Effect of a micro entrepreneur-based community health delivery program on under-five mortality in Uganda: a cluster-randomized controlled trial[1]

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Abstract

Background Systematic reviews of existing evidence show promising effects of community health worker (CHW) programs as a strategy to improve child survival, but also highlight challenges faced by CHW programs, including insufficient incentives to deliver timely and appropriate services. We assessed the effect of an incentivized community health delivery program in Uganda on all-cause under-five mortality.

Methods and Findings A cluster-randomized controlled trial, embedded within the scale-up of a new community health delivery program, was undertaken in 214 clusters in 10 districts in Uganda. In the intervention clusters micro entrepreneur-based community health promoters (CHPs) were deployed over a three-year period (2011-2013). On average 38 households were surveyed in each cluster at the end of 2013, for a total sample size of 8,119 households. The primary study outcome was all-cause under-five mortality (U5MR). U5MR was reduced by 27% (adjusted RR 0.73, 95% CI 0.58-0.93). No harm was reported.

Limitations Our study had some limitations. First, contamination is plausible because the study clusters, within each zone, were geographically close. Second, we rely on retrospective recall information. Both of these limitations most likely caused us to estimate a lower bound on the treatment effect. Third, the CHPs were blinded to the trial status of the village they were assigned to and as a consequence no surveillance and monitoring system was put in place in the trial clusters. Mortality rates were calculated based on cross-sectional household survey data collected at the end of the trial, thus raising concern that differential in- or out-migration flows by assignment groups could cause confounding bias in the main mortality estimates. However, measured in- and out-migration into the study clusters were similar across assignment groups, and baseline household characteristics of the eligible households, and pre-trial infant mortality rates, were not statistically different between the intervention group and the control group.

Conclusion With the accumulated know-how we have today few would question the potential of community health care provision. How to best ensure that CHW deliver timely and appropriate services is, however, largely an open question and motivates the continued search for innovative approaches. We study one such approach which harnesses the power of franchised direct selling (business-in-a-bag) to provide community health providers with incentives to increase access to low-cost, high-impact health products and free basic newborn and child health services. We believe the results are likely to advance a global conversation about how to best motivate CHWs to deliver timely and appropriate services.

The trial was registered before the endline survey in the Pan African Clinical Trials Registry (#PACTR201308000601715)

Introduction

In many developing countries the primary strategy to extend primary health care from facilities to underserved rural communities is community health workers (CHW).[1] Systematic reviews of existing studies show that CHWs can be impactful in promoting positive health behavior and in providing basic curative and health services.[2-10] The findings from reviews of randomized controlled trials of CHW programs and CHW-led interventions, however, are mixed.[7,9] Two proof-of-principle studies cited as evidence in the WHO and UNICEF home-visits strategy statement documented large reductions in neonatal mortality (36-54%).[11,12] Four trials delivered in a program setting documented smaller (8-15%), and in three out of four trials insignificant, impacts.[13-16] Two studies assessed the impact of community-based training of mothers, of which one focused on teaching mothers curative treatments of malaria[17] (40% reduction in under-5 mortality), and one focused on teaching child care to expectant and postpartum women[18] (no significant impact on neonatal and infant mortality). One trial assessed the impact of Integrated Management of Childhood Illness (iMCI) program in Bangladesh[19], finding no significant effect on under-5 mortality.

Lack of incentives for CHWs to deliver timely and appropriate services has been highlighted as a key challenge in traditional CHW programs.[2,3,4,6,10] Specifically, community health work is often voluntary, but workers face competing opportunities such as paid-work or home production, that may lead them to devote less time to caregiving. This might help explain why strong impacts of CHW programs come from studies in settings with high quality of supervision and support. Such a monitoring system may not be achievable in routine field situations. How to incorporate incentives to motivate CHWs in large-scale CHW programs, and the impact that will have, are open questions.

We assess a community health worker program in Uganda – the community health promoter (CHP) program – where community health promoters operate as micro-

entrepreneurs earning an income on the sale of preventive and curative products to keep them motivated and active in the community. The underlying hypothesis was that these incentives, coupled with small financial incentives to encourage CHP agents to register pregnant women and visit newborns within the first 48 hours of life, would motivate agents to actively provide Integrated Community Case Management (iCCM) and Maternal, Newborn and Child Health services (MNCH).

Methods

Setting and intervention

In 2007 Living Goods, a US based NGO active in Uganda, in collaboration with BRAC Uganda began piloting a new community health delivery model intended to provide iCCM and MNCH services. Unlike volunteer-based community health worker programs, the community health promoters (CHP) program 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 was organized into geographically based branches, and managed by branch managers and supervised by the two NGOs (Living Goods and BRAC Uganda). Each CHP was assigned to a specific cluster, which in most cases corresponds to a village.

The CHP program is ongoing and by the end of 2013 it was operating in 883 clusters (villages), organized in 29 branches, located in 23 districts, spread over all four regions of Uganda (see figure 1). Within the next two years, the program is estimated to reach more than 4000 clusters, organized in 143 branches, with a total population of 4.3 million.

