Testing the Effectiveness and Sustainability of an Integrated Care Group Model as Compared to the Traditional Care Group Model

Operations Research Final Report

June 2014

Principal Authors:

Jennifer Weiss, Concern Worldwide US

Delphin Sula, Concern Worldwide Burundi

Raphael Makonnen, Columbia University

The Mabayi Child Survival Project in Mabayi District, Cibitoke Province, Burundi is supported by the United States Agency for International Development (USAID) through its Child Survival and Health Grants Program. The Mabayi Child Survival Project is managed by Concern Worldwide under Cooperative Agreement No. GHN-A-00-08-00005. The views expressed in this material do not necessarily reflect the views of USAID or the United States Government.

TABLE OF CONTENTS

Annexes

ACRONYMS

ACT	Artemisinin-based Combination Therapies
BCC	Behavior Change Communication
BPS	*Bureau Provincial de Santé* (Provincial Health Bureau)
CCM	Community Case Management
CGV	Care Group Volunteer
C-HIS	Community Health Information System
CHW	Community Health Worker
CI	Confidence Interval
Colline	Literally "hill" in French—an administrative unit of a Commune
EBF	Exclusive Breastfeeding
FGD	Focus Group Discussion
HC	Health Center
HDDS	Household Dietary Diversity Score
ITN	Insecticide-Treated Net
IYCF	Infant and Young Child Feeding
KPC	Knowledge, Practice, and Coverage Survey
M&E	Monitoring and Evaluation
MOH	Ministry of Health
MUAC	Mid-Upper Arm Circumference
NGO	Non-Governmental Organization
OR	Operations Research
ORS	Oral Rehydration Solution
PBF	Performance-Based Financing
RCT	Randomized Controlled Trial
Titulaire	Head Nurse at Health Centers
TPS	*Technicien de Promotion de la Santé* (Health Promotion Technician)
USAID	United States Agency for International Development
WHO	World Health Organization
WRA	Women of Reproductive Age

Testing an Integrated Care Group Model for Community-based Health Promotion in Burundi

This operations research was funded by the U.S. Agency for International Development through the Child Survival and Health Grants Program from September 2008 – October 2013.

December 2013

A Care Group Volunteer conducts a home visit.

Photo by Adele Fox, Concern Worldwide.

Key Findings:

- There is sufficient evidence to conclude that the Integrated Care Group model is not inferior to the Traditional model.
- The Integrated model demonstrated sufficiently similar practice and knowledge outcomes, as well as functionality and sustainability measures.
- There is a significant cost differential between the Traditional and Integrated models, with the Traditional model costing $0.90 more per beneficiary per year
- The Integrated Care Group model should be adopted and scaled-up as a lower cost yet equally efficacious social and behavior change intervention in Burundi and other resource poor settings.

Background and Setting

Burundi is one of the poorest countries in the world. Child mortality rates remain unacceptably high at 139 per 1,000 live births and the country is not on track to achieve Millennium Development Goal 4 of 61 per 1,000 by 2015. As in most low-income countries, children in Burundi die primarily from the cumulative effect of largely preventable diseases and undernutrition.

Within this context, Concern Worldwide implemented a USAID Child Survival and Health Grants Program-funded initiative from 2008 – 2013, which targeted 46,708 women of reproductive age (WRA) and 60,353 children under five in Mabayi District, Cibitoke Province. The objectives of the project were to improve household maternal and child health and nutrition practices, increase access to quality child health services, and strengthen community leadership in health. Concern's principal partner in planning and implementation was the Ministry of Health (MOH) at the national, provincial, and district levels, especially the members of the Mabayi District Health Team (DHT), who played an essential role in all aspects of the project.

Problem and Solution

Decentralization of the health system in Burundi has been slow to take hold since reforms began in the mid-1990s. A national Community Health Strategy was finalized in 2012, which includes a role for one community health worker (CHW) per village to conduct general health promotion. However, human resource constraints and a lack of viable service delivery mechanisms impede the intensive, interpersonal actions which are required for population-level behavior change. Community-based strategies that strengthen the capacity of the MOH and leverage the potential of CHWs for effective behavior change need to be identified, evaluated, and scaled up.

The Care Group model is an evidence-based delivery strategy for social and behavior change interventions that has contributed significantly to improved child health outcomes in a number of contexts. However, due to the intensive management responsibilities of Care Group activities performed by full-time project staff, it may be difficult for the MOH to sustain Care Groups following the conclusion of the program. Concern designed the Integrated Care Group model to increase integration with the local MOH structure by task shifting Care Group facilitation and supervision duties from project staff to MOH structures. In the Integrated Care Group model, Care Group Volunteers (CGVs) are trained and supervised by CHWs, who are in turn trained and supported by *Titulaires* (the head nurses at the health centers [HCs]). This adjusted method of implementation is intended to increase the feasibility of scaling up a sustainable Care Group model by national Ministries of Health in under-resourced health system settings.

OPERATIONS RESEARCH EXECUTIVE SUMMARY

Intervention

Concern Worldwide implemented the Traditional and Integrated Care Group models in two clusters of Bukinanyana Commune. Care Groups were established in the same way in both study areas using standard Care Group practices, including community sensitization to Care Groups, census of all households with pregnant women and children under five, and election of CGVs based on census results. Based on formative research and the project's technical intervention areas, behavior change modules were developed and used to promote evidence-based nutrition, malaria, diarrhea and pneumonia management behaviors. In both study areas, Care Group meetings were held twice per month and CGVs conducted home visits at least once per month, during which they provided targeted health promotion messages, screened for acute malnutrition, and collected vital events data.

In the Traditional Care Group study area, paid Project Animators supervised Promoters, who in turn supervised CGVs. CHWs in the Traditional area may have also assisted with CGV supervision by carrying out household visits to ensure that CGVs had effectively delivered messages. In the Integrated area, CHWs supervised CGVs by conducting follow-up household visits, reviewing CGV registers, and trouble-shooting problems during Care Group meetings. CHWs in both study areas are supervised by health facility-based *Titulaires*, as dictated in the Community Health Strategy.

Methods

The study was conducted in Bukinanyana Commune, one of three mountainous and rural communes in Mabayi District, Cibitoke Province, Burundi. The five MOH zones in Bukinanyana Commune were grouped into two clusters based on population size. Each cluster was then randomly assigned to either the intervention area (Integrated Care Groups) or comparison area (Traditional Care Groups).

The Care Group models were assessed to determine whether the Integrated model achieved the same levels of knowledge and practices of key child health and nutrition behaviors among caregivers of children age 0-23 months as the Traditional model (Hypothesis 1) and whether the Integrated model achieved the same level of functionality and sustainability as the Traditional model (Hypothesis 2).

Hypothesis 1 was assessed through measuring 40 key child health and nutrition knowledge and practice indicators related to diarrhea, malaria, pneumonia, and nutrition. Data was collected through baseline (October 2010) and endline (May 2013) surveys of caregivers of children age 0-23 months, with non-inferiority statistical testing conducted at endline. Hypothesis 2 was assessed through monthly monitoring of five Care Group key operational indicators, such as Care Group meeting attendance, home visits conducted, and reporting in both Traditional and Integrated areas.

A qualitative process evaluation was also conducted at mid-term and was designed to document the successes, challenges, and changes associated with implementation of both the Traditional and Integrated Care Group models in a prospective manner. A total of 15 focus group discussions (FGDs), five in-depth interviews, and 20 non-participant observations were completed.

Findings

Hypothesis I: Overall, there is strong evidence that the Integrated model is not inferior to the Traditional model. Thirty-six of the forty indicators (90%) were not inferior in the Integrated area. The non-inferiority of the Integrated model is particularly evident among the *practice* indicators, with only one practice indicator being inferior in the Integrated Area. Non-inferiority was more moderate among the *knowledge* indicators, primarily because of lower than expected knowledge among mothers of food intake requirements for children at different ages.

