# Combined infant and young child feeding with small-quantity lipid-based nutrient supplementation is associated with a reduction in anemia but no changes in anthropometric status of young children from Katanga Province of the Democratic Republic of Congo: a quasi-experimental effectiveness study

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**ABSTRACT**

**Background:** Small-quantity lipid-based nutrient supplements (SQ-LNS) are efficacious in controlled settings; data are scarce on the effectiveness utilizing health care delivery platforms.

**Objective:** We evaluated the impact of an infant young child feeding (IYCF)–SQ-LNS intervention on anemia and growth in children aged 6–18 mo in the Democratic Republic of Congo following a quasi-experimental effectiveness design.

**Methods:** An intervention health zone (HZ) received enhanced IYCF including improved counseling on IYCF during pregnancy until 12 mo after birth and daily use of SQ-LNS for infants 6–12 mo; the control HZ received the standard IYCF package. We analyzed data from 2995 children, collected in repeated cross-sectional surveys. We used adjusted difference-in-difference analyses to calculate changes in anemia, iron and vitamin A deficiencies, stunting, wasting, and underweight.

**Results:** Of mothers, 70.5% received SQ-LNS at least once in the intervention HZ, with 99.6% of their children consuming SQ-LNS at least once. The mean number of batches of SQ-LNS (28 sachets per batch, 6 batches total) received was 2.3 ± 0.8 (i.e., 64.4 ± 22.4 d of SQ-LNS). The enhanced program was associated with an 11.0% point (95% CI: −18.1, −3.8; $P < 0.01$) adjusted relative reduction in anemia prevalence and a mean +0.26-g/dL (95% CI: 0.04, 0.48; $P = 0.02$) increase in hemoglobin but no effect on anthropometry or iron or vitamin A deficiencies. At endline in the intervention HZ, children aged 8–13 mo who received ≥3 monthly SQ-LNS batch distributions had higher anthropometry $z$ scores [length-for-age $z$ score (LAZ): +0.40, $P = 0.04$; weight-for-age $z$ score (WAZ): +0.37, $P = 0.04$] and hemoglobin (+0.65 g/dL, $P = 0.007$) and a lower adjusted prevalence difference of stunting (−16.7%, $P = 0.03$) compared with those who received none.

**Conclusions:** The enhanced IYCF–SQ-LNS intervention using the existing health care delivery platform was associated with a reduction in prevalence of anemia and improvement in mean hemoglobin. At endline among the subpopulation receiving ≥3 mo of SQ-LNS, their LAZ, WAZ, and hemoglobin improved. Future research could explore contextual tools to maximize coverage and intake adherence in programs using SQ-LNS. *Am J Clin Nutr* 2020;112:683–694.

**Keywords:** effectiveness, quasi-experiment, integrated IYCF-SQ-LNS, child growth, micronutrients

## Introduction

Stunting and anemia are major public health issues globally. More than 150 million children <5 y of age suffer from stunted linear growth (1). At the individual level, anemia and stunting can adversely affect cognitive development, immunity, and overall nutritional status during the critical period from conception to 2 y of age (2–4). As a result, it is a priority to identify interventions to reduce anemia and stunting that can be effectively implemented by local health systems, governments, and international organizations (2, 5).

To optimize healthy growth and development of young children, it is recommended that infant and young child feeding (IYCF) practices include immediate initiation of breastfeeding, exclusive breastfeeding for the first 6 mo of life, and the

introduction of micronutrient-rich, age-appropriate foods starting at 6 mo of age. A randomized controlled trial (RCT) of nutrition education interventions to improve IYCF practices and delivered through health services decreased stunting prevalence in Peruvian children (6). While most countries have a standard care package with counseling on IYCF (7, 8), guidance has been generic and not context specific (9), which has contributed to lack of impact on key indicators. Programs are implemented with large gaps in coverage (10). In response to this, UNICEF introduced the community-based IYCF counseling package in 2010, which includes several planning, training, and counseling tools to support programming and to strengthen the capacity of health workers (11). Furthermore, in 2020, UNICEF published updated programming guidance on improving young children's diets during the complementary feeding period (12, 13).

Over the past decade, home fortification interventions (also known as point-of-use fortification) have gained recognition as an efficacious approach for the prevention of anemia and other micronutrient deficiencies (14). Multiple micronutrient powders and small-quantity lipid-based nutrient supplements (SQ-LNS) have been used to fill nutrient gaps and support healthy infant growth and development (15, 16). For young children starting at 6 mo of age, these products are intended to be mixed into local complementary foods to increase the needed essential nutrient composition of the local foods, which may not be nutrient dense. SQ-LNS are single-serve sachets containing ≤20 g (≤120 kcal) of a paste typically containing peanuts, sugar, vegetable fat, skimmed-milk powder, and vitamin and mineral fortificants. The majority of studies on the impact of SQ-LNS on child nutritional status have used randomized controlled designs (17–20) reporting mixed overall associations on growth, while others found beneficial impacts on hemoglobin and reductions in anemia and iron deficiency (ID) (21, 22). It is noteworthy that recent evaluations in programmatic contexts in Madagascar and Bangladesh found a positive impact on iron biomarkers [ferritin and soluble transferrin receptor (sTfR)], anemia reduction, and improvements in child growth and development (23, 24).

The need for wider exploration of an integrated IYCF–SQ-LNS package within community health delivery platforms has been suggested (25), but, to our knowledge, few large-scale programs have attempted this, even though it might be an effective nutrition intervention in resource-poor settings. Based on comprehensive formative research (26), we conducted an integrated community-based enhanced IYCF–SQ-LNS program to evaluate the effectiveness on anemia, iron and vitamin A status, and child growth indicators in children 6–18 mo of age from 2 health zones (HZs) within Katanga Province of the Democratic Republic of Congo (DRC).