Fig 1: Map of districts and distribution of clusters

[Figure 1 about here]

Notes: District boundaries underwent repeated modifications in recent years in Uganda. The map refers to the original definition of the 56 Districts that was in place until 2005, before the wave of reforms started (there are currently 111 districts in the country). Green fully-colored areas indicate districts that were part of the study, while cross-hatched areas indicate districts excluded from the study, but in which the program was also implemented. Red and blue dots indicate respectively control and intervention villages included in the study.

The CHPs were selected through a competitive process among female community members aged 18 to 45 who applied for the position in each village and who possessed basic writing and math skills. Eligible candidates received 2 weeks of health and business training, covering preventing, diagnosing and treating childhood illness, recognizing danger signs for referral, healthy pregnancy and newborn care, and nutrition. At the end of the training, a skills test was administered to determine who would become an active CHP. Selected CHPs also attended a one-day training each month to review and refresh key health and business topics.

The CHPs tasks were 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 to sell preventive and curative health products. The CHPs were also instructed to visit newborns within the first 48 hours of life and to encourage pregnant women to deliver in a facility or with professional assistance. The product line they had at disposal included 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 were sold by the CHP at a discount. The retail price was determined by branch managers with a target of keeping prices for preventive and curative products at least 20% lower than the prevailing local market prices. The CHPs in turn purchased these products directly from Living Goods or BRAC branches at wholesale prices between 30-50% below market prices and therefore earned an income on each product sold. Thus, the CHPs operated as micro-entrepreneurs with financial incentives to meet household demand.

The broad product mix had three potential benefits: (i) driving up total sales and income for the CHPs; (ii) enabling the NGOs to cross-subsidize prices (dropping prices on essential health products and increasing the margins on other products); (iii) motivating agents to be out visiting households regularly by including high-velocity items like soap and fortified foods in the product mix.

The business training received by the CHPs stressed the importance of building up a customer-base by providing free services like health education, referrals, and newborn visits. In addition, the CHPs received small performance-based incentives to encourage registering of pregnant women and visits of newborns ($0.65 per registration/newborn visit). In 2012, one of the implementers (Living Goods) also began using mobile technology to promote coverage and health services.

Study design and participants

The study was a parallel-group, stratified cluster randomized controlled trial, embedded in the roll-out of the CHP program. 214 clusters (rural villages) took part in the trial. The clusters were located in 12 geographical zones spread across Uganda (see figure 1). Within each zone, the clusters were randomly divided into an intervention group and a control group. In 11 zones out of 12 the randomization was balanced (1:1). In one zone and for operational purposes the randomization was unbalanced (2:1). A CHP was assigned to each cluster in the intervention group. No CHP was assigned to the control clusters. The mean number of household per cluster was 237 at baseline.

The main objective of the trial was to assess the impact on under-five mortality of having a CHP working in the cluster. The evaluation design and implementation was independent of program implementation. All clusters were enumerated at baseline and a smaller household survey was administered to a randomly selected sample of households (on average 16 per cluster) to verify balance across assignment groups.

The outcomes of interest were measured through a cross-sectional household survey administered between September and December 2013; approximately three years after the CHPs began operating in the intervention clusters. Before implementing the survey, each cluster was enumerated. A random computer-generated sequence was then used to select 40 households to be surveyed in each cluster (if less than 40 eligible households were available, all were sampled). Sampled households were visited and asked for written informed consent to participate in the survey. Conditional on receiving the consent, an appointment was scheduled for the following day. The respondent was the female household head if available at the time of the interview or the primary female health care giver of the household. If neither could be found, or the household refused to participate, a replacement household was chosen (this happened in 7.2% of the cases, without any systematic difference between intervention and control clusters). Random back-checks were performed to ensure that all enumerators correctly followed the protocol. No violation was identified.

The survey was implemented by Innovations for Poverty Action (IPA) Uganda, an external organization based in Uganda and specialized in data collection. The survey teams were all composed by local staff with previous experience in data collection. Different survey teams operated in the different districts covered by the evaluation, to ensure that every staff member was familiar with local customs and spoke the local language. Data collectors were always masked to whether they were interviewing in an intervention or control cluster. The questionnaires were programmed using SurveyCTO-Open Data Kit (ODK), version 1.16. Answers to the survey questions were recorded in a digital form and on a daily basis they were encrypted and stored on a secure server provided by SurveyCTO. Data were eventually combined in one single dataset.

The trial was embedded in the rollout of the full CHP program (883 clusters) and there were no differences in program implementation between the intervention clusters (115 clusters) and the 768 clusters that were not part of the trial.

The CHPs were blinded to the trial status of the village they were assigned to avoid that the evaluation itself affected the CHPs behavior. As a consequence, no surveillance and monitoring system was put in place in the trial clusters and we did not track a pre-determined set of households to avoid the CHP focusing their efforts on the households that were tracked at the expense of those who were not. Mortality rates were calculated based on cross-sectional household survey data collected at the end of the trial, using data from households that had resided in the same cluster throughout the trial. To ensure that these households were not systematically different in the two assignment groups, we tested for differential in- and out-migration during the trial period and checked for balance across assignment groups using pre-trial determined observable household characteristics, and pre-trial infant mortality rates, collected at the end of the trial period.

