endline, and >80% power to detect a 5% change in the MR intervention group, and a 20% change in the MRV-CCD intervention group between baseline and endline, at a level of 5% significance. Taking into account a 15% non-retention rate and a design effect of 1.2, we will aim to enroll 1214 into the caregiver cohort or n=607 in each intervention group.

Table 4. Sample size estimation* parameters, MR compared to MRV-CCD groups, caregiver cohort, pre-post and differences-in-differences

	Prevalence of key outcome			Power	Sample size	Adjusted Sample size (15% LTFU, DE 1.2)
Arm	**Baseline**	**Endline**	**Expected Change**			
MR (Malezi radio)	10%	15%	5%	81%	430	607
MRV-CCCD (Malezi radio + radio + CCD program)	25%	45%	20%	>99%	430	607
Difference	15%	30%	15%	90%	860	1214

*Sample Size and Power estimated by a simulation of the DID Analysis using R Software Package.

Objective 3. To determine whether the introduction of short video job aids (training, provision, supportive supervision) to the Malezi II CCD program improves the quality of counseling provided by the CHW in the clinic and the home, using pre-post observation fidelity checklists for all CHWs working in the MRV-CCD communities.

The Malezi I evaluation assessed CHW-reported time spent in the home providing ECD messages to pregnant women or caregivers of children under 5 at baseline (14-17%) and endline (64-74%). While the change was substantial, we estimate that the actual CHW counseling skills would be lower using an observation checklist compared to CHW self-reported behaviors. We conservatively estimate that CHWs in the MRV-CCD intervention group, already trained in the Malezi I CCD program, will score at 50% on the baseline observation checklists in this evaluation, increasing 15-20% after introduction and capacity building in using the short videos.

Table 5 shows that a sample size of 123 CHWs will achieve 80% power to detect a 15% change between baseline and endline in CHW quality of counseling checklist score, taking into account a correlation of 0.4 between measures, a 5% non-retention rate and a design effect of 1.1.

Table 5. Sample size estimation* parameters, MRV-CCD CHW cohort, pre-post

	Prevalence of key outcome			Power	Sample size	Adjusted Sample size (5% LTFU, DE 1.1)
Arm	**Baseline**	**Endline**	**Expected Change**			
MRV-CCD (Malezi radio + radio + CCD program)	30%	45%	15%	80%	102	118
	50%	65%			106	123
	70%	85%			78	90

*STATA 14 paired proportions large-sample McNemar's test at 5% level significance.

Selection Criteria for Study Communities

The study will be implemented in probability selected geographic areas of the catchment villages surrounding selected health facilities in four districts of Tabora region. The health facilities will be purposefully selected, including the district hospital in each of the four districts. Each primary health facility has clearly designated villages assigned to that facility (about 3-7), and each village has recognized boundaries, administrative units and census enumeration areas (EA), defined by the National Bureau of Statistics (NBS). Further details on sampling EA units are described later in this protocol. District hospitals do not have village catchments because they are secondary level facilities, but up to about 7 villages immediately surrounding the district hospital will be included in the sampling frame.

All facilities will meet the following eligibility criteria at baseline:

1. Accessible by road in all seasons
2. Has at least 3 CHWs and sufficient health provider staff to maintain MNCH/PMTCT clinic as expected (2-5 days per week)

The MRV-CCD and MR communities each have additional recruitment criteria.

MRV-CCD catchment communities should also:

- Be located in Nzega or Igunga districts
    - Exclusion: Malezi CCD-program supported facilities in Tabora Municipal, because there are no comparably urban facilities in non-Malezi districts.

MR facility catchment communities should also:

- Be located in Kaliua or Uyui
- Have new antenatal care attendees in the past year comparable to facilities in MRV-CCD communities (within about 25% variance).

Given the small cluster size, it was not possible to randomly allocate sites to intervention groups.

Sampling within Study Communities

Study communities are defined as the villages within the catchment area of the selected health facilities (n~30). The NBS EA census maps, estimating the total number of households in that EA as of the last census (2012) will constitute the sampling frame. The sampling unit will be the EA, and the sampling approach will use probability proportional to size (PPS). This will result in the final selection of EAs being statistically representative of the total population within selected study communities of each study district.

EAs average about 50 households, and do not overlap with other recognized administrative units (ward, village, hamlet, street), but their area and population size could vary from 20-100 households, and household size varies as well. The most recent census showed 19% of rural households had children under 5 years, and that Tabora averaged six persons per household. Since this evaluation targets caregivers of children 0-24 months of age at the time of recruitment, that means that an estimated 7.6% of households would be considered eligible ([19/5]*2). Thus a sample of about 250-300 EAs will be selected, using the estimate of 8% of households being eligible. Then, recruitment rates will be monitored to know whether additional EAs will be needed or not. In case they are needed, a second sampling also using PPS will be done, and all households in the second-sample EAs will be visited. In case too many EAs are sampled, and our expected sample size would be far exceeded by including all sample EAs, targets by ward will be calculated (proportional to expected sample size), and once the target has been reached within a ward, no additional EAs will be included for that ward. However, once an EA is "opened," all households in that EA should be enumerated, even if the target is then exceeded for that ward.