Hypothesis II: Overall, all five Care Group operational indicators nearly met or surpassed project targets, and there was no significant difference in Care Group functionality between the two models. Care Group functionality fluctuated during the project, but the models performed similarly towards the end of Concern's support to Care Group activities. The sustainability measures demonstrate similar outcomes, with a somewhat better sustainability trend in the Integrated model compared to the Traditional model.

The mid-term process evaluation highlighted that CHW supervision by health facility staff was an ongoing challenge in both study areas. As a solution, Concern worked with the *Titulaire* to identify an

alternate 'focal point' for all Care Group activities, usually a more junior nurse who had fewer time constraints. The process evaluation also found that the CHWs had taken on a more active role in Care Group meeting facilitation and reporting in the Traditional area than had originally been anticipated. Concern did not discourage CHWs from taking more of a leadership role in Care Group activities in the Traditional area, and believes it is a sign of community approval of the structure of the Integrated model. That said, although Promoters did maintain lead responsibility for all Care Group facilitation and supervision duties, it is possible that the greater CHW involvement in the Traditional area diluted the differences between the two models as they were tested over the life of the study.

Conclusions

There is sufficient evidence to conclude that the Integrated Care Group model is not inferior to the Traditional model. The Integrated model demonstrated sufficiently similar knowledge and practice outcomes, as well as functionality and sustainability measures.

This research has also reinforced the existing evidence that Care Groups are a highly effective strategy to achieving key child survival priorities. CGVs are a valuable source of health education messages in their community, and the Integrated Care Group model demonstrates how CGVs provide a means to extend the reach of CHWs to achieve high levels of behavior change at the individual and household levels. In addition, and as similarly demonstrated in other Care Group projects, CGVs are able to effectively collect and report community health information system (C-HIS) data, including vital events. The Integrated Care Group model demonstrates how such data may be integrated into national HIS through both CGVs and CHWs.

In addition to being a lower cost model, there are clear positive externalities to the Integrated model compared to the Traditional model. Through training and supervising CGVs in the Integrated area, the CHWs simultaneously strengthen their own knowledge and skills, as well as their ability to deliver quality health services to their target households. Moreover, CHWs gain a higher status in the community as they engage in supervisory activities comparable to non-governmental organization (NGO) staff.

Recommendations

Concern recommends that the Integrated model be scaled-up in Burundi and that CGVs be integrated as a formal component of the community health system to improve coverage of key health and nutrition interventions at the individual and household levels. Existing CHW performance-based financing (PBF) policies could be revised to include key Care Group operational indicators to further incentivize and institutionalize the model. While NGOs will still have a role in the medium-term to build the capacity of the MOH at the district level to implement the Integrated model, it is conceivable that the model could be scaled-up and institutionalized within existing community health structures.

A final recommendation is to prioritize funding for future sustainability studies on this research. Given that this study only provides initial estimates of sustainability, Concern recommends that further research examining health and nutrition outcomes, as well as Care Group operational indicators, be conducted in both the Integrated and Traditional study areas within the next two years.

Use of Evidence

Throughout this operations research (OR) study, the MOH has demonstrated a keen interest in the potential of the Integrated Care Group model. MOH representatives have praised the model for its ability to extend coverage of key interventions to all eligible households, strengthen linkages between the community and health facilities, and incorporate C-HIS data into the national HIS. The official findings from this study were shared with the MOH, UNICEF, and other in-country development partners in September 2013 and will be used as a basis for continued advocacy in the coming years.

The Mabayi Child Survival Project in Mabayi District, Cibitoke Province, Burundi is supported by the American people through the United States Agency for International Development (USAID) through its Child Survival and Health Grants Program. The Mabayi Child Survival Project is managed by Concern Worldwide under Cooperative Agreement No. GHN-A-00-08-00005. The views expressed in this material do not necessarily reflect the views of USAID or the United States Government.
For more information about the Mabayi Child Survival Project, visit: www.concernusa.org.

Acknowledgements

This OR study was funded by the U.S Agency for International Development through the Child Survival and Health Grants Program. Alyssa Davis, former Health Advisor at Concern Worldwide Burundi, conceptualized the Integrated Care Group model and led its initial field implementation. Dr. Gayane Yenokyan and Bing He of the Johns Hopkins University Biostatistics Center advised on non-inferiority testing methods. We wish to thank the Mabayi District Health Team, as well as Ministry of Health professionals at the district health centers, Community Health Workers, and Care Group Volunteers, who were the central actors in this study and who provided rich lessons and information.

Introduction

Burundi is one of the poorest countries in the world. It is ranked 178th out of 186 countries on the Human Development Index. Its post-independence history is marked largely by the ethnically-driven civil war which lasted from 1993 - 2003. While most of the displaced have since returned, the impact of the war on physical and psychosocial health and livelihoods continues. Child mortality rates remain unacceptably high at 139 per 1,000 live births and the country is not on track to achieve Millennium Development Goal 4 of 61 per 1,000 by 2015 (1). As in most low-income countries, children in Burundi die primarily from the cumulative effect of largely preventable diseases and undernutrition (2).

Within this context, Concern Worldwide implemented a USAID Child Survival and Health Grants Program-funded initiative from 2008 – 2013, which targeted 46,708 Women of Reproductive Age and 60,353 children under five in Mabayi District, Cibitoke Province. The objectives of the project were to improve household maternal and child health and nutrition practices, increase access to quality child health services, and strengthen community leadership in health. The project's technical interventions focused specifically on infant and young child feeding (IYCF), vitamin A and micronutrients, prevention and treatment of malaria, prevention and control of diarrheal disease, and pneumonia case management. Concern's principal partner in project planning and implementation was the Ministry of Health (MOH) at the national, provincial, and district levels, especially the members of the Mabayi District Health Team (DHT), who played an essential role in all aspects of the project.

As outlined in the 2011 – 2015 National Health Development Plan, the Burundian MOH is structured as a three-tiered pyramid. At the national level, six MOH departments and nine different national health programs are tasked with leading strategic planning, the coordination of donors and in-country partners, the formulation of sectoral policy and regulatory standards, and the allocation of funds. National-level officials also serve as Master Trainers for several MOH programs and are thus heavily involved in the training and supervision of staff at the lower levels. Under the immediate supervision of the national level are 17 provincial health offices, or *Bureaux Provinciaux de Santé* (BPS). The BPS coordinate health activities in their respective provinces and, as part of the MOH's new performance-based financing (PBF) scheme, play a lead role in the supervision and verification of PBF activities at the health facilities. BPS officials, in turn, oversee the operations in the 45 health districts (each of which contains two to three communes and a population of between 100,000 to 150,000) that cover a total of 63 district hospitals and 735 public health facilities countrywide.

Decentralization of the Burundian health system has been slow to take hold since reforms began in the mid-1990s due to past and recurring periods of conflict and insecurity and the general lack of investment in the health sector. District-level management was only established in 2008;

previously, health facilities had been directly supervised by the province. Community health has only recently begun to be addressed. A national Community Health Strategy was finalized in 2012, which includes a role for one Community Health Worker (CHW) per village to do home visits and health education. However, the MOH has limited capacity to conduct meaningful community outreach beyond the walls of the health facilities due to human resource constraints and lack of viable service delivery mechanisms.

Extending the reach of the public health system through a well-trained and supported community health workforce is a crucial step to increasing equity in health care access and facilitating household level behavior change. Concern sought to develop a feasible solution that would effectively 'extend the reach' of the CHW in each village to every household with a pregnant woman or children under five with high impact interventions proven to address child mortality (3). Concern also sought to build the capacity of the government health system to oversee community-level initiatives.

The solution, described below, was implemented in Bukinanyana Commune, one of three mountainous and rural Communes in Mabayi District, Cibitoke Province, Burundi. Bukinanyana was selected in collaboration with the district officials as the study location as it is the most populous and underserved of the three communes in the district, with no other NGOs active in the Commune, and has the most limited availability of health services.