## Methods

### Setting and program context

The integrated IYCF–SQ-LNS program, known locally as the IMIKA program, which stands for "Good Food for the Nourishment of Infant and Young Children" (in Kiswahili), was piloted in 1 HZ in the Katanga Province. The population estimate for the HZ was 129,502 people with an estimated 2525 children aged 6–12 mo. The province was selected for this pilot because the infant and young child health characteristics were poor, but the province was generally less affected by the political instability affecting the rest of the country, which could have disrupted program implementation. The intervention and control HZs were in the same province and in the same district but were noncontiguous in order to avoid program spillover. Despite efforts to select comparable HZs, there were some key differences in the 2 zones, including that the intervention HZ was more rural and depended heavily on agriculture compared with the control HZ, which included more urban areas and a wider range of sources of income. This challenge was accommodated in lieu of selecting nonadjoining HZs with similar demographics but risking substantial program spillover from the intervention to the control HZ.

In the control HZ, the population received the usual standard of care provided throughout the DRC based on the Essential Nutrition Actions (ENA). The usual ENA standard of care included the following: *1*) iron–folic acid supplementation, antimalarial medication, and individual IYCF counseling during antenatal care visits; *2*) individual counseling on IYCF and child health by community health workers (CHWs) during clinic visits; *3*) monthly group counseling on IYCF and child health and growth promotion at health clinics; and *4*) IYCF counseling during health worker outreach clinics. In the intervention zone, the enhanced IYCF–SQ-LNS/IMIKA program included 3 additional components, briefly as follows: *1*) a nutrition education campaign for mothers and pregnant women based on the UNICEF community-based IYCF program tools, *2*) the introduction of SQ-LNS (Nutributter® formulation by Nutriset) for daily consumption mixed into complementary foods among children 6–12 mo of age, and *3*) reinforcement of the role of CHWs. Training for the enhanced IYCF–SQ-LNS program was based on the UNICEF community-based IYCF program tools with additional modules on the appropriate distribution, storage, and use of SQ-LNS. Training sessions were implemented using a cascade approach. Training for selected CHWs from the HZs occurred at a central location (Lubumbashi). After this, the trained CHWs went back to train other CHWs in

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the CDC, UNICEF, or the Government of the Democratic Republic of Congo.

Supplemental Tables 1–3 are available from the "Supplementary data" link in the online posting of the article and from the same link in the online table of contents at https://academic.oup.com/ajcn/.

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Abbreviations used: BIV, biologically implausible value; CHW, community health worker; DiD, difference-in-difference; DRC, Democratic Republic of Congo; ENA, Essential Nutrition Actions; GLMM, generalized linear mixed model; HZ, health zone; ID, iron deficiency; IMIKA, Good Food for the Nourishment of Infant and Young Children Program (in *Kiswahili*); IYCF, infant and young child feeding; LAZ, length-for-age *z* score; LQAS, lot-quality assurance survey; PD, prevalence difference; pp, percentage point; PR, prevalence ratio; RCT, randomized controlled trial; RBP, retinol binding protein; SF, serum ferritin; SQ-LNS, small-quantity lipid-based nutrient supplements; sTFR, soluble transferrin receptor; WASH, water, sanitation, and hygiene; WAZ, weight-for-age *z* score; WLZ, weight-for-length *z* score.

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their respective health area (*aire de sante*) within each HZ. CHWs in the intervention area were provided with motor bikes as both as an incentive and a way to improve their access to remote communities. Motor bike distribution did not occur in the comparison HZ. While both the intervention HZ and the comparison HZ received counseling, the intervention HZ included outreach counseling by CHWs on IYCF and SQ-LNS, in addition to facility-based counseling, while the comparison HZ received only facility-based counseling and no SQ-LNS distribution or counseling. A full description of the enhanced IYCF–SQ-LNS program is detailed elsewhere (27). Informed consent was obtained from each mother/caregiver, and for illiterate participants it was administered in the presence of a literate adult household member. The Ministry of Health and the National Statistics Office in Lubumbashi in DRC reviewed and approved the protocol for the impact evaluation. The University of Lubumbashi School of Public Health ethics committee approved this evaluation.

### Education and communication around the enhanced IYCF and SQ-LNS

Before launching the program, formative research was conducted on the acceptability, appropriate use, marketing, and behavior change strategies needed to support the introduction of an enhanced IYCF–SQ-LNS intervention. The formative data collection included a month-long acceptability trial in 2010, which confirmed the SQ-LNS were well accepted (26). Focus groups with caregivers of young children and key informant interviews with mothers, fathers, and health workers were conducted to develop product packaging and messaging pertaining to the SQ-LNS and to assess the knowledge, attitudes, practices, and barriers to optimal IYCF practices. The product was locally branded as "*Kulabora*" in Swahili, which translates to "eating better."

The enhanced IYCF program had comprehensive counseling and educational components that targeted all mothers and their children (up to 12 mo of age) and pregnant women in the intervention catchment area, but not the comparison HZ, as detailed elsewhere (27). This was achieved by developing information, education, and communication materials and messages and tailored key messages, which were reinforced through various channels in the intervention site. The 4 key messages were as follows: *1*) put your baby to the breast within an hour of giving birth; *2*) only give breast milk (no water or other foods) to your baby until they are 6 mo of age; *3*) from 6 mo of age, continue to breastfeed and give solid foods enriched with fish, caterpillars/insects, and eggs, even when you provide Kulabora; and *4*) wash your hands with soap or ash before preparing food, eating, giving food to your baby, and after using the toilet. These messages were included in flipchart teaching aids, during educational sessions, other in-person interactions, on posters, on the Kulabora packaging, and in radio spots.