Recruitment into the Caregiver Cohort

Recruitment into the caregiver cohort will take place in two stages, whereby potentially eligible caregivers are identified through household enumeration, screened for study eligibility, and invited to verbally consent to participate in the listenership survey (stage I). On another day during the baseline data collection period, all eligible and participating caregivers will be revisited for re-screening, informed consent, enrolment into the caregiver cohort, and full baseline survey administration (stage II). We expect less than 5% loss between recruitment into in stage I

(listenership) and stage II (caregiver cohort). However, based on study methodology for complete enumeration of every "opened" enumeration area, it is possible that we will complete more than the expected number of listenership surveys in some wards. Where the number of listenership surveys completed is more than 10% greater than the ward's target for cohort enrollment, selection of listenership participants for caregiver recruitment in that ward will be made using systematic random sampling. Those who participate in stage I only at baseline but are not selected for recruitment into the caregiver cohort, will not be continued in the study, and will therefore not be revisited for the endline listenership survey.

Data collectors with at least secondary or higher education, and trained in enumeration, eligibility determination, verbal consent and listenership survey administration will conduct stage I study procedures. Research Associates (RAs) with at least post-secondary or higher education, and trained in eligibility determination, written consent procedures, and the full caregiver survey will conduct stage II study procedures.

Stage I: Enumeration of households and caregiver listenership survey

Data collectors (enumerators) will be escorted by local leaders to facilitate community entry, complete listing within the EA boundary, and household introductions. All households within the selected EAs will be enumerated and classified as an eligible household for study recruitment if at least one caregiver of a child 0-24 months of age at the time of the enumeration visit resides in that household with the child.

Enumeration is defined as the process of identifying structures that are households (as opposed to vacant or commercial buildings), assigning a unique number to each household, and determining the study eligibility status of each household. After appropriate introductions, enumerators will ask to speak to an adult (>18 years) in the household, and ask how many people live in the household and whether the household includes any children "age 2 or younger" and will record the answer. If there are no young children reported, the household will be documented as ineligible and no further information collected. If there are young children in the household, a complete listing of any child 0-24 months of age, by first name and date of birth (or approximate age), will be collected. A complete listing of children "age 2 or younger" is done to ensure that no child 0-24 months is missed, as it will allow for further screening of potentially eligible caregivers by verifying exact age using dates of birth as reported by caregivers.

Household classification outcomes of enumeration are:

1. Eligible and willing to participate
    - Caregiver-verified child 0-24 months of age lives in household
2. Potentially eligible
    - Neighbor or other household resident reports child(ren) under 2 live in household, but listing not completed and/or caregiver verification not done
3. Potentially eligible, refused
    - Household informant refused participation at household level
4. Eligible, refused
    - Caregiver-verified child 0-24 months lives in household, but caregiver refused participation
5. Not eligible
    - No child 0-24 months lives in household

6. Unknown
    - No knowledge of household residents after >=2 attempted visits (vacant, absent)

Caregiver participation outcomes from households classified as *eligible and willing to participate* (1) are:

- Verbally consented, completed listenership, accepted referral for recruitment into caregiver cohort
- Verbally consented, completed listenership, refused referral for recruitment into caregiver cohort
- Refused listenership (and therefore not referred for recruitment into caregiver cohort)

A household is defined as any structure where one or more people eat and sleep. Vacant households will be enumerated based on information provided by a neighbor or other community member (local leader). There could be several "households" in a family compound, if they are separated by their physical structure.

Selection of caregivers for the listenership survey will be done using the listing of children, age 0-24 months, in the household. The enumerator will ask to speak with caregivers of all listed children in order to identify only those children who are verified as 0-24 months years, by birth date, or caregiver reported age. If the household has more than one caregiver of children with verified ages 0-24 months years, the caregiver of the youngest child will be selected for participation. In case the caregiver with the youngest child is not present at the time of enumeration, another eligible caregiver will be selected. If no caregiver of listed children is available at the time of enumeration, the enumerator may return at a later time or another day to complete the enumeration visit.

Verbal consent will be obtained before administering the listenership survey and collection of contact details for stage II recruitment into the study. During the verbal consent process, the study will be described, and respondents will be asked permission to be re-contacted by a RA for further discussion about study participation (i.e. written consent and baseline survey). Household address, name and phone contacts (if available) will be documented by the enumerator and shared with the research associate for stage II recruitment.

Stage II: Caregiver cohort enrolment and follow-up

Consenting caregivers at stage I may be revisited by a RA, by appointment or directly through a home visit (if no appointment could be made by phone). After a brief study re-introduction, the RA will request to come inside the house without the escort and will complete the recruitment procedures in a private setting. Recruitment procedures entail eligibility re-screening, written informed consent, and documentation of enrolment. After enrolment, the baseline caregiver survey will be administered that day or another date/time, as agreed.

Data Collection: Caregiver Cohort

Both survey instruments described below will be programmed onto tablets for offline electronic data collection, with pre-programmed skip patterns and synchronization to a server as soon as the tablet's data access is enabled. This will allow for close monitoring of data collected in real time, and identification of any systematic errors or weaknesses in specific questions or sections that may

require clarification or re-training of research associates. All interviews should be done in a private room or location; the caregiver's young child(ren) may be present.

The enumeration listing will require about 5-10 minutes to complete, and will include documentation of children in the household 0-24 months, by date of birth, age, and first name. Household ID number and location coordinates, and other details describing location will also be documented.

The screening form will require about 5-10 minutes to complete, and will include documentation of all inclusion and exclusion criteria, household identification details, and confirmation by the data collector that the respondent provided informed verbal consent for participation.

The locator form will require about 5-10 minute to complete, and will include documentation of the household's location and description, and the caregiver's contact details (phone numbers), and preferred times/days to be re-contacted for stage II participation.

The listenership survey will require 15-30 minutes to complete, and will include questions about the household's socio-economic status (assets, wall/roof materials) and the informant's demographics (age, sex, position in household in relation to the child, employment, followed by questions about their exposure to radio communication, and recall of health education messages (including ECD-related) with respect to content, and source. Most study questions on this survey instrument have been used previously in Tanzania by this team or other researchers.