Fieldwork lasted a total of 20 months (June 2011 – February 2013); followed by six months of monitoring ongoing activities for an initial assessment of sustainability (March – August 2013).

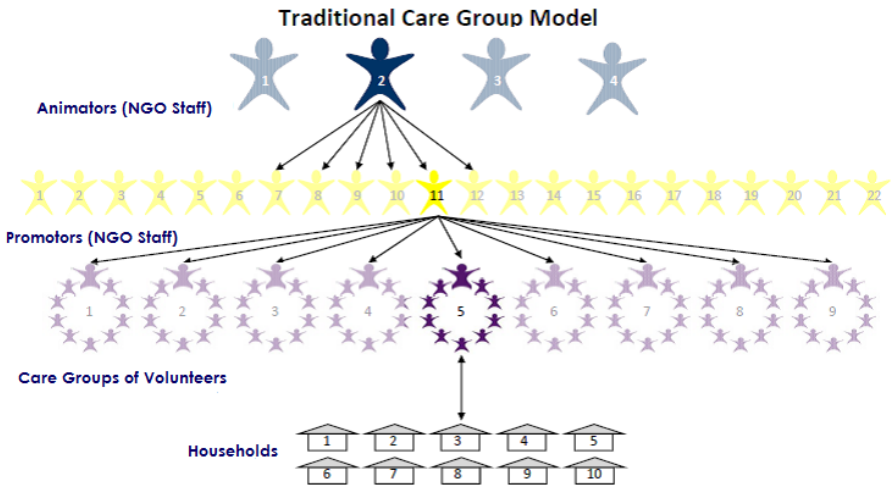
Intervention Design

The Care Group model is a community-based implementation strategy for the delivery of social and behavior change interventions. The model was pioneered by World Relief in Mozambique in 1995 and has since contributed to improved child health outcomes in a number of contexts (4, 5). A Care Group is a group of 10-15 mothers of children under five years of age who regularly meet together with project staff for training and supervision. They are different from typical mother's groups in that each mother is responsible for regularly visiting 10-15 of her neighbors to share what she has learned and facilitate behavior change at the household level. Care Groups create a multiplying effect to equitably reach every beneficiary household with interpersonal behavior change communication. They also provide the structure for a community health information system that reports on new pregnancies, births and deaths detected during the monthly home visits (6).

In the Traditional Care Group model, project staff supervise and facilitate all Care Group activities: CGVs are trained and supervised by Health Promoters, each of which train and support approximately six to nine Care Groups, and who are in turn supervised and supported by more senior-level project staff (7). **Figure 1** depicts the structure of the Traditional Care Group model.[1] The total number of Promoters and Care Groups will vary depending on the geographic size and target population of each project.

[1] This description is only intended to give an overview of the most common structures and mechanisms for implementation of the Traditional Care Group model. It is acknowledged that these structures and mechanisms have varied across projects and organizations. For example, CHWs may be included in the Care Groups along with the CGVs.

Figure 1: Structure of the Traditional Care Group Model

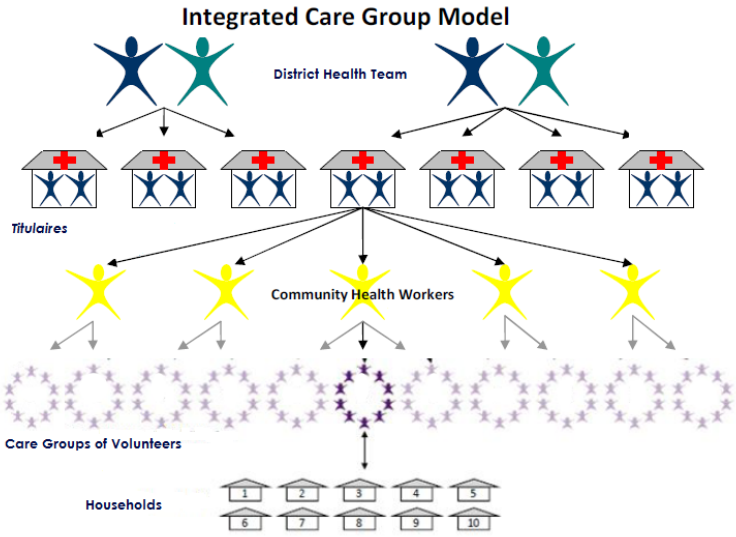


Due to the intensive management and supervision responsibilities of Care Group activities performed by full-time paid staff, it may be difficult for communities and the MOH to sustain Care Groups following the conclusion of the program. The sustainability strategy for some Care Group projects may plan for CHWs or other community actors to take over the facilitation of the Care Groups after project completion, but this is understandably difficult if such actors have not received the proper training to facilitate the Care Groups and are not provided with a system for ongoing supervision and support.

Concern Worldwide designed the Integrated Care Group model to reduce the dependence of Care Group implementation on full-time, paid NGO staff, while increasing integration with the local MOH structure. This is accomplished through task shifting of Care Group facilitation and supervision duties from project staff to appropriate MOH staff and CHWs, while still satisfying the established Care Group Criteria (8). The intention of developing this adjusted method of implementation is to increase the feasibility of the Care Group model to be scaled up and sustained by national Ministries of Health in under-resourced health system settings.

In the Integrated Care Group model, CGVs are trained and supervised by CHWs, who are in turn trained and supported by *Titulaires* in conjunction with Animators (full-time, paid NGO staff, who would normally be referred to as 'Supervisors' under the Traditional model). Each CHW is responsible for training and supporting two to four Care Groups. Therefore, instead of investing the majority of time, effort, and funding into the training of Care Groups directly by project staff during the life of the project, emphasis is given to building the capacity of MOH staff (*Titulaires*) to provide training, supervision and support to CHWs in the facilitation of Care Groups. **Figure 2** depicts the structure of the Integrated Care Group model as conceptualized and implemented by Concern Worldwide in the context of the Burundian health system.

Figure 2: Structure of the Integrated Care Group Model



Components of the Intervention

This section details the components of the Traditional and Integrated Care Group models as they were implemented in Bukinanyana Commune. Care Groups were established in the same way in both study areas, using standard Care Group practices including community sensitization to Care Groups, census of all households with pregnant women and children under five, and election of CGVs based on census results (7). An overview of the roles and responsibilities performed by the key actors in each study area is provided in **Table 1** and described throughout the text below.

Table 1: Roles of Key Actors in Traditional and Integrated Care Groups[2]

Actor	Role	
	Traditional Care Groups	**Integrated Care Groups**
Animators (Project Staff)	Facilitate implementation of all field activities.	
	Train *Titulaires* and *Techniciens Promotion de la Santé* on Care Group modules	
	Support *Titulaires* to train CHWs in Care Group modules and supervise CHWs	
	Support Health Promoters to train/supervise CGVs	N/A
	Support compilation of monthly reports from HCs	
Promoters (Project Staff)	Facilitate Care Group meetings	N/A
	Supervise CGVs	N/A
	Compile and submit reports	N/A
***Titulaires* (MOH)**	Receive training on Care Group modules	
	Train CHWs on Care Group modules	
	Supervise CHWs	
	Compile monthly reports	

[2] It was originally intended that the *Titulaires* in the Traditional area would have less involvement in Care Group activities. This was later revised in order to align with the MOH Community Health Strategy regarding CHW training and supervision. CHWs in the Traditional area also took a more active role in Care Group activities than was originally planned, particularly with respect to Care Group activity supervision and reporting. This was an organic evolution over the course of Care Group implementation and one that Concern did not discourage.

Table 1: Roles of Key Actors in Traditional and Integrated Care Groups[2]

Actor	Role	
	Traditional Care Groups	Integrated Care Groups
Community Health Workers (MOH)	Participate in Care Group meetings	Facilitate Care Group meetings
	N/A	Supervise CGVs
	Assist in compilation and submission of reports (variable)	Compile and submit reports
Care Group Volunteers	Conduct home visits (provide health education, screen for malnutrition, refer sick children to health facility, collect vital events data)	
	Attend Care Group meetings	
	Submit reports	

Cascade Training

Based on formative research, the project's Training Officer developed content for BCC modules covering the four key technical areas of the project. **Table 2** outlines the topics covered in each module.