The IMIKA program also strengthened the role of CHWs who formed an integral part of IYCF counseling and, for SQ-LNS, the monthly distribution, as well as counseling on the appropriate storage and use of SQ-LNS. Mothers of children 6–12 mo of age in the intervention zone were expected to receive 4 strips of 7 sachets of SQ-LNS (i.e., a monthly totaling 28 sachets, which we refer to as a batch) at their nearest health facility during their monthly clinic visits or for very-hard-to-access areas through outreach services by health center staff. Each child was eligible to receive 6 batches, 1/mo from 6–12 mo of age. Each of the 7 sachets detailed pictorially how to use SQ-LNS (Kulabora) and included a key message: *1*) give 1 packet per child per day, *2*) wash your child's hands with soap and water before feeding, *3*) breastfeed your child before giving food, *4*) put a small amount of food that you think your child will eat in a separate bowl, *5*) mix the Kulabora into the food, *6*) feed the food mixed with the Kulabora to your child, and *7*) Kulabora is for children from 6 to 12 mo of age. In September 2012, the enhanced IYCF counseling started, and Kulabora distribution started in May 2013 and continued until after the completion of all evaluation data collection, ending approximately March 2015.

### Lot-quality assurance survey assessments

Three rounds (February 2013, July 2013 and February 2014) of lot-quality assurance surveys (LQASs) (28) were conducted in all 13 health areas in the intervention zone. This was an additional effort to monitor the enhanced intervention package put in place to check if the program was functioning reasonably well before going to the effort of conducting the endline survey. Health areas/posts were graded on 21 benchmark questions that ranged from SQ-LNS stocks, staff training, health worker activities, program coverage in terms of SQ-LNS, and group counseling. A pass or fail grade was assigned if a predefined coverage target was achieved or not. Corrective action was implemented in low-performing health centers as needed.

### Program evaluation surveys

A pre-post, quasi-experimental effectiveness study design was used to evaluate the IMIKA program. Repeated serial cross-sectional baseline and endline surveys were conducted in the intervention and the comparison HZs. The baseline survey was conducted in October 2011 and the endline survey in October–November 2014 in both sites. Caregivers of children 6.0–11.9 mo of age were expected to receive monthly distributions of SQ-LNS for a maximum of 6 distributions per child. The endline survey occurred in October–November 2014, 6 mo prior to the end of the SQ-LNS supply, which was expected to last until March 2015.

The baseline and endline surveys followed a 2-stage cluster-sampling design. In the first stage, 30 clusters were randomly selected from each HZ (60 total) using probability-proportional-to-population-size sampling. The enumeration team made a list of all children aged 6.0–17.9 mo in each selected cluster, and 22 children from each cluster were randomly selected. There was no replacement for any reason. The same clusters were used for the baseline and the endline data collection, but different households and children were randomly selected, as the children selected in the baseline sample had aged out of the intervention. The estimated sample size provided 80% power to detect a relative decline in the prevalence of anemia and ID of 15% and 20%, respectively, at an $\alpha$ of 0.05.

### Study population, enrollment, and survey modules

The enhanced IYCF–SQ-LNS intervention was designed for pregnant women and children aged <12 mo. However, the age

range for the evaluation was children aged 6–18 mo, even though those >12 mo would have aged out of the program. This was done in order to reduce the difficulties and costs associated with identifying enough children within a much narrower age band and because the expectation was that any effects would persist among those children who had aged out of the program. Due to cost, and typical reduction in health care–seeking behavior of mothers of children >1 y of age, it was not possible to expand the age range of the intervention.

Trained enumerators asked caregivers questions pertaining to household sociodemographic characteristics and knowledge, attitudes, experiences, and behaviors relating to nutrition, IYCF, anemia, and SQ-LNS. The enumerators asked mothers to recall various breastfeeding practices for the selected child aged 6–18 mo, such as how soon after birth breastfeeding was initiated, whether the child was breastfed yesterday, and when water and complementary foods were first introduced. Also, at baseline and endline, a 24-h recall of all the foods and drinks (including meals and snacks) children consumed in the previous day and night was collected in accordance with the standard WHO/UNICEF IYCF indicators approach (29). In the endline survey only, mothers were asked about exposure to specific parts of the IMIKA program, such as familiarity with their CHW, participation in group counseling sessions, and awareness of radio messages on IYCF. Extensive information was also collected on the use of the SQ-LNS, including how it was consumed (mixed or eaten alone), if the child liked the SQ-LNS, any changes (both positive and negative) since the child started consuming the SQ-LNS, and how many monthly batches had been collected from the nearest health facility.

### Anthropometry and laboratory data

After the questionnaire was completed, anthropometric measures of the children were taken by trained enumerators following standardized protocols (30). Weight was measured using electronic Seca® 874 scales to the nearest 10 g. Length was measured using a wooden Shorr® measuring board to the nearest millimeter. Age was calculated using date of birth from either a child health card or birth certificate (if available) and the date of survey. If no reliable proof of age was available, age was estimated in months using a local events calendar or by mother/caregiver report.