All households and especially households with younger children were potential recipients of visits from the CHPs. While the CHPs were recommended to focus attention on providing services to households living within their cluster, they were not prevented from selling or providing advice also to households outside the cluster, including control clusters. Similarly, households living outside the intervention clusters could visit a CHP in an intervention cluster.

Households in both intervention and control clusters could benefit from primary health care services provided by other actors, including private clinics, public primary health dispensaries and village health teams (a government community health worker program).

The rollout of the CHP program, including the trial clusters, was overseen by an advisory board including individuals with expertise in international public health and health

service research as well as officials from the Uganda Ministry of Health. The trial was approved by the ethic committee of Fondazione IRCSS (D2291696), by the Harvard IRB (protocol P20141-101), by the Uganda National Council for Science and Technology (UNCST) (SS3195), and by the IRB Office of the Joint Clinical Research Center (JCRC) in Uganda. The trial was registered in the Pan African Clinical Trials Registry (#PACTR201308000601715) and the registration can be accessed online (http://www.pactr.org).

Randomization and masking

Figure 2 describes the trial profile. As the full CHP program was rolled out over time, the randomization of clusters was also phased in over time. We began in 2009 with a sample of 200 clusters (villages) in 10 geographic zones (8 districts). The clusters were stratified by zone and village size (below or above 400 villages) and, within each stratum, half of the clusters were assigned to the intervention group and half were assigned to the control group through a simple randomization procedure (computerized random numbers) generated by the researchers using Stata 10 (StataCorp, College Station, TX) statistical software. In 2010, a year before the evaluation began; a decision was taken to only include villages with less than 400 households at baseline as the design of the trial was deemed less suitable for villages where the CHPs only would be able to serve a small minority of the households. As a consequence, 10 strata with 94 villages (47 intervention and 47 control clusters) were deemed ineligible. 60 clusters organized in one new geographic zone were added in the end of 2010. Half of these 60 clusters were randomly assigned to the intervention group and half were assigned to the control group, following the same procedure adopted for the other zones. An additional zone was added in the beginning of 2011. For operational purposes, 1/3 of the 48 clusters in the final zone were randomly assigned to the control group and the remaining 2/3 of the clusters were allocated to the intervention group. The final sample for the trial thus

consisted of 214 villages (115 intervention clusters and 99 control clusters) in 12 zones (10 districts). The program was fully operational in all intervention clusters in the beginning of 2011.

Fig 2: Trial Profile
[Figure 2 about here]

Outcomes

The pre-specified primary outcome was under-five mortality rate (U5MR). Secondary outcomes were infant mortality rate (IMR) and neonatal mortality rate (NMR). All mortality rates were calculated using the sample household survey data collected at the end of the trial. The household survey recorded detailed birth and death information for all children under five living in the households at the time of the survey as well as for all children that died under the age of five in the previous three years. For each child, we defined 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 (January 2011) 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 (see Figure S1). Under-five mortality was then 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. Infant mortality was calculated 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. Neonatal mortality was calculated as number of deaths during the trial period within the first month of life per 1000 births.

Additional secondary outcomes of interest were CHP interactions (program coverage); follow-up visits; health knowledge, prevention, under-five morbidity (in self-

reported malaria and diarrhea); treatment of under-five children for malaria and diarrhea; antenatal, delivery, and postnatal care. Data on all secondary outcomes were collected in the endline sample household survey.

In- and out-migration flows were derived by combining data on the number of households residing in cluster j at baseline, denoted by b_j, and at the end of the trial, denoted by e_j, where subscript j refers to a cluster. Under the assumption that the share of households that had moved in to cluster j during the trial period, out of the total number of households sampled for the household survey administered at the end of the trial in cluster j, $\hat{\theta}_j$, provides an unbiased estimate of the share of households in cluster j that moved in to the cluster during the trial period, out of the total number of households living in the cluster, θ_j, the estimated number of households that moved in to cluster j, denoted i_j, is $i_j = \widehat{\theta_j} \times e_j$, and the estimated number of households that moved out, denoted by o_j, is $o_j = b_j - (1 - \widehat{\theta_j}) \times e_j$. The rate of in-migration is i_j/b_j and the rate of out-migration is o_j/b_j.

One change to the secondary outcomes took place during the evaluation. Pneumonia was included among the specific diseases targeted by the program. But due to changes in the regulatory environment, there was a delay in the authorization to include antibiotics among the list of health products provided by the CHPs and pneumonia-related outcomes were therefore left out from the evaluation.

Statistical analysis

The sample size was designed to detect a reduction in overall under-five mortality. In a community-based trial in 2009 with significant overlap in the regions covered to the CHP study, U5MR was 18 deaths per 1000 child-years with a coefficient of variation of the incidence rates (k) of 0.32.[20] On the basis of these data, and 120 child-years of observations in each cluster (three years, 2011-2013, and 40 child observations per year), a sample size of

214 clusters, of which 115 clusters are allocated to the intervention group and 99 clusters to the control group, would detect a 27% reduction in under-five mortality with 80% power at the two-sided 5% significance level.