Each module included a curriculum with detailed information used for training the *Titulaire* in the technical area, as well as counseling cards with drawings on the front and key messages on the back for use by CHWs and CGVs. In both study areas, the Animators trained the *Titulaires* on the module content on a quarterly basis, who then trained the CHWs on a monthly basis. In the Integrated area, CHWs would then cascade the training they received to the CGVs *directly* during the bimonthly Care Group meetings, while in the Traditional area, the Promoter would train the CGVs (with support from the CHWs) during the bimonthly Care Group meetings.

Table 2: Care Group Module Topics

Nutrition	• Definition and consequences of malnutrition and screening for malnutrition • Recognition of complications and danger signs of malnutrition • Nutrition and micronutrient supplementation during pregnancy • Immediate and exclusive breastfeeding for children age 0-5 months • Complementary feeding for children age 6-8 months and 9-23 months • Food groups (strength, energy, micronutrient) • Micronutrient supplementation for children
Malaria	• Malaria transmission, symptoms, and danger signs • Malaria in pregnant women: consequences and complications • Care-seeking for malaria
Diarrhea	• Diarrhea symptoms and danger signs • Home-based management of diarrhea • Hand-washing practices; how to build a tippy-tap • Water treatment and food hygiene
Pneumonia	• Definition, danger signs, and care-seeking • Home practices to prevent pneumonia

Care Group Meetings

In both study areas, Care Groups met twice per month. During the first meeting of the month, the CGVs were taught the behavior change lesson to focus on during their home visits. The second meeting of the month was used for reporting, retraining on the monthly message if required, and discussing any problems encountered during home visits.

In the Traditional area, the Animators informed the Promoters of the date of the next Care Group meeting, who in turn informed the CHWs, who then informed the CGVs. Promoters had primary responsibility for facilitating Care Group meetings, though CHWs did play a supporting role,

particularly in the part of the meeting dedicated to reporting. In the Integrated area, the date and time of the following meeting was agreed upon between the CHWs and CGVs at the end of each Care Group meeting, with CHWs facilitating all aspects of the Care Group meetings.

Household Visits

CGVs in both study areas conducted household visits at least once per month, during which they provide targeted health education and promotion messages, screened for acute malnutrition, and collected vital events data for the C-HIS.

Supervision Systems

In the Traditional area, Animators supervised Promoters, who in turn supervised CGVs. CHWs in the Traditional area may have also assisted with CGV supervision by carrying out household visits to ensure that CGVs had effectively delivered messages. In the Integrated area, CHWs supervised CGVs by conducting follow-up household visits, reviewing CGV registers, and trouble-shooting problems during Care Group meetings. In both study areas, members of the local administration voluntarily took up a supervisory role of the CGVs, in terms of helping them solve problems such as poor meeting attendance or drop-outs.

CHWs in both study areas were supervised by the health facility-based *Titulaires*, as dictated in the Community Health Strategy.

Reporting Systems

In both study areas, CGVs submitted their reports to the Head Volunteers for compilation. In the Integrated area, the Head Volunteers submitted their reports to the CHWs, who then compiled the Head Volunteers' reports and submitted them to the *Titulaires* at the health facilities.

In the Traditional area, reporting practices were variable. Some Care Groups followed the same process as the Integrated area; while in other Care Groups, the Promoters took an active role in the compilation and/or submission of the reports to the health facility.

In both study areas, the *Titulaires* compiled the reports and submitted them to the DHT and to Concern.

Study Design and Methods

Research Questions and Hypotheses

The Care Group models were assessed to determine whether the Integrated Care Group model achieved the same levels of knowledge and practices of key child health and nutrition behaviors among caregivers of children age 0-23 months as the Traditional Care Group model, and whether the Integrated Care Group model achieved the same level of functionality and sustainability as the Traditional Care Group model.

Two hypotheses guided the study design:

Hypothesis 1: The Integrated Care Group model is associated with at least the same coverage of the knowledge and practice of key health and nutrition behaviors among caregivers of children age 0-23 months as compared to the Traditional Care Group model after two years of implementation.[3]

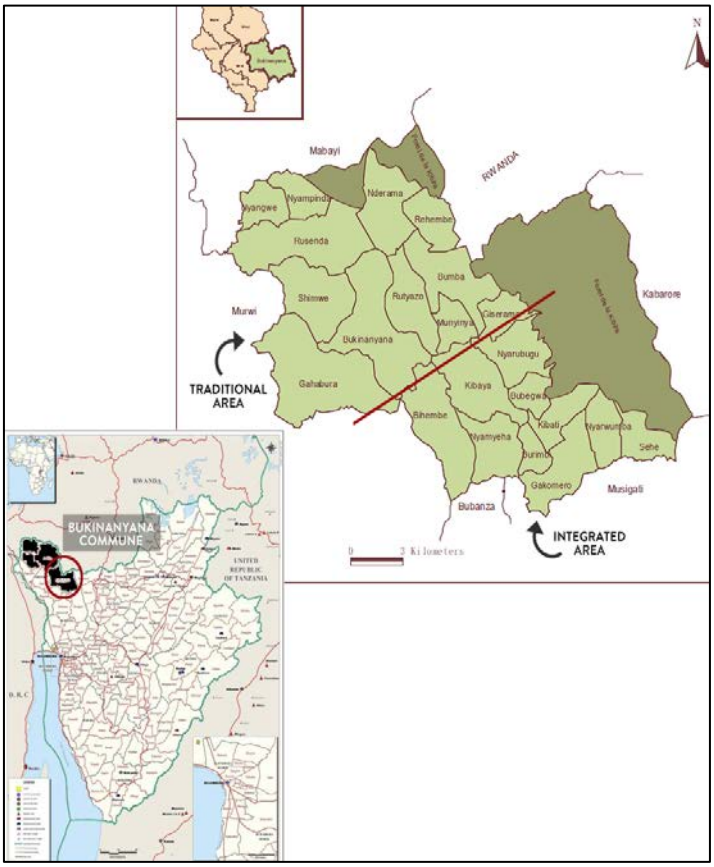
[3] The wording of the hypothesis was modified after consultation with the Johns Hopkins Biostatistics Center to better articulate the non-inferiority method used in the study.

Hypothesis 2: There is no significant difference in the func tionality or sustainability of Care Groups implemented through the Integrated Care Group model as compared to those implemented through the Traditional Care Group model after two years of implementation.

Study Design

The five MOH zones in Bukinanyana Commune were grouped into two clusters based on population size (group one consisted of three zones and group two consisted of two zones). Each cluster was then randomly assigned to either the intervention area (Integrated Care Groups) or comparison area (Traditional Care Groups). See **Figure 3** for a map of the study area. Given that that there were only two clusters, the study is quasi-experimental in nature (pre-post with a comparison group).

Figure 3: Map of the Study Area



Study Population

The total population in the study area (Bukinanyana Commune) in 2013 is 113,341. The primary study population consists of the 14,433 children age 0-59 months and pregnant women living in Bukinanyana Commune that were reached by Care Group activities (Hypothesis 1). The secondary study populations are the CGVs, CHWs, Promoters, Animators, and *Titulaires* associated with the implementation of the two Care Group models in the study area (Hypothesis 2).

Table 3 summarizes the study population in the two study areas:

Table 3: Operations Research Study Population

	Traditional	Integrated	Total
Children age 0-59 months and pregnant women	7,758	6,675	14,433
Animators (Project Staff)	1	1	2
Promoters (Project Staff)	6	0	6
Titulaires (MOH)	4	3	7
CHWs (MOH)	34	26	60
CGVs	503	478	981

Methods for Evaluative Research

Hypothesis 1 was assessed through measuring 40 key child health and nutrition knowledge and practice indicators related to diarrhea, malaria, pneumonia, and nutrition. **Table 4** summarizes the indicators measured; the full list of indicators is provided in **Annex A**. Data was collected through baseline (October 2010) and endline (May 2013) surveys of caregivers of children age 0-23 months.