The caregiver survey will require about 60 minutes, and include questions as follows:

- Child characteristics (registration status, feeding)
- Baseline exposure to CHW home visits, child health, health care seeking
- ECD and early stimulation knowledge and practices (including discipline) – excerpted from UNICEF's MICS6* tool (42,43) and Stellenbosch University's RISE tool designed for standardized ECD/CCD program monitoring and evaluation
- Depression, anxiety, parenting stress, and cognitive ability (non-verbal IQ)
- Household environment (safety, play, shared caretaking)
- Exposure to Malezi program videos and radio messaging (at endline only)

Outcomes and Measures: Caregiver Cohort

Primary outcomes of caregiving behaviors/practices are:

- Caregiver knowledge: Reported knowledge about ECD and perceived importance of early stimulation
- Caregiver behaviors/practices: Reported responsiveness and discipline practices
- Child stimulation practices: Reported early stimulation practices, such as play, communication, teaching, access to education materials

Secondary outcomes are:

- Child environment: Reported risk and safety measures/practices, observed risks in the household environment
- Acceptability of videos: Caregiver perceptions of ECD videos (e.g., culturally acceptable, useful)

Other measures included as potential confounders or covariates are:

- Caregiver cognition: Evidence suggests that maternal intelligence may moderate the intervention effects (44).
- Parenting stress: Parenting stress, parent-child interactions, perception of child behaviors. There is literature to suggest that parenting stress is prevalent in Africa (45) and is strongly associated with child neglect and lower quality parenting environments (46).
- Caregiver depression: Evidence suggests that depression may reduce the quality of caregiving (14).

The following standardized assessments are included:

IQ - Ravens Standard Progressive Matrix (Ravens): Maternal cognition will be measured using the Raven's Standard Progressive Matrices (often referred to simply as Raven's Matrices) (47). It is the most common test administered to groups ranging from 5-year-olds to the elderly and has been used widely in Sub-Saharan Africa (48). It is a non-verbal assessment, making it culturally sensitive, and takes between 12-15 minutes to administer, dependent on caregiver capacity. It is used to measure abstract reasoning, with the score being regarded as a non-verbal estimate of intelligence.

The measure includes 60 questions, and is presented as a series of 2-dimensional pattern-matching matrices in which 1 small section is missing. Participants are asked to choose from 6 options the one that best fits the missing section. The items become progressively more difficult, and the assessment is stopped when the participant gives 3 consecutive incorrect answers.

The raw scores from the Ravens assessment will be calculated by totaling the number of correct answers given. These continuous raw scores will be used as an indication of general cognition given that tables establishing norms for the Tanzanian adult population are not available. Raw scores will be tested for normal distribution, and a midpoint continuous score can be used as a cut-off for low and high cognition within the group.

Caregiver stress and the quality of the parent-child relationship - Parenting Stress Index (PSI-36): The PSI is a widely used robust measure of three parenting related domains: Parental distress, parent-child relationship dysfunction (e.g. quality of relationship), and the extent to which the caregiver perceives the child is difficult (49). The scale is composed of 36 statements (12 per sub-scale domain) which are scored 1 (strongly disagree) to 5 (strongly agree), and can be summed to reflect the total score for each domain. A defensive responding score can also be calculated to determine social desirability biases.

To determine parenting stress, items are scored into each of the 3 subscales, with each subscale score ranging from 12-60. The PSI-36 Total Stress Score is a composite score of the three subscales (scores range 36-180) with higher scores indicating higher parental stress (50).

Caregiver mental health, depression - 9-item depression/anxiety scales, PHQ-9 and GAD-7: The 9-item Patient Health Questionnaire tool has been widely used in resource limited settings, and recently validated in a Tanzanian primary care population, showing 78% sensitivity and 87% specificity in detecting depression when compared to a gold-standard psychiatric assessment (51). The items are scored on a 4-point scale, from 0-3, and a cut-off score of 9 was determined to be optimal in classifying depressive symptoms, though a continuous score could also be used.

The General Anxiety Scale of the Patient Health Questionnaire, measures the seven criteria of anxiety in the Diagnostic and Statistical Manual of Mental Disorders (52). These 7 items can establish provisional anxiety diagnosis and assess symptom severity. A systematic review and meta-analysis of both the PHQ9 and GAD7 (53) found that the GAD-7 has good operating characteristics for detecting generalized anxiety, panic, social anxiety and post-traumatic stress disorder. The GAD-7 has been used in LMIC settings (54,55), with HIV infected populations (56,57) and in South Africa (58).

Caregiver behaviors/practices will be measured using the UNICEF Multiple Indicator Cluster Survey (MICS): MICS is a widely validated survey used in over 100 countries over the past two decades and had been used in large-scale surveys in 27 African countries. The data collection will be limited to relevant sub-sections of the MICS -- Early Child Development, Child Discipline, and selected items related to birth registration, child feeding, and health seeking/utilization (42,43).

Recruitment into the CHW Cohort (MRV-CCD Group)

CHWs will be recruited through the facility they are attached to in the 12-16 MRV-CCD intervention group facilities only in Nzega or Igunga districts. Research associates will liaise with the nurse in-charge of the reproductive health clinics to know the day/time that CHWs come to the clinic for work or reporting responsibilities. The research associate will describe the study to the CHWs in a group or individually, and then obtain informed consent in a private meeting.