Intention-to-treat analyses were done to compare intervention and control clusters with respect to each outcome. Intention to treat was defined by cluster of residence at baseline, as measured in the endline sample household survey. Households that migrated out from the baseline cluster were not included in the final analysis, nor were households that migrated into the trial clusters.

For mortality rates we report rate ratios computed using a Poisson model, adjusting for the stratified randomized design using binary zone indicators, with the rate ratios derived by the use of the marginal standardization technique and the 95% CIs estimated with the delta method.[21,22] For behavioral outcomes we report risk ratios adjusted for the stratified randomized design. Standard errors were clustered at the cluster level to account for intra-cluster correlation across households located in the same cluster. For in- and out-migration flows we report mean differences based on a linear model adjusting for the stratified randomized design using binary zone indicators. Stata 12 (Stata Corp, College Station, Texas) was used for statistical analysis.

Role of the funding source

The funding source had no involvement in the design and conduct of the trial, including data gathering, data analysis, and report writing.

Results

The analysis was based on a sample of 7018 households, and their 11563 under-5 children, that have lived in the same cluster throughout the trial.

Table 1 reports balance tests using baseline data. Baseline characteristics, health behavior and morbidity were not systematically different between households in the intervention group and the control group.

Table 1: Baseline characteristics

	Intervention group	Control group	p-value
A. Clusters			
Number of clusters	115	99	
Households per cluster	250 (113)	221 (107)	0.226
Households with under-5 children per cluster	86 (47)	78 (46)	0.665
Distance to main road	5.6 (11.6)	6.8 (12.7)	0.126
Distance to electricity transmission line	1.8 (1.5)	1.8 (1.5)	0.707
Distance to health center	1.4 (1.1)	1.7 (1.2)	0.256
Number of health centers within 5 km	8.3 (5.0)	7.3 (5.2)	0.459
Distance to hospital	10.4 (8.5)	11.1 (8.5)	0.916
B. Households			
Number of household	1755	1763	
Household size	6.2 (2.8)	6.0 (2.7)	0.118
Number of children under-5 in household	1.7 (0.9)	1.7 (0.9)	0.621
Number of female under-5 in household	0.88 (0.82)	0.86 (0.80)	0.585
Age of children under-5 in household	2.5 (1.1)	2.4 (1.1)	0.070
Female household head (FHH): No education	201 (13%)	212 (14%)	0.584
FHH: Primary education	721 (48%)	720 (47%)	0.566
FHH: Some secondary education	582 (39%)	611 (40%)	0.812
Household has cement floor	890 (51%)	915 (52%)	0.930
Household has thatched or tile roof	181 (10%)	216 (12%)	0.053
Treat water before drinking it	1390 (82%)	1395 (81%)	0.295
Slept under a treated mosquito net last night	865 (52%)	870 (52%)	0.898
Child affected by malaria (last month)	1281 (43%)	1246 (41%)	0.375
Child affected by diarrhea (last month)	523 (18%)	460 (15%)	0.104

Data are n (%) or mean (SD) from baseline census (for cluster outcomes, panel A) and baseline sample household survey data (for household outcomes, panel B). Data for medium and high voltage electricity transmission lines was obtained from the Africa electricity transmission network (AICD) study. A variety of sources were consulted to generate the original dataset, including documents and maps from national utilities, regional power pools and the World Bank. Health Centers takes into account facilities from HCIII (i.e. parish-level health centers, roughly one per 5000 people) and above. Hospitals refer only to district/national hospitals (roughly one per 500.000 people). Distance measures are all expressed in kilometers. Shares are computed relative to the total valid answers (missing answers are excluded).

Detailed data on mortality was not collected at baseline. However, endline data can be used to compute infant mortality for the two years preceding the intervention; i.e., in 2009 and 2010 (Table 2, panel A). IMR was 52.4 per 1000 child-years in the intervention group compared to 50.0 per 1000 child-years in the control group (adjusted RR 0.97, 95% CI 0.70-1.33).

Table 2: Baseline characteristics of households not lost to follow-up and surveyed at endline

	Intervention group	Control group	p-value
A. Infant mortality			
Years of exposure to risk of death under 1 year	1927	1743	
Deaths under 1 year	101	87	
Mortality rate per 1000 years of exposure	52.4	50.0	0.830
B. Households			
Number of household	3787	3217	
Household size	5.2 (2.3)	5.3 (2.3)	0.518
Age household head	36.4 (12.1)	36.7 (12.4)	0.641
Years of education household head	8.0 (0.4)	8.0 (0.2)	0.320

Data are n (%) or mean (SD) from endline sample household survey data for household that have remained in the cluster throughout the trial, with values scaled back to baseline period.