Table 4: Indicators Measured for Hypothesis 1

Indicator Type	Example of Indicators Collected
Knowledge	• Danger signs in sick children • Critical times for hand-washing • Importance of increased food and iron supplementation during pregnancy • Breastfeeding and complementary feeding practices • Food groups and components of balanced diet
Preventive Practices	• Iron supplementation during pregnancy • Immediate and exclusive breastfeeding • Complementary feeding practices • Hand-washing • Insecticide-treated net (ITN) use
Sick Child Practices	• Diarrhea: care-seeking, use of oral rehydration solution (ORS), feeding practices for children with diarrhea • Malaria: care-seeking within 24 hours, treatment with artemisinin-combination therapy (ACT) • Pneumonia: care-seeking and treatment with antibiotic
Contact Intensity	• Contact with trained health information providers • Attendance at community meetings where health of child was discussed

Hypothesis 2 (Care Group functionality and sustainability) was assessed through monthly monitoring of five key Care Group operational indicators for all Care Groups in both Traditional and Integrated areas. These indicators represent standard processes monitored in Care Group projects:

1) Average number of Care Group meetings per month
2) Percentage of Care Groups with at least 80% Volunteer attendance in at least one meeting per month
3) Percentage of households with children under five or pregnant women who have received at least one household visit by a CGV per month
4) Percentage of CGVs who reported C-HIS data to Promoters (Traditional area) or CHWs (Integrated area) per month
5) Percentage of CHWs who submitted completed monthly reports on Care Group activities and C-HIS data to HCs per month

The Care Group operational indicators were monitored over two key stages: 1) during the implementation of Care Groups with project support from Concern (June 2011 - February 2013) for an assessment of functionality and 2) during the implementation of Care Groups without project support from Concern (March 2013 - August 2013) for an initial assessment of sustainability.

Methods for Hypothesis 1 (Knowledge and Practice)

Sample

A non-inferiority method was identified as the most appropriate option for testing Hypothesis 1, since the objective of the research was to determine whether or not the Integrated Care Group model results in either comparable or inferior results as the Traditional Care Group model. Non-inferiority studies aim to show that a new treatment or intervention is not unacceptably worse than the usual standard of care. In regular superiority studies, which form the bulk of public health research, the null hypothesis is that there is *no* difference between two interventions while the alternative hypothesis is that there *is* a difference between two interventions. Non-inferiority

studies switch this convention. In these trials, the null hypothesis is that there *is* a difference between the two groups, specifically that the new intervention is worse than the old by more than the non-inferiority margin. The alternative hypothesis is that there is *no* difference between the two groups, specifically that the difference in effect between the old intervention and the new intervention is less than the non-inferiority margin (10, 11). A non-inferiority margin of ten percentage points was chosen for this study, based on a review of previous Care Group observational studies, general Food and Drug Administration guidance to use 10% at a minimum, and the technical experience of Concern Worldwide with Care Groups in other settings.

The baseline sample size was calculated to detect a difference of 10% between the two intervention groups for each indicator being considered (alpha 0.05, beta 80%). The target sample size was 345 mothers of children age 0-23 months per cluster. This represented the base sample size of 310 mothers plus 10% to account for non-response and loss to follow-up.

The sample size for the endline survey was calculated to detect a non-inferiority margin of 10 percentage points for the two intervention groups for each indicator being considered (one-sided alpha 0.05 or two-sided alpha of 0.1, beta 80%). The target sample size for the baseline was 345 per study area. This represented the base sample size of 226 mothers plus 10% to account for non-response and loss to follow-up, as well as to ensure sufficient sample size for the sick child indicators. Experience from the baseline survey showed the non-response/untraceable rate was closer to 15% so the target sample for the endline was increased further, making the target for each arm 363 mothers.

The sampling frame used for both the baseline and endline surveys was obtained from a census of all households with children under five years of age in Bukinanyana Commune that was conducted by Concern in July 2010 (baseline) and April 2013 (endline).

Table 5 details the actual sample size for the baseline and endline KPC surveys.

Table 5: Sample Size for Baseline and Endline KPC Surveys

Respondent Category	Baseline			Endline		
	Traditional	Integrated	Total	Traditional	Integrated	Total
Total caregivers of children age 0-23 months	**296**	**297**	**593**	**347**	**353**	**700**
0-5 months	39	27	66	51	59	110
6-23 months	257	270	527	296	294	590
Sample size for sick child conditions						
Caregivers of children with fever during the previous two weeks	90	96	186	159	166	325
Caregivers of children with diarrhea during the previous two weeks	87	95	192	109	89	198
Caregivers of children with cough/difficulty breathing during the previous two weeks	93	83	176	173	162	335

Survey Questionnaire

The 2008 Rapid CATCH indicators and their associated modules relevant to the program's technical interventions were used as the foundation of the survey questionnaire. Additional questions were added to capture contact intensity. Each questionnaire was designed to record the sample number, informed consent, and interviewer and supervisor verification of information. Respondent name and location were also collected, but were deleted from the dataset before analysis was conducted.

The questionnaires were initially developed in English then translated into French and Kirundi by members of the survey team. See **Annex B** for a copy of the questionnaire.

Data Collection, Entry, and Analysis

Baseline data was collected in September 2010 entered into Epi-Info from the hardcopy questionnaires. Data cleaning, recoding, and bivariate analysis was conducted using SPSS versions 17 and 20. Chi-squared tests for proportions and independent sample T-tests for means were used to determine statistically significant differences between the two groups at baseline.

Endline data was collected in May 2013. No data entry was required as all data was collected digitally using PSIFusion software. The completed survey dataset was exported into Excel for initial cleaning. Further cleaning, recoding and bivariate analysis were done in SPSS versions 20 and 21. STATA 10 was used to conduct non-inferiority testing on endline data. Non-inferiority was determined by constructing two-sided 90% confidence intervals (CIs) and comparing the upper bound of the difference between Traditional and Integrated Care Groups to the pre-specified non-inferiority margin of 10 percentage points (12). If the CI's upper bound was less than the predefined margin, then non-inferiority was able to be claimed for the Integrated Area as compared to the Traditional Area at a 0.05 level of significance. The Agresti-Caffo method was used to calculate confidence intervals rather than the traditional Wald method because the Agresti-Caffo method has better statistical properties (12).

Methods to Assess Care Group Functionality and Sustainability

Care Group functionality and sustainability was assessed through the collection of monthly monitoring data from Care Group activity registers in both study arms to assess the five key Care Group operational indicators. CGVs submitted reports to CHWs who in turn submitted reports to *Titulaires* and Concern. Targets for each indicator were set at 80%, based on common practices for other Care Group projects. In the first 21 months of study implementation (June 2011 – February 2013), quarterly averages of the five Care Group operational indicators were calculated to assess Care Group functionality. At the end of February 2013, Concern withdrew support to Care Group activities: Animators ceased supporting Care Group activities in both study areas, and Promoters were pulled out of the Traditional area. In the last six months of study implementation (March – August 2013), the five Care Group operational indicators were monitored monthly to assess Care Group sustainability.

Methods for Formative Research and Process Documentation

In the context of research on implementation models that aim to deliver behavior change interventions at the community level, it has been noted that retrospective and external assessments do not sufficiently penetrate the "black box of implementation" (9). As such, this study aimed to document the context, challenges, and changes associated with implementation of both the Traditional and Integrated Care Group models in a prospective manner. To do so, Concern conducted a mid-term qualitative process evaluation of the OR in September 2011 to document the implementation and functionality of the two models and the successes, challenges, and changes associated with their implementation; as well as elicit and document responses from the full range of actors and community members involved in the implementation of the two models.