A capillary blood specimen was collected in a 500-$\mu$L Microtainer® with EDTA through a finger prick. One drop of blood from the Microtainer® was used for the evaluation of hemoglobin by the photometric method using the HemoCue® 301 hemoglobin system (HemoCue® AB). One drop was used to test for malaria using a malaria antigen (HRP2/pLDH) combo rapid test kit for *Plasmodium falciparum* and *Plasmodium vivax*. The Microtainers® were stored in a cool box during the day and transported to a central laboratory in each zone where they were processed at the end of the day. The Microtainers® were centrifuged at 3500 rpm for 10 min at room temperature using a fixed-speed centrifuge, and the plasma was pipetted into cryovial tubes and PCR tubes. The processed specimens were then frozen and stored at −20°C. At the end of the survey, the specimens were shipped to Germany, where the VitMin Laboratory used an ELISA to assess serum ferritin (SF), sTfR, retinol binding protein (RBP), C-reactive protein (CRP), and α1-acid glycoprotein (AGP) (31).

### Statistical data analyses

Descriptive statistics are presented as percentages. Statistical significance was set at $P < 0.05$, and all analyses were adjusted for clustering with Taylor series variance estimation. Analyses were conducted with SAS version 9.4 (SAS Institute). Child anthropometric variables were converted into $z$ scores [length-for-age (LAZ), weight-for-age (WAZ), and weight-for-length (WLZ)] based on the WHO 2006 growth standards (32). Biologically implausible values (BIVs; i.e., WAZ $-6 <$ WAZ $> +5$, LAZ $-6 <$ LAZ $> +5$, WLZ $-5 <$ WLZ $> +5$) were flagged and excluded from subsequent analyses (32). Six BIVs or 0.23% of observations were excluded. Key outcome measures included anthropometric $z$-score indices (LAZ, WLZ, and WAZ) and nutritional biomarkers (hemoglobin, SF, sTfR, and RBP). Each outcome was assessed as a continuous variable as well as a categorical indicator.

Anemia was defined according to WHO classifications as anemic (hemoglobin <11.0 g/dL) and "severe or moderate anemia" for hemoglobin <10.0 g/dL (33). Moderate and severe anemia were combined to a single category due to the low prevalence of severe anemia. All clusters in both HZs were located <1000 m so hemoglobin concentration was not adjusted for altitude. ID was defined as SF <12 μg/L. RBP concentrations of less than the 0.7-μmol/L cutoff were used to define vitamin A deficiency. SF, sTfR, and RBP biomarkers were adjusted for inflammation using the Biomarkers Reflecting Inflammation and Nutritional Determinants of Anemia (BRINDA) regression correction technique (34–36).

We used an additive difference-in-difference (DiD) (37–39) modeling technique to test and quantify program impact and the associations between the integrated IYCF and SQ-LNS and program indicators between the 2 HZs in pre- and post-surveys. Generalized linear mixed models (GLMMs) with cluster as a random effect were used to examine associations. The DiD effects, their 95% CI, and $P$ values were obtained from GLMMs that accounted for HZ (intervention vs. control) and time (endline vs. baseline) and included an interaction term between HZ and time for quantifying program impact. This use of DiD from mixed models to quantify program impact allowed interpretation of average program effect for an average child within each cluster and was well suited for our design of repeated serial cross-sectional data of different children (38, 39). Two separate GLMMs were used to explore these associations, i.e., *1*) continuous and *2*) categorical variable outcome analysis.

It was determined a priori that the multivariable DiD models would adjust for the following confounding covariates: child's sex and age; maternal age, education, and ethnicity; urban versus rural; household's primary source of income; household asset tertile (from a cumulative count of all household possessions); the presence of another child <5 y old in the household; and malaria test positive status of the index child. Further, multivariate mixed linear models were used to calculate prevalence differences (PDs; %) for binary program indicators that were measured at endline only in both HZs. Rao-Scott chi-square test was used to compare differences in proportions for selected categorical indicators

and a design-based *t* test was used for continuous variables as appropriate.

Additionally, in the intervention HZ, program exposure also included the SQ-LNS intervention component, which was captured in a variety of indicators. Components included "mother received SQ-LNS for her child at least once," number of times SQ-LNS received, and mothers who received 1 batch (28 SQ-LNS sachets) at the last distribution, among several other variables. We evaluated the potential dose–response effect of the SQ-LNS among children 8 to 13 mo old in the intervention HZ who were eligible to receive ≥3 monthly SQ-LNS distributions (3 × 28 sachets) and eligible to receive LNS within the last month. This 8–13-mo age group was selected because SQ-LNS were distributed during routine monthly health facility visits; however, timely introduction of solid foods/complementary feeding at 6 mo in the villages in both HZs was low, ∼27% (27). Children who were only 6 or 7 mo old would have had no or limited time to consume SQ-LNS sachets as they would have received only 1 or 2 batch distributions at maximum, whereas children aged 13 mo would have recently finished SQ-LNS intake and have had a high potential exposure to SQ-LNS over the prior 6 mo. Hence, the 8–13-mo age range enabled us to identify a subpopulation of children most likely to have sufficient program exposure to expect a biological impact.

For this dose–response analysis we created 3 categories of Kulabora exposure: *1*) no SQ-LNS received, *2*) low exposure (received 1–2 batches of SQ-LNS), and *3*) higher exposure for ≥3 mo of distribution of SQ-LNS batches, equivalent to ≥50% of the total SQ-LNS sachets. GLMM was used to estimate relative differences in program indicators across the 3 categories of SQ-LNS exposure. In the intervention HZ, we also quantified adjusted PDs of indicators between endline and baseline. We note that adjusted prevalence or mean difference estimates were all calculated from estimable functions of marginals (i.e., least-square means) (40) that accounted for potential confounding covariates. Therefore, estimates might not approximate the value obtained from algebraic subtraction of crude differences in prevalences (or means) and are also subject to missing covariates in the full GLMM.