Table 3 reports tests on selective in- and out-migration using enumeration data at baseline and endline combined with data from the sample household survey. At baseline 50617 households were residing in the trial cluster, 4132 of whom were estimated to have migrated out from the baseline cluster by the end of the trial. The average rate of out-migration per cluster was 7.1% and was not statistically different between the intervention group and control group (p=0.991). An estimated 7962 households moved into the trial clusters during the intervention period. The average rate of in-migration per cluster was 15.3% and was not statistically different between the intervention group and control group (p=0.478). The share of sampled households that has moved in to the cluster during the trial period, out of the total number of sampled households, was not statistically different between the intervention group and control group (p=0.614).

Table 3: Population data and flows

	Intervention group (115 clusters)	Control group (99 clusters)	p-value
Rate of in-migration	0.16 (0.12)	0.15 (0.11)	0.478
Rate of out-migration	0.07 (0.13)	0.07 (0.13)	0.991
Share of migrants	0.14 (0.09)	0.13 (0.08)	0.614

Data are mean (SD) estimated by combining data from baseline census, endline census, and endline sample household survey. P-values are adjusted for the stratified randomized design. Rate of in-migration is i_j/b_j and rate of out-migration is o_j/b_j, where $i_j = \widehat{\theta_j}\times e_j$, $o_j = b_j - (1 - \widehat{\theta_j})\times e_j$, b_j is number of households residing in cluster *j* at baseline, e_j is number of households residing in cluster *j* at endline, and $\widehat{\theta_j}$ (the share of migrants) is an estimate of the share of households in cluster *j* that moved in to the cluster during the trial period, out of the total number of households living in the cluster at endline based on the sample household survey.

Panel B of Table 2 shows that pre-trial determined observable household characteristics for the households used in the analysis; i.e., household that had remained in the same cluster throughout the trial and surveyed in 2013, such as household size at the start of the trial and age and years of education of the household head, were not statistically different between the intervention group and the control group. Infant mortality (panel A) in the two years preceding the intervention was also similar in the intervention and control group.

Table 4 presents adjusted rate ratios describing the impact of the CHP program on the primary outcome – child mortality. U5MR was reduced by 27% (adjusted RR 0.73, 95% CI 0.57-0.93). The RR for IMR corresponds to a 33% reduction in the IMR (adjusted RR 0.67, 95% CI 0.51-0.87). The RR for NMR implies a 27% reduction in mortality for newborns (adjusted RR 0.73, 95% CI 0.55-0.98).

Table 4: Under-5 mortality, infant mortality, and neonatal mortality rates

	Intervention group (5894 children)	Control group (5059 children)	Adjusted rate ratio (95% CI)	p value
Under 5 years				
Years of exposure to risk of death	12294	10731		
Deaths under 5 years	183	206		
Mortality rate per 1000 years of exposure	14.9	19.2	0.73 (0.57 - 0.93)	0.010
Infants				
Years of exposure to risk of death	3553	3015		
Deaths under 1 year	134	160		
Mortality rate per 1000 years of exposure	37.7	53.1	0.67 (0.51- 0.87)	0.003
Neonates				
Number of births	3521	2978		
Deaths under 1 month	98	106		
Mortality rate per 1000 births	27.8	35.6	0.73 (0.55 - 0.98)	0.034

Data are n and mortality rates from endline sample household survey. The number of month of exposure to the risk of death during the trial period is used to compute under-5 and infant mortality and is defined as the difference between the birth date of the child, or the start date of the trial (January 2011) if the child was born before that date, and the date that the child turned five (one for infant mortality) years if that occurred during the trial period, or the date of the endline household survey if the child was less than five (one) years old at that time, or the date of the death of the child. Neonatal mortality is calculated as number of deaths during the trial period within the first month of life per 1000 births. Adjusted rate ratios are computed using a Poisson model, adjusting for stratified randomization. Confidence intervals are constructed using robust standard errors clustered at the cluster (village) level.

The analysis of secondary outcomes (Table 5) showed that 24% of the households in the intervention clusters have been visited by a CHP in the 30 days preceding the survey. While there was evidence of spillovers – 5% of the households in the control group have also been visited by a CHP – households in the intervention group were more than 4 times as likely to have benefited from such a visit.