A total of 15 FGDs were completed with beneficiary mothers, husbands of CGVs, CGVs, CHWs, Promoters, *Titulaires,* TPS, local administrative leaders, and Health Management Committee members. FGDs were grouped by participant category and by study area. In-depth interviews were conducted with two TPS, two Concern Animators, and one member of the Mabayi DHT. FGD and in-depth interview transcripts were translated from Kirundi into French by the note-takers and

imported into Weft qualitative data analysis software. Transcripts were coded by theme, and all responses were moved to a master document, where they were organized by code and study area for all participants. Patterns emerging from each code were then summarized and supported by quotations.

Non-participant observation techniques were also applied: quality checklists adapted from previous Care Group projects were developed to rate the quality of five home visits in each study area and five Care Group meetings in the Traditional area and six Care Group meetings in the Integrated area. A percentage score was calculated for each completed quality checklist and any comments were included in the overall analysis and comparison of results.

In addition to the process evaluation, Concern also developed a program learning brief, which described in detail the process through which Care Groups were established and implemented.

Ethical Considerations

Ethical approval for this study was obtained from the Trinity College of Dublin Health Policy and Management's Centre for Global Health Research Ethics Committee.

Findings

Formative Research and Process Documentation

The mid-term process evaluation conducted in September 2012 provided extensive qualitative data on the functioning of the two Care Group models. Several key findings have emerged from the data.

There is an overwhelming amount of qualitative data to suggest that Care Group activities in both areas have vastly increased the communities' knowledge, had an impact on behavior, particularly around care seeking, and had an impact on health outcomes. In addition, local administrative leaders and Health Committee members strongly support Care Group activities in both areas. However, CHW supervision by both *Titulaires* and TPS was an ongoing challenge in both study areas due to lack of time, lack of transport, and the financial disincentive of community-based work compared with health-facility based work following the introduction of performance-based financing. In both study areas, the Animators often took the most active role in supervising CHWs with regards to Care Group activities.

The process evaluation also found that the CHWs had taken on a more active role in Care Group meeting facilitation and reporting in the Traditional area than had originally been anticipated. This finding will undoubtedly serve to facilitate the transition to Concern's departure from the project in the Traditional area; however, it does impact the overall comparability of the two models and may limit the conclusions that may be drawn regarding the merits of one model over the other.

Please reference **Annex C** for the full process evaluation report, as well as **Annex D** for a Learning Brief summarizing the key inputs and processes for establishing Integrated Care Groups in Burundi.

Adaptations to Intervention over the Course of the Study

Following the mid-term process evaluation, selected changes were made to Care Group implementation in both study areas to address challenges identified. *Titulaires* in both study areas were originally expected to have a key role in CHW training and supervision; however due to the responsibilities of the *Titulaire* as head nurse at the health facility, there was often limited time for them to do so. As a solution, Concern worked with the *Titulaires* to identify an alternate 'focal point' for all Care Group activities, usually a more junior nurse who had fewer time constraints.

As noted above, the role of CHWs in the Traditional area was significantly more active than originally anticipated, especially in regards to Care Group meeting facilitation, reporting, and supervision of CGVs. Concern did not discourage CHWs from taking more of a leadership role in Care Group activities in the Traditional area, and believes it is a sign of community approval of the structure of the Integrated model. That said, although Promoters did maintain lead responsibility for all Care Group facilitation and supervision duties, greater CHW involvement in the Traditional area may have diluted the differences between the two models as they were tested over the life of the study.

Evaluative Research

Hypothesis I: The Integrated Care Group model is associated with at least the same coverage of the knowledge and practice of key health and nutrition behaviors among caregivers of children age 0-23 months as the Traditional Care Group model

Participant Characteristics

Table 6: Demographic and Socioeconomic Characteristics of Households with Children Age 0-23 months

Characteristic	Percent, CIs, & p-value		
	Traditional n = 296	Integrated n = 297	p-value
Age			
0-5 months	14.9% (10.8-19.0)	9.8% (6.4-13.2)	0.075
6-11 months	25.1% (20.1-30.1)	29.0% (23.8-34.1)	0.333
12-23 months	60.0% (54.4-65.6)	61.3% (55.7-66.9)	0.815
Household Composition			
Mean # of children	1.9 (1.8-1.9)	1.8 (1.7-1.9)	0.297
Male head of household	96.6% (94.5-98.7)	95.9% (93.6-98.2)	0.815
Education			
Illiterate	66.2% (60.8-71.6)	67.2% (61.8-72.6)	0.862
Basic literacy	27.0% (21.9-32.1)	26.4% (21.3-31.4)	0.926
Completed primary	6.8% (3.9-9.6)	5.1% (2.5-7.6)	0.486
Household Economy			
Agricultural work, other's land	17.9% (13.5-22.3)	29.3% (24.1-34.5)	0.002
Sell crops	28.7% (23.5-33.9)	16.8% (12.5-21.1)	0.001
Work outside home	42.9% (37.0-49.0)	46.8% (41.0-53.0)	0.384
HDDS	4.65 (4.4-4.9)	4.20 (4.0-4.4)	0.004

Table 6 presents demographic and socioeconomic status data for the two groups at baseline. The age and household composition indicators showed no statistically significant differences. The vast majority of households were headed by males, and the majority of respondents were illiterate.

There was a statistically significant difference in three of the four household economy measures. The percent of households who worked on other people's land to earn money was significantly higher in the Integrated area (30% versus 18%), while the percent who sold crops to earn money was significantly higher in the Traditional area (29% versus 17%). The mean Household Dietary Diversity Score (HDDS), which ranges from 0 to 11, was significantly higher in the Traditional area (4.7) compared to the Integrated area (4.2).

These three economic status measures suggest that households in the Traditional area may be wealthier than those in the Integrated area. Providing casual labor on other people's farms is usually an activity in which

poorer households are engaged and is sometimes considered a coping strategy (14). On the other hand, households who sell crops (including cash crops) are generally better off than those who rely on subsistence farming. Lastly, the HDDS is a proxy measure for household socioeconomic status. A more diversified diet is correlated with higher household income (15). However, differences in economic status between the two study areas did not persist at end line. Concern Burundi staff hypothesize that at baseline, villages in the Integrated study area had less access to markets than the Traditional area, which is home to the main towns and commercial centers in the area. Since 2010, security has improved, as have the availability of motorcycle taxis, which have served to increase access to markets in villages in the Integrated area.

Despite the potential wealth differences between the two groups at baseline, the two areas are largely comparable. Nine of the 12 socioeconomic and demographic indicators show no statistically significant differences. Moreover, the differences that are statistically significant favor the Traditional area since greater wealth is associated with better health knowledge and behaviors. Nonetheless, the lack of perfect comparability between the two groups at baseline may have introduced selection bias in this study.

Non-Inferiority Analysis Findings

Overall, the project successfully demonstrated that the Integrated model was not inferior to the Traditional model as measured by 40 key health and nutrition indicators: 36 of the 40 indicators (90%) in the Integrated area were not inferior to those same indicators in the Traditional area. Of the 27 practice indicators, 25 (93%) were not inferior. Of the 13 knowledge indicators, 10 (77%) were not inferior.

The full results of non-inferiority testing for all 40 indicators are provided in **Annex A.** Presented in this section are ten of the 40 outcome indicators measured. These indicators represent key child health and nutrition practices with a robust causal associate with child morbidity and mortality (3).

Table 7 presents the results of the non-inferiority testing for the ten key child health and nutrition practices in the Integrated Care Group and traditional Care Group areas. All ten indicators were non-inferior in the Integrated Care Group area, compared to where Traditional Care Groups were implemented.