## Results

**Table 1** describes core characteristics of the surveys. There were 1288 children included in the baseline survey and 1307 children in the endline survey. Participation rates were high (>96%) and were similar across both HZs over time (**Figure 1**). Less than one-third (30.6% baseline vs. 29.5% endline) of control HZ mothers were <24 y old (younger mothers), and in the intervention HZ this was 35.1% and 37.4% at both time points. The proportion of younger children (6–11.99 mo) was not different between baseline and endline (46.1% to 50.8, $P = 0.07$) in the control or in the intervention HZ (57.2% vs. 54.0%, $P = 0.35$). The proportion of male children was lower at endline (53.2% vs. 47.9, $P = 0.04$) in the intervention zone. In both zones, the proportion of mothers with incomplete or no formal education significantly increased over the period (control: 17% to 28.0%; $P < 0.0001$; intervention: 40.0% to 68.7%; $P < 0.0001$). Malaria prevalence increased markedly in both the intervention (34.9 to 58.1%, $P < 0.0001$) and control (8.2% to 24%, $P < 0.0001$) HZs over the 2 time points.

The results of selected program indicators (as percentages) and adjusted DiD or PD analyses for categorical outcomes are shown in **Table 2**. The proportion of mothers who received prenatal care from a facility-based health worker during their last pregnancy was significantly higher in percentage points (pp) in the intervention than in the control HZ (+5.4 pp; 95% CI: 1.7, 9.2; $P < 0.01$). Similarly, the program was significantly associated with a higher proportion of mothers who knew their current CHW in the intervention compared with the control HZ (multivariate adjusted DiD: +47.8% points; 95% CI: 41.8, 53.8; $P < 0.01$).

Table 2 shows that the receipt of specific services provided by the CHWs during the last pregnancy and birth of the index child was significantly higher in the intervention than in the control HZ. In the intervention HZ relative to the control HZ at endline, a higher proportion of mothers (PD = +15.3 pp; $P < 0.01$) had received breastfeeding information from a facility-based health worker and had received counseling on child feeding from their mobile CHWs (PD = +44.0%; $P < 0.01$). Similarly, in terms of current or recent utilization of health services and exposure to community programs, the intervention HZ was associated with a significantly higher proportion of households with bednet ownership (+7.7 pp), with children who slept under a bednet the night prior to the survey (+18.2 pp), and of mothers who received breastfeeding information from a health worker (+11.2 pp) and from their CHWs (+44.0 pp) ($P < 0.01$, each PD).

The proportion of mothers who had heard of Kulabora (SQ-LNS) was much higher in the intervention zone compared with the comparison zone (PD: +95.0 pp; $P < 0.01$), which indicates minimal spillover of the intervention. In the intervention zone, 70.5% of mothers had received ≥1 batch of SQ-LNS, and of those, 99.6% reported feeding the SQ-LNS to their child at least once. Of mothers who received their child's SQ-LNS allotment, 92.8% reported mixing the SQ-LNS into their child's food. Among mothers of children aged 9–12 mo, 73% received the SQ-LNS at least once, as did 60.3% of mothers with children aged 6.0–8.9 mo. Mothers of children aged 12.0–17.9 mo received an average of 2.7 batches, out of an expected 6 batches (1/mo from 6 to 12 mo). Among the mothers who reported receiving SQ-LNS 1 mo prior to the endline survey date, 91.3% reported receiving the expected 28 sachets per batch. Among mothers who had received their monthly SQ-LNS allotment (28 sachets) at the last monthly distribution (91.3%), 74.7% of those mothers reported that their child consumed all 28 sachets. The mean number of sachets consumed from the last distribution was 24.7 per child.

Results of program impact estimates of child growth and micronutrient indicators from baseline to endline are shown in **Table 3**. With the exception of hemoglobin concentrations, there were no significant program impacts (DiDs) in continuous growth and nutritional biomarker outcomes. Compared with baseline estimates, the mean hemoglobin concentration was lower in the endline survey in both zones. However, the decline in hemoglobin concentrations was smaller in the intervention zone than in the comparison zone, and the multivariate adjusted DiD in hemoglobin was significant (0.26 g/dL; $P = 0.02$).

While the prevalence of anemia increased in both zones between the baseline and endline surveys, the increase was significantly less in the intervention zone [64.8% to 72.2% (+7.4%) vs. 32.1% to 48.7% (+16.6%) in the comparison zone]. Further, in the multivariate DiD model, the IMIKA program was associated with a −11.0% ($P = 0.003$) adjusted change in the prevalence of any anemia. Similarly, there was also a significant