Table 5: Process indicator outcomes

	Intervention group (3790 households)	Control group (3228 households)	Adjusted risk ratio (95% CI)
Household Interaction with CHPs			
Household visited by a CHP in the last 30 days	895/ 3790 (24%)	173/3228 (5%)	4.20 (2.65-6.65)
Health Knowledge			
Knows diarrhea is transmitted by drinking untreated water	1599/3790 (42%)	1205/3228 (37%)	1.11 (1.04-1.18)
Believes Zinc is effective in treating diarrhea	954/3790 (25%)	734/3228 (23%)	1.16 (1.05-1.29)
Mosquito bites are the only cause of malaria	354/3790 (9%)	229/3228 (7%)	1.39 (1.12-1.72)
Ever heard of food with added vitamins or nutrients	2341/3790 (62%)	1907/3228 (59%)	1.08 (1.02-1.14)
Believes bednets can help prevent catching malaria	3739/3768 (99%)	3179/3209 (99%)	1.00 (1.00-1.01)
Believes a woman giving birth should deliver at hospital/facility	3780/3790 (100%)	3218/3228 (100%)	1.00 (1.00-1.00)
Prevention			
Treat water before drinking it	3067/3786 (81%)	2497/3227 (77%)	1.05 (1.01-1.09)
Child slept under a treated bednet last night	2395/5894 (41%)	2034/5059 (40%)	1.13 (1.06-1.21)
Child ever received a Vitamin A dose	4317/5894 (73%)	3692/5059 (73%)	1.00 (0.97-1.03)
Morbidity and treatment of sick children			
Child sick with malaria during last 3 months	2934/5884 (50%)	2497/5047 (49%)	0.97 (0.92-1.03)
Treated with ACT for (at least) 3 days	1940/2927 (66%)	1666/2495 (67%)	1.01 (0.96-1.05)
Child sick with diarrhea during last 3 months	1482/5885 (25%)	1210/5049 (24%)	1.02 (0.95-1.10)
Treated with ORS/Zinc	567/1480 (38%)	395/1206 (33%)	1.16 (1.04-1.30)
Follow-up, counselling and behavior			
Follow up by after child sick with malaria	401/2881 (14%)	206/2454 (8%)	1.74 (1.38-2.21)
Follow up by after infant sick with malaria	50/346 (14%)	19/285 (7%)	2.04 (1.16-3.59)
Follow up after child sick with diarrhea	135/1248 (11%)	68/980 (7%)	1.63 (1.13-2.35)
Follow up after infant sick with diarrhea	30/213 (14%)	15/195 (8%)	2.13 (1.07-4.20)
Follow up visit in the first week after delivery	205/1064 (19%)	98/861 (11%)	1.71 (1.31-2.24)
Advised to give birth with qualified assistance	680/1074 (63%)	501/868 (58%)	1.10 (1.02-1.19)
Gave birth in a health facility	927/1080 (86%)	740/875 (85%)	1.01 (0.96-1.05)
Received antenatal care for current pregnancy	215/370 (58%)	205/342 (60%)	0.98 (0.86-1.11)

Data are n (%) from endline sample household survey. Group assignment is based on the cluster of residence of the household. Follow up visits after child/infant sick with malaria/diarrhea for children reported sick in the last 3 months. Follow-up visits in the first week after delivery for women that delivered in the last 12 months. Shares are computed relative to the total valid answers (missing answers are excluded). Adjusted risk ratios are computed using a Poisson model, adjusting for stratified randomization. Confidence intervals are constructed using robust standard errors clustered at the cluster (village) level.

The CHP program resulted in improved health knowledge: households in the intervention group were 11% (95% CI 4-18, p=0.001) more likely to know that diarrhea is transmitted by drinking untreated water; 16% (95% CI 5-29, p=0.004) more likely to know that zinc is effective in treating diarrhea; and 39% (95% CI 12-72, p=0.003) more likely to know that mosquito bites are the only cause of malaria. They were also 8% (95% CI 2-14,

p=0.004) more likely to have heard of food with added vitamins or nutrients. Knowledge about bednets and the importance of professional assistance when giving birth did not differ between control and intervention groups.

The CHP program promoted preventive behavior. Households in the intervention group were 5% (95% CI 1-9, p=0.010) more likely to have treated their water before use and their children were 13% (95% CI 6-21, p<0.001) more likely to have slept under an insecticide-treated bednet.

Self-reported morbidity in malaria and diarrhea did not differ between control and intervention groups. Conditional on falling sick with malaria children in the intervention group were as likely as children in the control group to have received treatment with ACTs for at least 3 days. Conditional on falling sick with diarrhea children in the intervention group were 16% (95% CI 4-30, p=0.008) more likely to have received treatment with ORS/Zinc.

The largest increases in the intervention relative the control group were observed for follow-up visits and counseling. Households with a newborn baby were 71% (95% CI 31-124, p<0.001) more likely to have received a follow-up visit in the first week after birth, and households with a child under-five that fell sick with malaria or diarrhea were, respectively, 74% (95% CI 38-121, p<0.001) and 63% (95% CI 13-135, p=0.009) more likely to have received a follow-up visit. For households with infants that fell sick with malaria or diarrhea the increases were 104% (95% CI 16-259, p=0.013) and 113% (95% CI 7-320, p=0.030), respectively. A significantly higher share (10%; 95% CI 2-1, p=0.013) of women in the intervention group had been advised to give birth with professional assistance, although the share that gave birth in a health facility and the share of the currently pregnant women that had received at least some antenatal care did not differ between control and intervention groups.

No harm or unintended effect of the intervention was reported.

Discussion

We estimate that the CHP program in Uganda reduced U5MR by 27%, IMR by 33%, and NMR by 27% after 3 years. These effects are supported by changes in health knowledge, preventive behavior, case management of malaria and diarrhea, and home visits.

While a growing body of evidence has identified effective interventions that can be delivered by community health workers, a key consideration for the success and sustainability of such programs is how high-quality performance by community workers can be achieved and maintained. This study is the first impact evaluation of a community health delivery intervention based on an incentivized approach. Unlike previous studies that have primarily focused on the impact of specific interventions that could be delivered effectively in a community setting, our focus is on how to ensure that community health workers successfully implement a set of interventions proven to be effective if delivered and the impact that may have on child health.