Table 7: Non-Inferiority Analysis Results for Select Indicators

No.	Indicator	Traditional		Integrated		Non-Inferior?
		N	Percent (CI)	N	Percent (CI)	
1	% mothers who received >= 90 days of iron-folate supplementation during most recent pregnancy	347	19.7% (14.7-24.8)	353	16.9% (12.3-21.5)	Yes
2	% children who slept under an ITN the previous night	347	32.0% (27.02-36.93)	353	34.9% (29.94-39.95)	Yes
3	% caregivers who report washing hands with soap during at least 3 of 4 critical times in last 24 hours	347	22.8% (18.33-27.20)	353	34.7% (29.66-39.65)	Yes
4	% children age 0-5 months exclusively given breast milk day prior to interview	51	92.2% (84.5-99.8)	59	91.5% (84.2-98.8)	Yes
5	% breastfed children age 6-23 months who ate from >=4 food categories during previous 24 hours	267	52.1% (46.0-58.1)	263	55.9% (49.8-61.9)	Yes

Table 7: Non-Inferiority Analysis Results for Select Indicators

No.	Indicator	Traditional		Integrated		Non-Inferior?
		N	Percent (CI)	N	Percent (CI)	
6	% children with diarrhea in last two weeks who received ORS or recommended home fluids	109	89.4% (81.77-97.02)	89	92.5% (85.10-99.80)	Yes
7	% children with diarrhea in last 2 weeks whose mothers sought outside advice or treatment for illness	109	81.7% (74-89)	109	86.5% (79-94)	Yes
8	% children with febrile episode in last 2 weeks taken to appropriate place for treatment	159	99.3% (97.87-100)	166	98.7% (96.85-100)	Yes
9	% children with febrile episode in last 2 weeks treated with anti-malarial within 24h after fever began	159	17.0% (11.08-22.88)	166	20.5% (14.28-26.69)	Yes
10	% of children with cough and fast/difficult breathing in the last two weeks who were taken to a health facility or received antibiotics from an alternative source	173	88.3% (83.2 – 93.4)	162	92.3% (87.9 – 96.7)	Yes

*Upper bound limit of the confidence interval of the difference between the two groups does not exceed 10%

Hypothesis 2: There is no significant difference in the functionality or sustainability of Care Groups implemented through the Integrated Care Group model as compared to Care Groups implemented through the Traditional Care Group model

Summary of Findings

Table 8 presents data for the five Care Group operational indicators against their respective targets. The 'functionality' period is defined as the period of time during which Promoters were actively supporting Care Group activities in the Traditional area (June 2011 – February 2013), while the 'sustainability' period indicators represent the six-month period following the withdrawal of Promoters and other Concern support to Care Group activities in both study areas (March – August 2013). Analysis focuses on identifying any significant difference greater than 15 percentage points in the key operational indicators between Care Groups implemented through the Traditional or Integrated Care Group models during both the first phase and the second phase of analysis.

Overall, all five Care Group operational indicators nearly met or surpassed the targets during the functionality period, and there was no significant difference in Care Group functionality between the two models. Following the withdrawal of Concern support to Care Group activities at the end of February 2013, Care Group performance in both study areas remained largely unchanged.

Table 8: Care Group Functionality and Sustainability Indicators

Indicator	Target	Average Functionality, per quarter (June 2011 – Feb 2013)		Average Sustainability, per month (March – August 2013)	
		Traditional	Integrated	Traditional	Integrated
Average number of Care Group meetings per month	2	1.9	1.9	1.9	1.9
Percentage of Care Groups with at least 80% Volunteer attendance in at least one meeting per month	80%	87%	91%	83%	91%
Percentage of households with children under five or pregnant women who have received at least one household visit by a CGV per month	80%	94%	87%	95%	94%
Percentage of CHWs who submitted completed monthly reports on Care Group activities and C-HIS data to HCs per month	80%	94%	93%	93%	96%
Percentage of CGVs who reported C-HIS data to Promoters (Traditional area) or CHWs (Integrated area) per month	80%	96%	96%	94%	95%

Number of Care Group Meetings and Attendance

The average number of monthly Care Group meetings remained above 1.6 during the entire project implementation period for both groups and seemed to level out around the overall average of 1.9 by the end of the study period. The target of two meetings per month was largely met, and this continued to be the case following the withdrawal of Concern support to Care Group activities in both study areas.

The percent of Care Groups with at least 80% volunteer attendance in at least one Care Group meeting per month remained above its target during the functionality period. Following the withdrawal of Concern support to Care Group activities in both study areas, meeting attendance in the Traditional Care Group area began to drop, eventually dipping below the target of 80% after four months. Meeting attendance in the Integrated Care Group area during the sustainability period was consistently above the target value of 80%.

The mid-term process evaluation also assessed the quality of the Care Group meetings in both study areas using a quality checklist. Although the meeting observations were carried out with a very limited sample size, results suggest that the overall quality of Care Group meetings may be slighly higher in the Traditional area. This is not unexpected, as the Promoters have a higher level of education than the CHWs and are salaried members of project staff whose primary funtion is to facilitate Care Group activities. Each Promoter is responsible for up to nine Care Groups, as opposed to CHWs in the Integrated area, who are responsible for just two to four. Promoters are therefore more practiced with meeting facilitation techniques and the content of the messages due to the increased frequency with which they conduct meetings.

Home Visits

For the first three quarters of the functionality period, the Integrated Care Groups were performing at a noticeably lower level than the Traditional Care Groups, although this was eventually

strengthened and CGVs in both study areas achieved nearly the same reach in the final quarter. Coverage of Care Group home visits continued at the same high level following withdrawal of Concern support to Care Group activities in both study areas.

The mid-term process evaluation also assessed the quality of home visits in both study areas using a quality checklist. In both study areas, common weaknesses were asking the mother about her current practices before advising on the recommended behavior and asking the mother about her perceived barriers to adopting the recommended practice. Not surprisingly, areas of weakness identified during Care Group meetings are the same as those identified during home visits, particularly the failure to explore barriers to practicing a behavior. This reinforces the importance of the content and quality of Care Group meetings, which in turn influences the quality of the home visits.

Reporting

Overall, reporting rates by both CHWs and CGVs remained high during the functionality period and significantly exceeded the target of 80%. Following the withdrawal of Concern support to Care Group activities in both study areas, CHW reporting remained high in in the Integrated area, while in the Traditional area, CHW reporting fluctuated but overall remained above the 80% target. CGV remained high in both study areas during the sustainability period.

Discussion

Summary of Findings

Hypothesis I: Overall, there is strong evidence that the Integrated Care Group model is not inferior to the Traditional Care Group model. Thirty-six of the forty indicators (90%) were not inferior in the Integrated Area. The non-inferiority of the Integrated model is particularly evident among the practice indicators. Non-inferiority was more moderate among the knowledge indicators, primarily because of lower than expected knowledge among mothers of food intake requirements for children at different ages. There are some challenges in improving dietary intake and malaria indicators between baseline and endline in both study areas. However, the Integrated area was not inferior in the large majority of these measures.

Hypothesis II: Overall, all five Care Group operational indicators nearly met or surpassed project targets, and there was no significant difference in Care Group functionality between the two models. Following the withdrawal of Concern support to Care Group activities at the end of February 2013, Care Group performance in both study areas remained largely unchanged.

Data from the process evaluation also demonstrated that CHWs have sufficient technical capacity and time to lead Care Groups and train and supervise CGVs. CHWs have demonstrated great commitment and motivation to their role in Care Group facilitation, and would benefit from greater guidance from HC staff. Indeed, another key finding from this research was that *Titulaires* do not have sufficient time to train, supervise, and support CHWs. Therefore, other "focal points" (e.g. junior nurses) at the HC level should be tasked with training, supervising, and supporting CHWs in their day-to-day activities.

This research has also reinforced the existing evidence that Care Groups are a highly effective strategy to achieve key child survival priorities. CGVs are a valuable source of health education messages in their community, and the Integrated Care Group model demonstrates how CGVs provide a means to extend the reach of CHWs to achieve high levels of behavior change at the individual and household levels. In addition and as similarly demonstrated in other Care Group projects, CGVs are able to effectively collect and report C-HIS data, including vital events. The

Integrated Care Group model demonstrates how such data may be directly integrated into the national HIS through both CGVs and CHWs.