**TABLE 1** Demographic characteristics of children 6–18 mo of age in the baseline and endline surveys in 2 health zones (control and intervention) in Katanga Province, Democratic Republic of Congo

| | Control, *n* (%) | | Intervention, *n* (%) | |
|---|---|---|---|---|
| | Baseline ($n = 638$) | Endline ($n = 653$) | Baseline ($n = 650$) | Endline ($n = 654$) |
| Household characteristics | | | | |
| Household location | | | | |
| Urban | 317 (49.7) | 332 (50.8) | 108 (16.6) | 107 (16.4) |
| Rural | 321 (50.3) | 321 (49.2) | 542 (83.4) | 547 (83.6) |
| Primary source of income | | | | |
| Agriculture | 234 (36.7) | 258 (39.5) | 530 (81.5) | 536 (82.0) |
| Wage labor/daily work | 209 (32.8) | 248 (38.0) | 56 (8.6) | 85 (13.0) |
| Other | 195 (30.6) | 147 (22.5) | 64 (9.9) | 33 (5.1) |
| Asset tertile[1] | | | | |
| Tertile 1 (most assets) | 349 (54.7) | 298 (46.4) | 81 (12.5) | 114 (17.6) |
| Tertile 2 | 150 (23.5) | 176 (27.4) | 286 (44.0) | 264 (40.8) |
| Tertile 3 (fewest assets) | 139 (21.8) | 169 (26.3) | 283 (43.5) | 269 (41.6) |
| Number of children <5 y in the household | | | | |
| Only the index child | 135 (21.2) | 147 (23.3) | 178 (27.4) | 221 (34.1) |
| Two or more children <5 y | 503 (78.8) | 483 (76.7) | 472 (72.6) | 427 (65.9) |
| Maternal characteristics | | | | |
| Mother's age | | | | |
| Youngest tertile (<24 y) | 195 (30.6) | 191 (29.5) | 227 (35.1) | 243 (37.4) |
| Middle tertile (24–30 y) | 227 (35.6) | 230 (35.5) | 201 (31.1) | 185 (28.5) |
| Oldest tertile (>30 y) | 216 (33.9) | 227 (35.0) | 218 (33.8) | 222 (34.2) |
| Highest level of education achieved | | | | |
| Incomplete/no formal education | 108 (17.0) | 183 (28.0) | 260 (40.0) | 449 (68.7) |
| Primary school | 309 (48.5) | 330 (50.5) | 329 (50.6) | 168 (26.7) |
| Secondary school or university | 220 (34.5) | 140 (21.4) | 61 (9.4) | 37 (5.7) |
| Maternal report of location for primary health care | | | | |
| Hospital | 64 (10.0) | 55 (8.4) | 81 (12.5) | 55 (8.4) |
| Health center | 456 (71.5) | 552 (84.5) | 431 (66.3) | 493 (75.4) |
| Health post | 118 (18.5) | 46 (7.0) | 138 (21.2) | 106 (16.2) |
| Child characteristics | | | | |
| Child's sex | | | | |
| Male | 334 (52.4) | 328 (50.2) | 346 (53.2) | 313 (47.9) |
| Child's age (6–17.99 mo) | | | | |
| 6–11.99 mo | 294 (46.1) | 332 (50.8) | 372 (57.2) | 353 (54.0) |
| Child's ethnicity | | | | |
| Bemba | 75 (11.8) | 87 (13.3) | 600 (92.3) | 592 (90.5) |
| Other[2] | 563 (88.2) | 566 (86.7) | 50 (7.7) | 62 (9.5) |
| Child's malaria status at time of survey[3] | | | | |
| Positive test for malaria | 52 (8.2) | 157 (24.0) | 227 (34.9) | 380 (58.1) |

[1]Based on a principal components analysis of household asset ownership including whether the household has a radio, television, mobile phone, refrigerator, stove, chair, bed, lamp, oven, hoe, sewing machine, bicycle, car, truck, and electricity.

[2]Other ethnicities include Luba, Balamba, Basanga, Rund, Hemba, Tabwa, Kasai, Kaonde, and Katshowe.

[3]Child was tested for malaria using a rapid test kit.

potential program association with moderate or severe anemia, with a DiD of −6.5% ($P = 0.04$).

We examined SQ-LNS dose–response in analyses from the endline survey in the intervention zone only among children 8–13 mo of age (**Table 4**). Children who received ≥3 mo of SQ-LNS batch distributions had a significantly higher adjusted mean LAZ (+0.40, $P = 0.03$), WAZ (+0.37, $P = 0.04$), and hemoglobin concentration (+0.65 g/dL, $P = 0.007$) than children who did not receive SQ-LNS in the full multivariable models. Children in the higher SQ-LNS category had a significant lower adjusted prevalence of stunting (PD = −16.7%; $P = 0.03$). **Supplemental Table 1** describes intervention arm–specific results for nutrition indicators. In sensitivity analyses (**Supplemental Table 2**), we found that mean ferritin concentrations in both intervention and control HZs and at both time points were significantly higher in malaria-positive compared with malaria-negative children. In contrast, hemoglobin concentrations were lower among malaria-positive children. This was consistent with the results of multivariate regression analyses (**Supplemental Table 3**). Here, malaria was positively associated with anemia [prevalence ratio (PR): 1.65; 95% CI: 1.52, 1.79] and iron deficiency anemia (PR: 1.28; 95% CI: 1.15, 1.43) but inversely associated with ID (PR: 0.61; 95% CI: 0.53, 0.70).

## Discussion

In this pre- and post-survey quasi-experimental effectiveness design in 2 HZs in the DRC, children aged 6–18 mo in an integrated IYCF–SQ-LNS intervention HZ experienced significantly smaller increases in the prevalence of anemia relative to

