Pre-Analysis Plan

Evaluation of Living Goods/BRAC entrepreneurial CHW model in Uganda

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1. Introduction

This document lays out the pre-analysis plan for the study titled "Evaluation of Living Goods/BRAC entrepreneurial CHW model in Uganda". The study was registered in accordance with WHO and ICMJE standards in the PACTR registry prior to baseline data collection, on 22/12/2015 (registration number PACTR201609001398349).

The study aims at evaluating the impact of an innovative model of community health delivery implemented in Uganda by two NGOs, Living Goods and BRAC. Unlike most volunteer-based community health worker programs, the community health promoters (CHP) program implemented by the two NGOs harnesses the power of franchised direct selling to provide CHPs with incentives to increase access to low-cost, high-impact health products and basic newborn and child health services.

The CHP program is organized into geographically based branches, and managed by branch managers and supervised by the two NGOs. Each CHP is assigned to a specific cluster, which in most cases corresponds to a village. The CHPs tasks are to conduct home visits, educate households on essential health behaviors, provide basic medical advice, referring the more severe cases to the closest health center, and sell preventive and curative health products. The product line they have at disposal include prevention goods (e.g. insecticide treated bednets, water purification tablets, and vitamins), curative treatments (e.g. oral rehydration salts, zinc, and ACTs), as well as other health-related commodities (e.g. diapers, detergent, and hand soap) and durables with health benefits (e.g. improved cook stoves, solar lights, and water filters). These products are sold by the CHP at a discount. The retail price is determined by branch managers with a target of keeping prices for preventive and curative products lower than the prevailing local market prices. The CHPs in turn purchase these products directly from Living Goods or BRAC local branches at wholesale prices. Thus, the CHPs operated as micro-entrepreneurs with financial incentives to meet household demand.

A first evaluation of the impact of the CHP program was conducted between 2011 and 2013. The evaluation, based on a cluster-randomized controlled trial, found that the CHP program was highly effective in reducing child mortality. This study, which also relies on a cluster-randomized controlled trial methodology, represents a follow-up evaluation, which

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takes advantage of the scaling up of the CHP program within Uganda. Its aim is to test whether the positive impact can be sustained as the project gets scaled-up. More specifically, the main question this study will answer is: *can the reduction in under-5, infant and neonatal mortality observed in the first study be sustained when the program is running at scale?*

2. Survey Components

The study covers 500 villages, spanning 13 districts of Uganda. There are 15 different branches of the two NGOs implementing the program located across the stud area. Villages were randomly allocated into a treatment (250 villages) and a control (250 villages) group after baseline data collection. The randomization was done within each one of the 15 areas (randomized block design). The CHP program started being implemented soon after baseline data collection only in the 250 treatment villages.

The baseline data collection took place in the first half of 2016 and had 4 different components:

1) *Household survey.* As the evaluation focuses on child health outcomes, the goal was to identify households in the study village most likely to have newborns (and hence be in need for health services for them) during the study period. On the basis of pre-testing and conversations with key local actors, we identified four key criteria for identifying eligible respondents: 1) female, aged 16-30 years old, 2) pregnant at the time of the baseline survey, and/or 3) with a young child less than three years old, and/or 4) married (formally or informally). Each village was enumerated prior to baseline and a random sample of eligible households (25 households per village) was selected to be surveyed. The selected households will be followed-up during the evaluation period. In the selection, priority was placed on pregnant women, then women with a young child, then married women. The survey respondent was always a permanent resident of the selected household, female, aged 16-30 years old, and either currently pregnant, with a young child, or married.[4] The final sample consisted of about 12,500 households.
2) *Anthropometric survey.* We recorded anthropometric data on all children below five years of age in the selected households.
3) *Community Health Worker survey.* The survey was administered to all active community health workers in the village to learn about their health knowledge and their activities.
4) *Drug quality survey.* We collected samples of medicines to treat malaria (ACT drugs) and pneumonia (amoxicillin) from local shops, using covert shopper approach, and we then tested the quality of the drugs.

A midline survey will be collected towards the end of 2017. The survey will have only a short household component.

Endline data collection will start in mid-2019 and will have the same 4 components as baseline.

[4] When multiple women in one household met the criteria, we selected the woman most likely to remain in this household for the next three years (e.g. wife of head of household), and if we still needed to choose, we prioritized the youngest eligible woman.

3. Outcomes

Primary Outcome

Our primary outcome of interest to evaluate the impact of the program is child mortality. We will compute child mortality using information contained in the household survey. The survey records: 1) detailed birth information on all children under five living in the households at the time of the survey; 2) detailed birth and death information on all children that died under the age of five during the study period; 3) detailed birth and (if the child died) death information on all children that were under the age of 5 and were recorded as living in the study households at the time of the baseline.