Inclusion criteria are:

- Assigned to one of the selected MRC-CCD intervention group facilities and catchment communities
- Working as a Malezi II project CHW*
- Able and willing to provide informed consent

** Attended Malezi I or II training, or capacitated for Malezi II project through on-job training and mentoring*

- There are no exclusion criteria.

Sampling for Observed Sessions

Facility group education sessions will be selected by convenience, and will be completed largely consecutively, as research associates are able to organize travel to all selected facilities, with approvals from and in coordination with District authorities and nurse in-charge of each facility. The study coordinator will monitor all completed facility observations and as data collection progresses and fewer CHWs at selected sites have not yet completed their observations, the supervisor will actively schedule site visits in collaboration with the nurse-supervisor so that duty rosters are shared, or even modified as needed to accommodate the data collection schedule.

Households for observation of CHW counseling to caregivers will be consecutively recruited from the enrolled caregiver cohort in the MRV-CCD intervention group. As caregivers are enrolled, their household location will coincide with a particular CHWs' catchment area and they will be matched to their respective CHW. With an expected 607 caregivers enrolled in the MRV-CCD group and even distribution by age group, we would expect about 150 to have children less than 6 months, 150 with children 6-11 months, and 300 with children 12-23 months. Also assuming even distribution of

enrolled caregivers by CHW catchment areas and by child age group, we would expect each CHW (about 120) to have about 5 caregiver-cohort enrolled households. The study coordinator will select caregivers for CHW observations largely consecutively, but will also purposely select caregivers of children if different age groups.

Data Collection: CHW Cohort

CHW's will be asked to complete baseline and endline structured interviews, and agree to being observed, at baseline and endline, during two group education sessions at the facility and two home visit counseling sessions with caregivers.

Pre-post questionnaire: At baseline the enrolment form will be used to collect information, using a structured tablet-based interview, on CHW characteristics (demographics, history of CHW work), training, ECD knowledge and attitudes. This form will be re-administered at endline, including a module on CHW use of, and attitudes toward the ECD videos.

Observation checklists: Two separate observation checklists will be completed by the RA, one for clinic health education session and another for the home session. These checklists will document (a) background information on the environment and participants (home/clinic, caregiver relation to the child, child age [home], or number of clients in the education session and topics discussed [clinic]); and (b) score a series of items describing what the CHW did on a two or three-point scale (done/not done or done, partly done, not done). These scored items are either the "soft skills" of mentoring, such as "actively listens to the caregiver with minimal interruption" or practical behaviors that help to build caregiver skills in early stimulation such as "asks how the caregiver gets the child to smile." The checklists at endline will assess specific aspects of video use, which will not be applicable at baseline.

Clinic observations: As described above, the RA will liaise with the nurse in-charge to know the CHW duty roster in order to schedule clinic observation visits. CHWs should not know in advance which day they will be observed, though it will be impossible for the CHW not to be aware of the observer once the session begins. Prior to the session starting, the RA will introduce him/herself to the caregivers attending the CHW's counseling session and explain his/her purpose for being there. We are requesting a waiver of informed consent for the observations as described below. Any caregiver who prefers not to be part of the session for any reason will be excused. The clinic sessions will last from 10-60 minutes.

Home observations: Each enrolled CHW will be observed at two home visits with two different caregivers. The RA will focus on observing the CHW's behaviors in mentoring and providing feedback to caregivers on ECD and early stimulation (CCD). The observing RA will explain to the CHW that s/he should do what they normally do to assess, support, educate and mentor caregivers during a home visit. While the CHW may discuss health issues beyond CCD (immunization, postnatal care, medical referrals for illness, etc.), the data collection tool completed by the RA will be focused on observing and rating of behaviors/practices and interactions related to CCD only.

Home visit sessions will also be audio/video recorded using lapel cameras worn by the CHW and the caregiver. Collecting video observations is a standard observational tool that allows for rigorous coding of counselor behaviors. Lapel video cameras are unobtrusive and can be worn by the CHW and caregiver in a manner that captures both perspectives. Thus, two separate videos of each

session will be viewed by independent RAs who will complete the checklist, in addition to the RA who will be present at the session and scoring the observation checklist in real time.

Only caregivers who have consented to participate in the study cohort will be visited for CHW observations. On arrival at the caregiver's home, the RA will first remind the participant about the study and reconfirm caregiver consent to being observed by the RA and video-recorded during the session before the CHW proceeds with the home visit observation. Caregivers will be free to decide not to be observed, or to allow observation without video recording, without penalty; the CHW counseling session will proceed with or without these evaluation components. The home sessions will last about 10-60 minutes.

Outcome and Measures: CHW Cohort

Outcomes characterizing CHW capacity and the quality of CHW-caregiver interactions, and how CHW capacity and mentoring skills may change between baseline and endline after introduction of ECD videos, are grouped into four main categories:

1. CHW knowledge: of ECD and early stimulation
2. Compliance with message delivery: How well does the CHW demonstrate clear communication of ECD messages?
3. Responsiveness and listening skills: Does the CHW demonstrate good listening and communication skills, establishing good rapport and showing empathy?
4. Acceptability of videos: Whether CHW report video job aid to be useful, user friendly and acceptable and whether any challenges with use were observed or reported.

Given their potential to modify CHW capacity to deliver the intervention, the following characteristics and standard assessments will also be completed with CHW.

IQ - Ravens Standard Progressive Matrix (Ravens): Refer to above description.

Mental health, depression/anxiety (PHQ-9, GAD-7): Refer to above description.

CHW reported activities: The intensity and frequency of CHW responsibilities (e.g. number of households visited, frequency of visits) will be assessed in the pre/post structured interviews, as well as CHW training and duration of working as a CHW.