In the CHP program, community health workers operated as micro-entrepreneurs earning an income on the sale of preventive and curative products. A concern with such a scheme is that it may encourage overuse of medications and inappropriate treatment at the expense of prevention and referrals. On the other hand, the provision of free services like health education and follow-up visits was viewed as strategy to build up a loyal customer base. More generally whether extrinsic incentives in some domains have positive or negative impacts on intrinsic motivation in other domains is an empirical question. The data does not suggest that the program only had an impact on incentivized services, with evidence of increases in the promotion of healthy behavior and changed health beliefs. While there was a large increase in visits of newborns, for which the CHPs received a small incentive payment, there were also large increases in follow-up visits of children sick in malaria and diarrhea, for which no direct incentives were attached.

Another concern is that charging for preventive and curative products, even when prices are subsidized, will disproportionately benefit the less-poor households. Table S1 however suggests similar impact across the household wealth distribution.

The case management of malaria was similar in the intervention and control group. Similar treatment pattern does not necessarily imply similar quality of treatment, however. The CHPs sell authentic ACT drugs. In the private market there is growing evidence that the market for antimalarial medicines is plagued by counterfeit and substandard (fake) products, with recent estimates suggesting that as much as a third of the antimalarial drugs sold contain too little or no active pharmaceutical ingredients.[23] Uganda is no exception: a smaller study conducted in the same research areas one year into the program estimated that 37 percent of the retail outlets were selling substandard antimalarial drugs.[24] Poor quality is not specific to ACTs but is a generic problem in the largely unregulated market for preventive and curative health products in many developing countries. The CHPs market share for ACT drugs and ORS were 11.3% and 14.1% respectively. Under the assumption that every third dose of ACT treatment sold in the private market is fake and that authentic drugs are provided in the public sector (about 40% of the market share), children in the treatment group are 19% less likely to be treated with a fake ACT medicine.

It is possible that the CHP program affected child mortality not only through the provision of iCCM and MNCH services, but also through the subsidized sale of other health-related commodities and durables (e.g. hand soap, improved cook stoves, fortified food, and water filters). The broad product mix, with high-velocity items like soap and fortified foods, and low-velocity but high returns per sold unit items improved cook stoves, was deemed crucial to motivate agents to be out visiting households regularly and for driving up total sales and income for the CHPs.

Our study has some limitations. The choice not to have surveillance or monitoring systems in place in the study villages implied that we had to rely on retrospective recall information. We used standardized data collection methods, and any potential recall lapses were expected to affect the intervention and control groups equally and thus lead to an attenuation bias that would lead us to estimate a lower bound on the impact of the CHP program on child mortality. We also used the end of trial sample survey to define baseline residence and thus the core sample for the analysis. Selective out-migration by assignment groups could have caused some confounding bias in our main estimates. However, measured in- and out-migration into the study clusters were similar across assignment groups (see table 3) and because baseline household characteristics of the sampled households that had lived in the same cluster for the whole study period were not statistically different between the intervention group and the control group (see table 2), we are confident that the results were not biased. Third, the possibility of contamination is plausible because the study clusters, within each zone, were geographically close. Analysis of behavioral data also suggested that some contamination occurred, most likely causing us to estimate a lower bound on the impact of the CHP program on child mortality.

With the accumulated know-how we have today few would question the potential of community health care provision. How to best ensure that CHW deliver timely and appropriate services is, however, largely an open question and motivates the continued search for innovative approaches. The CHP program we studied here harnesses the power of franchised direct selling (business-in-a-bag) to provide community health providers with incentives to increase access to low-cost, high-impact health products and basic newborn and child health services. The program is already active in close to 900 villages with a total population of 1.3 million and the scale-up is continuing. Within the next two years, the program is estimated to reach 4.3 million individuals in more than 4000 clusters. The impact

of the CHP program was conditional on existing facility based professional health care as availability of referral services is a crucial component to the program. Thus the findings should encourage government and non-government organizations to continue improving their facility based care but also points to the importance of integrating the program into the existing health service provision strategy. The process of integrating the CHP program we have evaluated here into the overall community care program is currently underway.

Other information

Contributors

JS, DYD and MBN were responsible for the conception and design of the study. All four authors contributed equally to the implementation of the trial. AG and JS conducted the quantitative analyzes, and wrote the initial draft of the paper. The final draft was edited by all authors.

Conflict of interest statement

We declare that we have no conflict of interest.