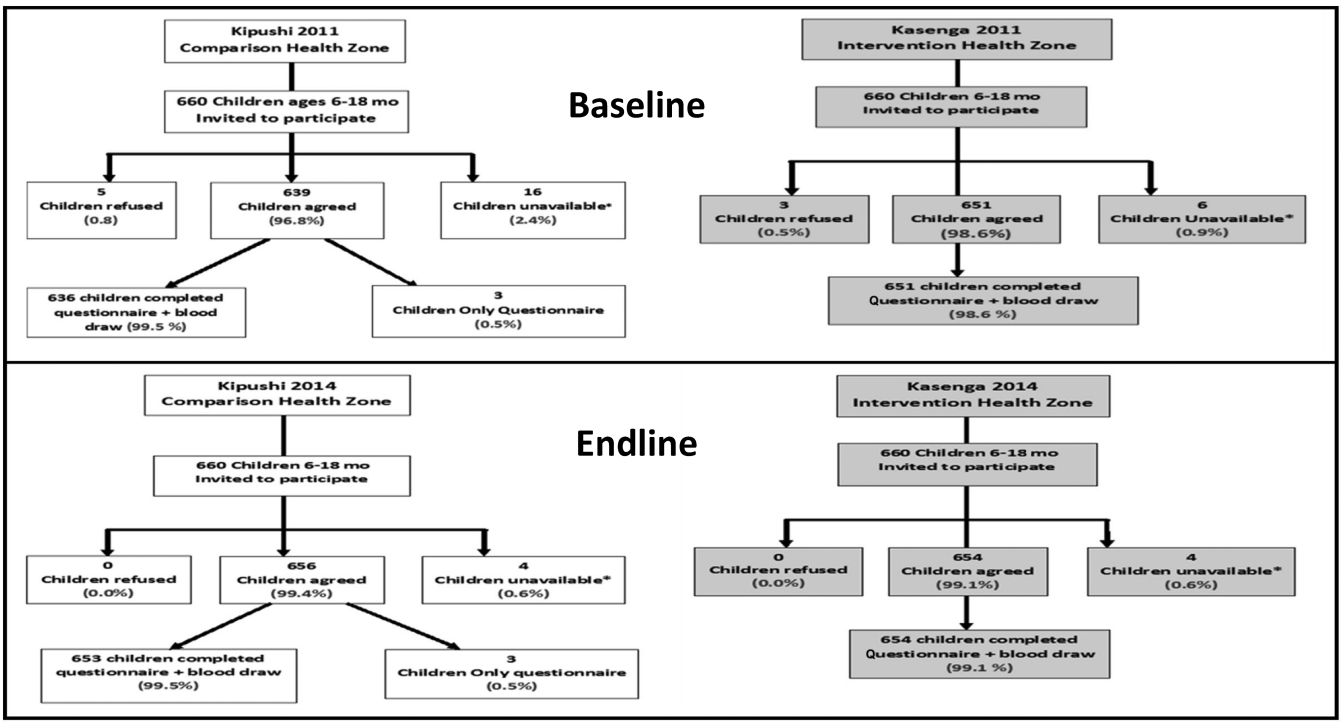


**FIGURE 1** Participant flow diagram and survey response rates across 2 health zones in Katanga Province, Democratic Republic of Congo. *children were considered unavailable if they were not available in their household after three attempted visits.

a comparison HZ and experienced significantly smaller declines in mean hemoglobin. Regardless of program arm, there was no impact on child growth indicators (stunting, wasting, and underweight). However, in the as-treated analyses, we observed an SQ-LNS biological dose–response in the intervention HZ at endline among children aged 8–13 mo, such that children with higher program exposure (receipt of ≥3 monthly batches of SQ-LNS) showed improvements in growth (LAZ, WAZ), lowered PD of stunting, and higher hemoglobin compared with children with no receipt of SQ-LNS. This evaluation is one of the first to examine the effectiveness of SQ-LNS integrated with an enhanced IYCF program and delivered within an existing community-based public health care system. The stand-alone impact of SQ-LNS on growth in various RCTs has been mixed, with studies in Bangladesh and Ghana showing a positive impact on child growth (17, 19), whereas similar studies in Malawi and Peru did not (22, 41). Nutrition education to improve IYCF practices has previously been shown to decrease stunting prevalence in children (6), but program impact may be context specific, particularly in settings where food access is not a limiting factor (6). Similarly, evidence from systematic review and meta-analyses of longitudinal trials from low- to middle-income countries found a small but significant positive association between complementary feeding with nutrition education interventions on child growth indicators in food-secure settings (42).

Given that per protocol analyses showed a positive impact in the DRC, this suggests that, on average, all children might not have received SQ-LNS monthly or the other components [e.g., wash, sanitation, and hygiene (WASH), counseling messages, or increased contacts with health service] and hence it is possible that, with improved program fidelity, the IYCF–SQ-LNS package may demonstrate greater effectiveness and impact at scale. Despite improvements in certain aspects of IYCF, there were very few changes in dietary indicators, such as dietary diversity (27), implying that even if products like SQ-LNS are available, efforts to improve the quality of locally available complementary foods, increasing dietary diversity, and food security should remain a priority.

Prior studies in other countries that provided SQ-LNS to mothers in pregnancy and to their infants (after 6 mo) had positive effects on growth (17, 19). SQ-LNS during pregnancy might avert adverse birth events like small-for-gestational age, low birth weight, and preterm birth, which can negatively impact growth indicators in childhood (43), as faltered growth trajectories are usually set in utero (44), especially in low- and middle-income countries. The current IYCF–SQ-LNS program gave children daily SQ-LNS only for a limited duration of 6 mo, and their mothers did not receive SQ-LNS during pregnancy (they did receive iron and folic acid supplements and malaria prophylactics). Considering the results in the broader literature, further exploration of the optimal timing of SQ-LNS might be an important area for future efficacy and effectiveness research. It is possible that the observed positive impact on child growth in the DRC might have been larger if mothers of these children had been given counseling plus SQ-LNS during pregnancy. The causes of child growth faltering are multifactorial, complex, and driven by both biological and contextual factors (water and sanitation, infectious diseases, poverty) (44–46), which might have been stronger in these rural HZs of Katanga Province, thereby limiting the overall impact of the IYCF–SQ-LNS package to improve other child growth indicators. Since this research is based on an