Media listenership: Questions from the caregiver listenership will be included in the CHW baseline/endline questionnaires, assessing exposure to radio communication, and recall of health education messages (including ECD-related) with respect to content, and source.

Scoring observations of CHW sessions

Video observations will be coded and scored by trained staff using a standardized checklist, and a sample of 20% of all videos will be double coded by another trained member of the study team to ensure reliability of coding.

Observation checklists for each CHW, by type of observation (clinic, home) and timing of observation (baseline, endline), will be averaged across all measures. Thus, a CHW's baseline or endline home score will be the average score of the in-person observation checklist scores (2 data points) and the video scores from two home visits (2 data points). A CHW's clinic score at baseline or endline will be

the average of two data points, based upon the in-person observation checklist scores at two clinic sessions. Each checklist score will impute missing values as the mean score for other values in that section, and an observation with more than 20% missing values will be considered invalid (and should be re-done).

Process Evaluation: MRV-CCD Group

The primary purpose of the process evaluation is to establish the fidelity of CHWs to the full Malezi II intervention package, specifically monitoring CHW practices and use of the short videos throughout the intervention period. The process evaluation component will also systematically collect routine program monitoring data from the MRV-CCD index facilities and CHWs with respect to developmental referrals made, number of group session held, and number of CHW home visits reported.

During the 9-month exposure period, research associates will aim to conduct CHW observation checklists (as designed for the baseline/endline data collection) on each MRV-CCD group CHW at least once/quarter for clinic sessions and twice/quarter for home sessions. This translates to about 246 home and 123 clinic checklists completed per quarter (total 369), or about 185/RA/quarter, or roughly 3 per day.

Focus group discussions

As part of the process evaluation, about four focus group discussions (FGD) will be held with approximately 6-10 CHW each in the MRV-CCD intervention group for a total estimated number of 24-40 purposively selected FGD participants. These will include CHWs from different districts to account for any potential geographic differences and CHWs will be further recruited to have a gender balance, and to represent those who have checklist scores at the higher and lower end of the distribution to ensure that all perspectives including challenges can be elicited. In addition to limited demographic data, topics in the FGD guide will address three main areas: CHW salience and relevance of the program to the CHW's work, barriers and facilitators to implementing the Malezi II program and experiences with use of the short videos as a job aid.

The FGDs will be conducted by qualitatively trained researchers and will include a facilitator and note-taker for each session. The FGDs will be conducted in Kiswahili and are expected to last between one and a half to two hours. All sessions will be audio recorded with the consent of the participants to allow for complete data capture and subsequent review for accuracy and quality assurance. For each FGD, about 6-10 CHW who work or reside in relative close proximity will be informed of the FGD meeting location and date following their agreement to join the study. Participants will be reimbursed for their transport to the FGD location and half per diem to cover other expenses related to being away from their home and communities for the day.

In-depth interviews

A sample of approximately 20-25 caregivers enrolled in the study cohort will be recruited to participate in in-depth interviews around the time that the FGDs are conducted. Caregivers who were recently visited by a CHW and observed by a research associate will be listed for selection in each district. About 20-25 CHWs assigned to those caregivers will be randomly selected, and then up to 2 caregivers assigned to those selected CHWs will be purposely selected based on the relative proximity to one-another geographically. If needed, this could allow for a "replacement" caregiver

who lives in the same geographic areas to be recruited if the first caregiver visited is unable to participate that day.

Given the established relationship with the caregiver, the CHW will be asked to call or visit the caregiver in advance to provide initial information about the interview and ask permission to visit for a possible interview and to schedule an optimal visit time. The research associate will accompany the research interviewer in order to facilitate appropriate household introductions because the research officer is known to caregivers and the communities through their observation visits with CHWs. CHWs should not be present during the IDI visit to facilitate an honest and open discussion about the support received from the CHW.

The IDIs will be conducted by a qualitatively trained researcher. The interviews will be conducted in Kiswahili, follow an IDI guide and are expected to last about 30-60 minutes. All IDIs will be audio recorded with the consent of the caregiver to allow for complete data capture and subsequent review for accuracy and quality assurance.

Data management

The day-to-day management of field operations and study data collection will be the responsibility of the study coordinator. The coordinator will oversee the development of a study database, and will design and implement data management SOPs and a tracking system for documentation of all entries to, and back-ups of the study database. The study coordinator will also work closely with the research associates based in Tabora who will play the front-line role in data collection, review and verification.

Data will be captured on some paper (e.g. enumeration activity) but mostly on electronic forms. Paper-based recruitment/screening documentation from the enumeration study that contains personal identifiers linked to a unique study patient identifier (PTID) will be accessible to study team members only, and stored separately from other forms in locked cabinets when not in use. These logs will be used to create an electronic master recruitment and enrolment log containing study PTID, basic characteristics (age, sex, date of baseline/ endline, household number, etc.), and recruitment outcomes (active, withdrawn, refused, ineligible). All paper-based data will be routinely collected from sites and brought to the EGPAF office in Tabora for temporary storage. Research associates or temporary data clerks will be responsible for close-to-real-time data entry (typically within 1-2 days of completion) of screening/recruitment data for internal study monitoring. These data will be entered into a cloud-based system (google form or custom database) that synchronizes the data to a server accessible by authorized study staff only.