Limitations

There were three main limitations to the study methods. First, the study was a pre-post quasi-experimental design with non-equivalent comparison groups. Since there were only two study areas (with one area randomly assigned to the Traditional intervention and the other assigned to the Integrated intervention) there may be some differences that confound the effects we see in the study. The baseline survey found wealth differences between the two groups, which may limit attribution. While these differences are likely to favor the Traditional area (i.e. make it more difficult to prove that the Integrated area is not inferior), the study is unable to fully account for these potential confounders.

Second, non-inferiority trials are usually conducted on pharmaceuticals, biologics, and medical devices. As such, previous randomized, placebo-controlled trials (RCTs) measuring the efficacy of the "active control" (in this case the Traditional model) are generally used by researchers to determine the margin of significance. The margin should be no greater than the smallest reliable effect size of the treatment (i.e. Traditional Care Group) compared to the placebo-control (no Care Group). In the case of Care Groups, no such robust RCTs are available. As such, the 10% margin was determined based on a review of previous Care Group observational studies, general Food and Drug Administration guidance to use 10% at a minimum, and the technical experience of Concern Worldwide with Care Groups in other settings (12).

Third, the baseline and endline surveys were conducted at different times of year, October 2010 and May 2013, respectively. May is the tail end of the long rainy season and the end of the "small hunger period", while October is the middle of the short rainy season and the "big hunger period." There is usually an increase in malnutrition and malaria cases in October. Therefore, it is likely that the baseline survey measured households when they were relatively worse off, while the endline occurred when households were better off. This does not affect the non-inferiority findings since these measures were taken at endline. However, seasonal variation does potentially confound the baseline versus endline results.

Cost Considerations

For an effective implementation strategy to be scaled-up, it must be cost effective and feasible for the health system to maintain. A previous evaluation of a $3.0 million USAID-funded Care Group project in Mozambique targeting 219,617 mothers with children age 0-23 months had an average cost of $2.78/beneficiary/year (16). Cost is a key factor to consider in scale-up, and NGO costs to implement an intervention may vary from MOH costs. Unfortunately this study did not track expenditures associated with the costs of implementing the two models and therefore does not have reliable data to make any conclusions on the relative cost savings of the Integrated Care Group model. Future studies assessing the Integrated Care Group model should specifically document project inputs, as well as costs borne by the MOH in the Integrated model's implementation for a true cost comparison.

Despite not having costing data available, there are clear positive externalities to the Integrated model compared to the Traditional model. CHWs train and supervise CGVs in the Integrated area. As such, they are simultaneously strengthening their own knowledge and skills, as well as their ability to deliver higher quality health services to their target households. Moreover, CHWs have gained a somewhat higher status in the community as they engage in supervisory activities comparable to NGO staff.

In addition to costing, we recommend a future sustainability assessment on this model. Given that this study only provides initial estimates of sustainability, Concern recommends that further research examining health and nutrition outcomes, as well as Care Group operational indicators, be conducted in both the Integrated and Traditional study areas within the next two years.

Conclusion and Utilization of Results

Based on these conclusions, Concern recommends that the Integrated model be scaled-up in Burundi and that CGVs be integrated as a formal component of the community health system to improve coverage of key health and nutrition interventions at the individual and household levels. Existing CHW PBF policies could be revised to include key Care Group operational indicators to further incentivize and institutionalize the model. While NGOs will still have a role in the medium-term to build the capacity of the MOH at the district level to implement the Integrated model, it is conceivable that the model could be scaled-up and institutionalized within existing community health structures.

Throughout the OR study, the MOH has demonstrated a keen interest in the potential of the Integrated Care Group model. Following a presentation on the Integrated Care Group model to the MOH, UNICEF, and other NGO implementing partners, representatives from the MOH, UNICEF, and the WHO visited the project area in May 2013 to observe the Integrated model in action. The MOH representatives praised the model, specifically noting the clear delineation of roles between CHWs and CGVs, as well as its ability to extend full coverage of key interventions to all households, strengthen linkages between the community and health facility levels, and incorporate C-HIS data into the national HIS.

Concern will continue to engage with the MOH and other key stakeholders to advocate for the formal inclusion of the Integrated Care Group model into the existing community health system. Existing human resources, such as MOH staff and CHWs, could easily be leveraged while the reproduction of BCC modules may continue to require partner support. In the medium-term, Concern envisages a continued need for NGO support to continue to build the capacity of the MOH at the national, provincial, and district levels to institutionalize the model into the nascent community health system.

Key considerations that remain to be addressed regarding the scale-up of the Integrated Care Group model by the MOH in Burundi and other settings include:

- Who will initiate the approach and how will key MOH staff be trained in its implementation?
- How will quality control and formal supervision of Care Group activities be provided?
- What data should CGVs collect?

The official findings of this study were disseminated to the MOH, UNICEF, and key implementing partners in September 2013. A manuscript will also be submitted for publication in the Global Health Science and Practice Journal and the findings will be presented at public health fora over the next year, including at the American Public Health Association and CORE Group meetings.

References

1. The World Health Organization and UNICEF. (2013). *Accountability for maternal, newborn, and child survival: The 2013 Update.*
2. UNICEF Burundi Background. Available at: http://www.unicef.org/infobycountry/burundi_2774.html
3. Jones, A. et al. (2003). *How many chlld deaths can we prevent this year?* The Lancet (362): 65-71.
4. Davis, T. et al. (2013). *Reducing child global undernutrition at scale in Sofala Province, Mozambique, using Care Group Volunteers to communicate health messages to mothers*. Global Health Science and Practice (1): 35-51.
5. Edward, A., Ernst, P., Taylor, C., Becker, S., Mazive, E., & Perry, H. (2007). *Examining the evidence of under-five mortality reduction in a community-based programme in Gaza, Mozambique.* Transactions of the Royal Society of Tropical Medicine and Hygiene (101): 814-822.
6. Purdy C., Weiss, W., Perry H. *The Mortality Assessment for Health Programs (MAP) System: An NGO Field Manual for Registering Vital Events and Assessing Child Survival Outcomes Using the Care Group Model.* 1st Edition. January 2013. Washington, D.C: CORE Group.
7. Hanold, M., Wetzel, C., Davis, T., Borger, S., Cutherell, A., & DeCoster, M. (2012). *Care Groups: A Training Manual for Program Design and Implementation.* Washington, DC.: Food for the Hungry.
8. Establishing Care Group Criteria. 2010. Available at: http://www.caregroupinfo.org/docs/Care_Group_Criteria_November_12_2010.pdf
9. Peterson, Stefan. (2010). *Assessing the scale-up of child survival interventions.* The Lancet (375): 530-531.
10. Christensen, E. (2007). *Methodology of superiority vs. equivalent and non-inferiority trials.* Journal of Hepatology (46): 947-954
11. Piaggio, P. et al. (2006). *Reporting of Noninferiority and Equivalence Randomized Trials: An Extension of the CONSORT statement.* Journal of the American Medical Association (295) 1,152-1,160.
12. Agresti, A. and Caffo, B. (2000). *Simple and Effective Confidence Intervals for Proportions and Differences of Proportions Result from Adding Two Successes and Two Failures.* The American Statistician (54:4) 280-288.
13. D'Agostino, R., Massaro J., & Sullivan, M. (2003). *Non-inferiority trials: design concepts and issues – the encounters of academic consultants in statistics*. Statistics in Medicine (22): 169-186.
14. Eriksen, S. and Silva, J.A. (2009). *The vulnerability context of a savanna area in Mozambique: household drought coping strategies and responses to economic change.* Environmental Science and Policy (12): 33-52.
15. Swindale, Anne and Paula Bilinksy. *Household Dietary Diversity Score for Measurement of Household Food Access: Indicator Guide (v.2).* Washington, DC: Food and Nutrition Techncial Assistance Project, Academy for Educational Development, 2006.
16. Perry, H. 2010. *Expanded Impact Child Survival Program Final Evaluation Report; Sofala Province, Mozambique.*