At endline, for each child, we will define the number of month of exposure to the risk of death during the trial period, defined as the difference between the birth date of the child, or the start date of the trial if the child was born before that date, and the date that the child turned five years if that occurred during the trial period, or the date of the endline household survey if the child was less than five years old at that time, or the date of the death of the child. Under-five mortality will then be calculated as number of under-five deaths over the trial period per 1000 child-years of exposure to the risk of dying under the age of five. We will also compute infant mortality as number of deaths during the trial period arising within the first year of life per 1000 infant-years of exposure, with infant-years of exposure calculated in a similar way as the child-years of exposure to the risk of death. Finally, we will compute neonatal mortality as the number of deaths during the trial period within the first month of life per 1000 births.[5]

Secondary outcomes

By relying on the 4 different survey tools mentioned above, we will collect a range of additional outcomes that will allow us digging deeper into the mechanisms behind the main result. Importantly, the collection of information on activity, knowledge and motivations of all community health workers operating in the study area will allow us to investigate whether and how the presence of private actors in health delivery interact with and affect the activity of other health actors.

In the table below we report the list of the variables we are planning to investigate in our analysis, arranged by category. The first column reports a short description of the variable, while the second column report the source used to construct it.

[5] International organizations such as UN and WHO typically express mortality in terms of deaths per 1000 live-births. Such organizations use data collected over long periods of time and rely on a life-table approach to compute mortality as a probability. Given that our evaluation lasts only for three years, the most appropriate approach in our case is to compute mortality as a ratio, following the steps described above, and to express it in terms of years of exposure. For completeness and in other to facilitate comparisons with other estimates, we will in any case also report results obtained using a life-table approach, although they should be considered less reliable.

1. Household (HH) interaction with CHP	
a. HH interactions with Living Goods/BRAC CHP	HH survey
2. Health Outcomes	
a. Height-for-age and Weight-for-height for children under-5 living in the household (expressed in z-scores)	Anthro survey
b. Malaria, diarrhea and pneumonia prevalence among children under-5	HH survey
c. Share of miscarriages and stillbirths	HH survey
d. Number and frequency of pregnancies and births	HH survey
3. Health Knowledge	
a. Respondent knowledge concerning causes and treatment of malaria and diarrhea	HH survey
b. Respondent knowledge concerning breastfeeding practices	HH survey
c. Respondent familiarity with food with added vitamins or nutrients	HH survey
4. Household Health Behavior	
a. Household standard prevention and treatment practices for diarrhea, malaria, and acute respiratory infections	HH survey
b. Household food consumption habits	HH survey
c. Ante-natal and post-natal care practices, including breast-feeding practices	HH survey
5. Health services	
a. Whether household received follow-up visits by health staff following health-related problems with children under-5, or delivery	HH survey
b. Whether household received referrals to a health facility due to health-related problems with children under-5, or pregnancy	HH survey
c. Whether pregnant women in the hoodhoods received counselling and health recommendations	HH survey
6. Community Health Workers knowledge and activity	
a. Level of satisfaction and confidence of health workers	CHW survey
b. Level of self-reported activity of the health workers	CHW survey
c. Knowledge of health workers concerning malaria and diarrhea	CHW survey
d. Revenues of the health workers	CHW survey
7. Drugs quality	
a. Average quality of the ACT and amoxicillin drugs sold in the village stores (village level variable)	Drug quality survey

b. Number of drug stores that opened (closed down) during the study period (village level variable)	Drug quality survey

4. Analysis

Empirical Model

Our primary specification will entail the regression of the outcome variables on a dummy for the treatment status of the village:

$$Y_{i,h,v,b} = \beta T_{v,b} + \tau_b + \varepsilon_{i,h,v,b}$$

Where Y is the outcome for individual i (depending on the outcome, it might be a child, a woman, or a community health worker), living in household h, in village v, and branch b. In some cases the outcomes will only be available at the household level. In few cases highlighted in the table above, the outcome will only be available at the village level (e.g. drug quality).

Given that we used the NGOs' branches as blocking variable when performing the initial randomization, all specifications will include branch fixed effects τ_b. Standard errors will always be clustered at the village level.

In order to increase precision, we will also report results including in the regression additional control variables collected at baseline $(X_{i,h,v,b})$.

Given the number of outcome variables in our study, multiple testing is a concern. We will therefore follow Kling, Liebman and Katz (2007) and calculate standardized effects for each family of outcomes listed above. We will also use randomization inference methods to test for joint significance across the different outcomes.

Finally, for the main outcomes we will report both robust standard errors as well as the p-values of tests of the null that treatment has no effect computed using randomization inference. [6]

Heterogeneous effects

Although we might not have enough power to clearly identify heterogeneous effects, we believe still plan to examine them, as they could provide additional insights on the effectiveness of the program. In particular, we plan to examine heterogeneous effects of the treatment on the main health outcomes with respect to:

1) *household characteristics*: baseline wealth; baseline distance from the CHP house

[6] We will construct these p-values using 1000 randomly selected permutations of the randomization allocation. The p-value is then constructed based on the proportion of test statistic values (squared of the estimated coefficients) that are greater than the actual test statistic value.

2) *village characteristics*: distance from the closest health facility; baseline average health knowledge of the health workers operating in the village; BRAC vs Living Goods area

Sample

The analysis will include the full sample of households that we have identified at baseline and that we have been able to track till endline. At both midline and endline we will survey baseline households even if they moved outside the study village (as long as we will be able to track them), unless they moved to a different district. We will check that any attrition caused by households that moved to a different district (or that we are not able to track in any way) is non-systematic. In practice, we will run the empirical model mentioned above, using baseline data and replacing the dependent variable Y with an indicator for whether the households could be tracked till endline or not. Non-systematic attrition would imply the coefficient β to be not statistically distinguishable from zero.