Caregiver surveys, CHW interviews, video and in-person observation checklists will be completed electronically using tablets (Open Data Kit software-based or other similar platform). Any questionnaires will include skip patterns, and alerts for missed items will be programmed to avoid user error. The quality of data and data entry also will be enhanced by automatic consistency checks and feasible range values, programmed into the study database. When there is no data access for immediate uploading of completed surveys, data will be stored temporarily on the device, and subsequently synchronized to a secure server as soon as the device is within data range (usually daily). Those data will be accessible from the server through a password-protected web-based dashboard for routine data download, quality reviews and back-ups. Only authorized study team members will be able to access these data.

Any paper-based data collected will be reviewed for quality control purposes by a study team member as soon after completion as possible, and by the coordinator on a routine basis during supervision. These data will be double-entered and discrepancies reconciled. Personal identifiers such as caregiver and child names will be included in the paper-based data forms for the purposes of data cleaning and verification, but no names will be entered into the study database. Video and audio files from the FGD will be stored similarly to electronic data back-ups, on secured hard drives or cloud storage with only authorized and password-protected access. Video and audio files will be archived with cleaned data files for three years after study closure, and then destroyed (i.e., deleted from laptops, devices, etc.), with their destruction documented.

The audio-recorded FGDs and IDIs will be transcribed and translated from Kiswahili to English. Transcripts will be reviewed by a member of the study team fluent in English and Kiswahili. Transcripts will be imported into a qualitative software program for analysis (MAXQDA or similar program). A codebook will be developed with deductive codes based on the IDI and FGD guides with inductive codes added during the coding process as needed. Trained qualitative coders will code the transcripts, and a study investigator will review a subset of transcripts to ensure consistency across different coders.

All paper-based study records (excluding regulatory records) will be destroyed three years after the analytic database is declared clean and frozen.

Data Analysis

Objectives 1 and 2: Caregiver Cohort

Descriptive statistics (range, median, mean, percent) will be used to review the data overall and describe participant background characteristics, radio listenership patterns and parenting perceptions, knowledge and practices, identifying any baseline differences in population by study group. Confidence intervals (CI) will be calculated around summary measures and statistical tests of significance (non-parametric) will be applied where appropriate to compare the distribution of characteristics or outcomes across study groups. The effects of radio exposure only (objective 1) will be described by comparing study outcomes at baseline and endline within the MR study group only. Within study group differences in study outcomes will be described comparing distributions of responses to key outcome variables at baseline and endline using statistical testing appropriate for paired groups such as the paired t-test, Wilcoxon or McNemar's tests. Regression modelling may be used to estimate the intervention effect while controlling for covariates.

The additional effects of the combined exposure to radio, short videos and Malezi CCD (MRV-CCD; objective 2), as compared to the radio only effect, will be described using a differences in differences (DID) analysis. The treatment effect can be found by obtaining the proportion of caregivers with the outcome in the MRV-CCD and MR groups at both time periods. The difference in outcomes between study groups at both time periods may be charted to visualize the DID as shown in Figure 4, whereby the DID is what remains after subtracting the baseline differences between the two groups from the endline differences (30-5%=25%). This will give an estimate of the extent of the improvement by the Malezi II full intervention. We will use regression modelling to estimate the intervention effect while controlling for covariates. We will use the following general form model:

$$Y = \beta_0 + \beta_1[Intervention] + \beta_2[Time] + \beta_3[Intervention \cdot Time] + \beta_4[Covariates] + \mathcal{E}$$

The interaction term coefficient β_3 will also estimate the extent of the DiD.

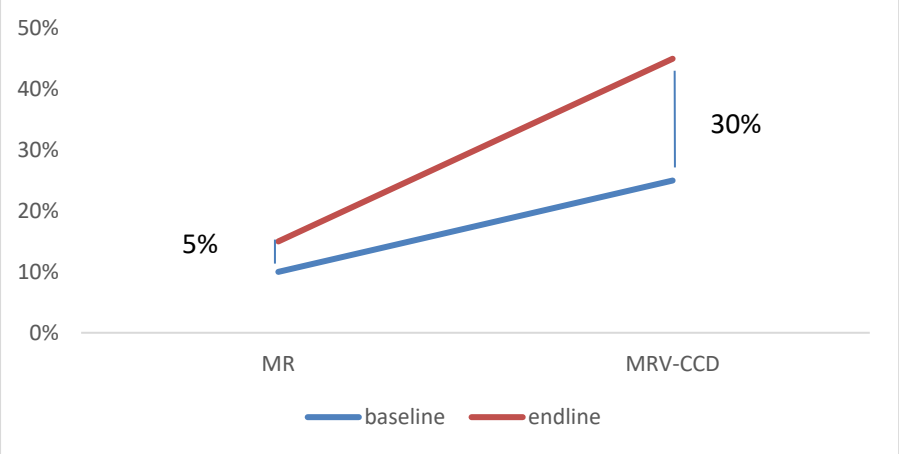

Figure 4. Differences in differences analysis graphic

Objective 3: Community Health Worker Cohort

Quantitative evaluation of the effect of the short videos on quality of CHW counseling will follow similar analyses as described above, including characteristics of the population, and statistical comparison of outcomes at baseline and endline (post-video introduction) within the CHW cohort. Some qualitative analyses will also be done to describe and summarize CHW opinions and suggestions regarding video content, design and use.

The audio-recorded FGDs with CHW will be transcribed and translated from Kiswahili to English by qualitative researchers. Transcripts will be reviewed by a member of the study team is in fluent in English and Kiswahili. Transcripts will be imported into a qualitative software program for analysis (MAXQDA or similar program). A codebook will be developed with deductive codes based questions in the FGD guide with inductive codes added during the coding process as needed. Study team members trained in coding skills will be responsible for coding the transcripts. A study investigator will review a subset of transcripts to ensure consistency across different coders.