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References

1. Singh P, Sachs JD. 1 million community health workers in sub-Saharan Africa by 2015. *Lancet* 2013, 382: 363-365.
2. Bhutta ZA, Zohra SL, Pariyo G, Huicho L. Global Experience of Community Health Workers for Delivery of Health Related Millennium Development Goals: A Systematic Review, Country Case Studies, and Recommendations for Integration into National Health Systems, WHO Geneva, 2010.
3. Christopher JB, May AL, Lewin S, Ross DA. Thirty years after Alma-Ata: a systematic review of the impact of community health workers delivering curative interventions against malaria, pneumonia and diarrhoea on child mortality and morbidity in sub-Saharan Africa. *Human Resources for Health* 2011: 9:27.
4. Gilmore B, McAuliffe E. Effectiveness of community health workers delivering preventive interventions for maternal and child health in low- and middle-income countries: a systematic review. *BMC Public Health* 2013, 13:847.
5. Gogiaa S, Sachdeva HS. Home visits by community health workers to prevent neonatal deaths in developing countries: a systematic review. *Bull World Health Organ* 2010; 88: 658–666B.
6. Haines, A., Sanders, D., Lehmann, U, Rowe, A.K., Lawn, J.E., Jan, S., Walker, D.G., Bhutta, Z.A. Achieving child survival goals: potential contribution of community health workers. *Lancet* 2007; 369: 2121–31.
7. Lewin S, Munabi-Babigumira S, Glenton C, et al. Lay health workers in primary and community health care for maternal and child health and the management of infectious diseases (Review). *The Cochrane Library* 2010, Issue 3.
8. Naimoli JF, Frymus DE, Quain EE, Roseman EL. Community and Formal Health System Support for Enhanced Community Health Worker Performance: A U.S. Government Evidence Summit USAID Final Report, 2012.
9. Okwundu CI, Nagpal S, Musekiwa A, Sinclair D. Home- or community-based programmes for treating malaria (Review). *The Cochrane Library* 2013, Issue 5.
10. Perry H, Zulliger R. How Effective Are Community Health Workers? An Overview of Current Evidence with Recommendations for Strengthening Community Health Worker Programs to Accelerate Progress in Achieving the Health-Related Millennium Development Goals, Johns Hopkins Bloomberg School of Public Health, 2012.
11. Kumar V, Mohanty S, Kumar A, for the Saksham Study Group, et al. Effect of community-based behaviour change management on neonatal mortality in Shivgarh, Uttar Pradesh, India: a cluster-randomised controlled trial. *Lancet* 2008, 372, pp. 1151–1162.
12. Baqui AH, El-Arifeen S, Darmstadt GL, for the Projahnmo Study Group, et al. Effect of community-based newborn-care intervention package implemented through two service-delivery strategies in Sylhet district, Bangladesh: a cluster-randomised controlled trial. *Lancet* 2008, 371: 1936–1944.
13. Darmstadt GL, Choi Y, Arifeen SE, et al. Evaluation of a cluster-randomized controlled trial of a package of community-based maternal and newborn interventions in Mirzapur, Bangladesh. *PLoS One* 2010, 5, p. e9696
14. Bhutta ZA, Soofi S, Cousens S, et al. Improvement of perinatal and newborn care in rural Pakistan through community-based strategies: a cluster-randomised effectiveness trial. *Lancet* 2011, 377: 403–412
15. Bhandari N, Mazumder S, Taneja S, Sommerfelt H, Strand TA, IES Group. Effect of implementation of Integrated Management of Neonatal and Childhood Illness (IMNCI) programme on neonatal and infant mortality: cluster randomised controlled trial. *BMJ* 2012, 344, p. e1634
16. Kirkwood BR, Manu A, Tawiah-Agyemang C, et al. Effect of the Newhints home-visits intervention on neonatal mortality rate and care practices in Ghana: a cluster randomised controlled trial. *Lancet* 2013, 22;381(9884):2184-92.
17. Kidane G, Morrow RH. Teaching mothers to provide home treatment of malaria in Tigray, Ethiopia: a randomised trial. *Lancet* 2000, 12;356(9229):550-5.
18. Sloan NL, Ahmed S, Mitra SN, Choudhury N, Chowdhury M, Rob U, Winikoff B. Community-based kangaroo mother care to prevent neonatal and infant mortality: a randomized, controlled cluster trial. *Pediatrics* 2008*,* 121(5).
19. Arifeen SE, Hoque DM, Akter T, et al.. Effect of the Integrated Management of Childhood Illness strategy on childhood mortality and nutrition in a rural area in Bangladesh: a cluster randomised trial. *Lancet* 2009, 1;374(9687):393-403.
20. Björkman M, de Walque D, Svensson J. Information is power : experimental evidence on the long-run impact of community based monitoring. Policy Research working paper; no. WPS 7015. Washington, DC : World Bank Group, 2014.

21. Brennan C, Kahan BC, Morris TP. Reporting and analysis of trials using stratified randomisation in leading medical journals: review and reanalysis, *BMJ* 2012; 345:e5840.
22. Norton, EC, Miller MM, Kleinman LC, Computing adjusted risk ratios and risk differences in Stata, *The Stata Journal* 2013; 13(3): 492-509.
23. Nayyar G, Breman JG, Newton PN, Herrington J. Poor-quality Antimalarial Drugs in Southeast Asia and Sub-Saharan Africa. *Lancet Infectious Diseases* 2012, 12(6):488-496.
24. Björkman M, Svensson J, Yanagizawa-Drott D. The Market for (Fake) Antimalarial Medicine: Evidence from Uganda. 2014. Mimeo.