Objectives 4-5: FGDs with CHWs and IDIs with caregivers

Qualitative data will be summarized through descriptive, text-based summaries by code. Textual data will be carefully read by investigators to identify recurrent patterns and themes, and to draw conclusions from issues connected to the study questions. Themes may include acceptability of CHW home visitation or use of the videos, perceptions of CHW authority on ECD/parenting, experiences with health provider counseling on ECD at health facilities, and recommendations for improving ECD education and interventions.

ETHICAL CONSIDERATIONS

No data collection will be done prior to approval of this protocol by the National Research Ethics Committee of the National Institute of Medical Research and the Advarra Institutional Review Board

in the USA. Research participants will only join the study after their informed consent has been obtained. This study will be registered with a clinical trials network.

Informed Consent

Study staff will read aloud all consent documents in the local language, Kiswahili. Each consent document will include information on who is carrying out the evaluation, the purpose of the evaluation, 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 questions or concerns. Caregiver and CHW participants will freely choose whether or not to participate in the study. They will be informed that their refusal to participate at any time will have no bearing on any community or health facility services received or their employment, respectively. The form will also include contact information for study investigators if there are questions later and the NIMR Secretariat if there are any complaints about the study. A copy of the consent form will be offered to all consenting participants.

As part of written informed consent procedures, the potential participant's ability to read, understand and sign the consent form will be assessed prior to consent. In cases where the participant is not literate, a witness will be invited to listen to the consent process from the start, and sign the consent document attesting to the fact that the research associate (RA) read the consent, answered all questions, and the respondent voluntarily chose to participate. The respondent will then place a mark on the form, leaving the space for name and date blank on the participant's line. The witness and RA will both sign and date the form, documenting the participant's name above the witness' signature.

Caregiver participants

Verbal consent will be obtained from eligible caregivers for enumeration and the listenership survey administration after reading the consent document to potential participants. A waiver of written informed consent is requested because participation in the enumeration and listenership survey presents no more than minimal risk of harm and involves no procedures for which written consent is normally required outside of the research context.

Written (signed) informed consent will be obtained from caregivers recruited into the caregiver cohorts. Caregivers who have verbally consented to participate in the listenership survey may be invited to participate further in the caregiver cohort study, after providing informed consent to the study procedures pertaining to the caregiver cohort: baseline and endline caregiver survey, endline listenership survey, and possible observed CHW visit in the home.

As described above, RAs will ask caregivers in households selected to participate in this activity to reconfirm their consent to be observed and video-recorded in the home. A study SOP will provide discussion points for the RA to ensure the observation activity is properly introduced to the caregiver. These include:

- The purpose of the observation is to learn more about how the CHW supports caregivers during home visits.
- The caregiver (along with the CHW) will be asked to wear cameras to video-record the session for independent scoring of the session.

- The RA will be completing a form related to how s/he observes the CHW. The RA will not ask any questions to the caregivers and no information provided by the caregiver will be written on the form. Only researchers will view the videos and they will only be used to observe how the CHW conducted the visit. The videos will be destroyed after the study is completed.
- The caregiver may choose not to allow the observation of the CHW that day, and this will not affect how the CHW supports the caregiver that day (RA to wait outside in such cases).

CHW participants

Written (signed) informed consent will be obtained from CHWs recruited into the CHW cohort, describing the baseline and endline interview, and observations of CHWs doing their work in homes and the clinic at baseline and endline. Permission to contact CHWs who are selected for FGDs will be included in the CHW consent for the CHW cohort.

FGD and IDI participants

An additional signed informed consent will be obtained separately from CHW cohort participants and IDI caregiver participants. The rationale for separate and additional consent documentation is that only a subset of CHWs (n~24-40) will be invited and the FGDs involve study procedures and compensation not described in the cohort written CHW consent. Similarly, only a subset of caregivers (n~20-25) will be invited to participate in an IDI and this is not currently described in the caregiver cohort consent.

For FGD participants, the consent process may be conducted in person or over the phone prior to the discussion. A member of the study team will meet in person or call selected participants by phone to read the consent document, which includes reimbursement of travel expenses and any requirements of reimbursement (e.g., official receipt), if applicable, so they are aware of these details prior to traveling to the FGD venue. At this time, they will also be provided with the FGD meeting location and time. If they agree to participate in the FGD, they must also agree to be audio-recorded. If they are consented in person, participants will be asked to sign and date the form and will be offered a copy of the consent to keep. If they are consented over the phone, participants will be provided with a copy of the form to read once they arrive at the FGD venue, will be asked to sign and date the form if they still agree, and will be offered a copy of the consent form to keep.

For IDI participants, the consent process will be conducted in person at the caregiver's home. If they agree to participate in the FGD, they must also agree to be audio-recorded. Participants will be asked to sign and date the form and will be offered a copy of the consent to keep. In cases where the participant is not literate, the same processes will be followed as described above.

Caregivers present at clinic-based CHW observed sessions

Verbal permission will be sought from caregivers who are present during the CHW observations of clinic group counseling sessions. For those caregivers who will be part of an observed group counseling session at the health facility, a study SOP will provide discussion points for the RA to ensure the observation activity is properly explained to caregivers prior to the start of the session. These include:

- The purpose of the observation is to learn more about how the CHW supports caregivers during group counseling at health facilities.

- The RA will be completing a form related to how s/he observes the CHW. The RA will not ask any questions to the caregivers and no information provided by the caregivers will be written on the form.
- No names or other information that could identify the caregiver will be documented.
- The caregiver may choose not to be a part of the observed counseling session, and this will not affect any medical services provided to the caregiver.

Because these sessions often take place in public settings, such as the clinic waiting area inside or on a verandah, or a gathering place outside (under a tree), and caregivers move in and out of the session as they arrive or are called by the providers for services, it is not feasible to limit attendance to only those who were present at the start of the session. Therefore, at the close of the session, the RA will thank the caregivers for allowing the observation and offer to meet with any caregiver who joined during the group (and missed the introduction) for explanation of what was happening and why.

A waiver of informed consent of caregivers attending these observed group sessions is requested based on the following criteria:

CFR 45.116.(3) *Requirements for waiver and alteration.* In order for an IRB to waive or alter consent as described in this subsection, the IRB must find and document that:

i. *The research involves no more than minimal risk to the subjects:* A member of the study team will observe a routine clinic activity that is focused on general child development, not on discussions of sensitive health information.
ii. *The research could not practicably be carried out without the requested waiver or alteration:* This is due to the fluidity of the sessions as described above.
iii. *If the research involves using identifiable private information, the research could not practicably be carried out without using such information in an identifiable format:* This activity does not involve the collection of identifiable private information.
iv. *The waiver or alteration will not adversely affect the rights and welfare of the subjects*: It will not adversely affect participants' rights and welfare given the very minimal risk involved, including for any privacy or confidentiality breaches.
v. *Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation:* Not applicable

Human Subjects Training and Confidentiality Protections

All EGPAF staff, including temporary or contracted data collectors will complete an appropriate training in human subjects' protections. This training will emphasize the ethical conduct of research such as the basic principles of research, responsibilities of researchers, examples of unethical research, informed consent, personal information, confidentiality, and documentation standards. In addition, all research staff will be required to sign a confidentiality agreement prior to interacting with participants.

All tablets used for electronic data capture will be kept in a secure location with password protection. Electronically collected data will be encrypted at the time of submission and stored to a secure server. The electronic database will also be password protected with use restricted to members of the study team only. Analytic databases will not record participant names or any other identifying contact details, but will be identified by unique PTID only. Names and contact details for

listenership respondents, caregivers and CHWs who are recruited into the study will be documented only on screening/recruitment documentation, whereby these identifiers are needed to ensure review of eligibility, verification of data integrity, verification of consent, and identification/tracing of cohort respondents for endline assessments. Those names and contact details will remain on separate screening, consent and master recruitment lists, and will only ever be linked to any participant's characteristics collected through the study using the study PTID. All documents linking identifiers and PTID (recruitment, consents) will be stored securely in locked drawers or cabinets when not in use. All electronic data will be housed in password-protected personal computers.

For the FGD, transcripts will not contain any participant names. We will request all participants to refer to themselves and others by their assigned number and not their names. Any names or other personally identifying information inadvertently spoken during the FGD and captured on the audio recording, will be removed during the transcription process. Names and contact details for CHW invited to FGDs will be documented only insofar as they are required to arrange logistics for their attendance at the groups. Names will also be viewed by non-study finance staff at EGPAF as required to account for their transport and per diem payments. Those names and contact details will not be linked to any particular group's transcript, audio-recording or demographic data.

Risks, Benefits and Compensation

This study does not pose more than minimal risk to participants. The majority of the content of questionnaires and observation assessment tools is not considered sensitive or personal information, with the exception of some questions on socioeconomic status, discipline practices, psychosocial status, and household risks. Thus, there is some risk of disclosure of information that some people might consider private and confidential to unauthorized persons. We will seek to mitigate this risk by (1) holding the interviews/observations in a private place; (2) ensuring that all study related personnel are trained in basic research ethics, which emphasizes the importance of confidentiality and data security; and (3) implementing strict protocols on data security and handling to minimize loss or unauthorized sharing of personally identifiable or sensitive (confidential) information.

Respondents in the caregiver cohort will be offered an age-appropriate toy as an expression of thanks for their time, equivalent to less than USD 5 (~11,000 Tanzanian Shillings [Tsh]), at both baseline and endline assessments. The toy will be a locally made of soft material, such as doll, animal or book. There will be no compensation provided to caregivers at the stage I listenership survey participation. CHWs will receive transport reimbursement of <USD 5 (Tsh 10,000) for meeting the interviewer at the clinic for baseline and endline interviews and for four home visits total (Tsh 5,000 for each). CHW cohort participants joining the FGDs will receive half per diem (about Tsh 30,000 or about 13 USD equivalent) to cover costs related to travel and being away from their homes and communities for a working day, and reimbursement of their transport, if applicable, as per official receipt. This compensation is determined according to EGPAF policies and is therefore subject to minor changes.

Caregivers participating in IDIs will not receive any compensation as these interviews are taking place at their homes, and the visit will be no longer than about one hour.

TIMEFRAME

The overall evaluation is expected to take about 2 years.

POLICY/PROGRAM SIGNIFICANCE AND DISSEMINATION

Outcomes from this evaluation will inform decision makers in Tanzania about the feasibility and effectiveness of a health systems-based ECD intervention, augmented by radio communications and/or short video use. The feasibility and potential contributions of ECD short videos to CHW skills and caregiver behaviors will inform the potential scale-up of digital job aids, and is an area the Government of Tanzania has already invested in through various other digital health initiatives. While this evaluation is not designed to be generalizable to other countries or globally, we believe that the findings from this evaluation can still make substantive contributions to literature on how nurturing care (ECD) interventions can be integrated into routine MNCH and HIV care in resource-constrained settings.

Results from this evaluation will be disseminated locally through meetings with R/CHMTs, nationally with Government policy-makers and program implementers, and internationally through presentations at scientific conferences and peer-reviewed journal publication.

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