**TABLE 2** Selected IYCF–SQ-LNS program indicators in 2 health zones (control and intervention) of Katanga Province, Democratic Republic of Congo[1]

| Characteristics | Control, *n* (%) | | Intervention, *n* (%) or mean ± SE | | Adjusted multivariate DID, % (95% CI) or PD | *P* |
|---|---|---|---|---|---|---|
| | Baseline (*n* = 638) | Endline (*n* = 653) | Baseline (*n* = 650) | Endline (*n* = 654) | | |
| Use of health services during pregnancy and birth | | | | | | |
| Mother received prenatal care from a facility-based health worker during her last pregnancy[2] | 586 (95.8) | 583 (93.6) | 621 (97.2) | 641 (98) | +5.4 (1.7, 9.2)[3] | <0.01 |
| Mother gave birth in a health facility | 594 (93.1) | 622 (95.3) | 588 (90.5) | 619 (94.6) | +1.9 (−1.9, 5.7)[3] | 0.33 |
| During her last pregnancy, mother received information on breastfeeding from a health worker[2] | — | 488(78.3) | — | 586(89.6) | +15.3 (8.2, 22.4)[4] | <0.01 |
| During last pregnancy, mother received information on breastfeeding from a CHW[2] | — | 3 (0.5) | — | 291(44.5) | +44.0 (37.2, 50.7)[4] | <0.01 |
| Current or recent use of health services and exposure to community programs | | | | | | |
| Mother knows her CHW | 539 (84.6) | 348 (53.5) | 498 (76.7) | 608 (93.1) | +47.8 (41.8, 53.8)[3] | <0.01 |
| Mother reports that the child received vitamin A within 6 mo prior to the survey | 527 (82.6) | 560 (85.8) | 335 (51.5) | 402 (61.7) | +5.7 (−0.9,12.3)[3] | 0.09 |
| Mother reports that the household has a bednet | — | 472 (72.3) | — | 506 (77.4) | +7.7 (1.9, 13.5)[4] | <0.01 |
| Interviewer observed the household bednet[5] | — | 302 (46.2) | — | 325 (49.7) | +4.8 (−2.2, 11.8)[4] | 0.18 |
| Mother reports child slept under a bednet last night[5] | — | 364 (56.2) | — | 471 (73.0) | +18.2 (11.8, 24.6)[4] | <0.01 |
| Mother reports she has received counseling on feeding her child from a health worker[5] | — | 486 (78.4) | — | 582 (89.0) | +11.2 (6.3, 16)[4] | <0.01 |
| Mother reports she has received counseling on child feeding from a CHW[5] | — | 2 (0.3) | — | 292 (44.6) | +44.0 (39.3, 48.6)[4] | <0.01 |
| SQ-LNS indicators | | | | | | |
| Mother has heard of Kulabora (SQ-LNS) | — | 9 (1.4) | — | 627 (95.9) | +95.0 (93.1, 96.9)[4] | <0.001 |
| Mother received SQ-LNS for her child at least once | No SQ-LNS distribution | | — | 461 (70.5) | — | — |
| Among children 6.0–8.9 mo (*n* = 179) | — | — | — | 108 (60.3) | — | — |
| Among children 9.0–11.9 mo (*n* = 174) | — | — | — | 127 (73.0) | — | — |
| Among children 12.0–17.9 mo (*n* = 301) | — | — | — | 226 (75.1) | — | — |
| Among mothers who received SQ-LNS (*n* = 459), number of times the mother received SQ-LNS | — | — | — | 2.3 ± 0.8 | — | — |
| Among children 6.0–8.9 mo (*n* = 108) | — | — | — | 1.6 ± 0.7 | — | — |
| Among children 9.0–11.9 mo (*n* = 127) | — | — | — | 2.2 ± 0.7 | — | — |
| Among children 12.0–17.9 mo (*n* = 224) | — | — | — | 2.7 ± 0.7 | — | — |
| Among mothers who received SQ-LNS (*n* = 461) | | | | | | |
| Mother received 28 sachets at last distribution[6] | — | — | — | 421 (91.3) | — | — |
| Mother fed SQ-LNS to her child at least once | — | — | — | 459 (99.6) | — | — |
| Mother reports selling/trading SQ-LNS | — | — | — | 2 (0.4) | — | — |
| Mother reports feeding SQ-LNS to someone other than the index child | — | — | — | 31 (6.7) | — | — |
| Mother reports mixing SQ-LNS into her child's food | — | — | — | 428 (92.8) | — | — |
| Mother reports feeding SQ-LNS to the child directly | — | — | — | 33 (7.2) | — | — |
| Mother usually received SQ-LNS from a health facility | — | — | — | 305 (66.2) | — | — |
| Mother usually received SQ-LNS from CHW | — | — | — | 23 (5.0) | — | — |
| Mother usually received SQ-LNS outside of health facility | — | — | — | 106 (23.0) | — | — |
| Among mothers who received 28 SQ-LNS sachets at the last distribution (*n* = 421) | | | | | | |
| Child consumed all 28 sachets | — | — | — | 313 (74.7) | — | — |
| Mean number of sachets consumed | — | — | — | 24.7 ± 7.1 | — | — |

[1]CHW, community health worker; DID, difference-in-differences; GLMM, generalized mixed linear regression model; IYCF, infant and young child feeding; PD, prevalence difference; SQ-LNS, small-quantity lipid-nutrient supplements.

[2]Facility-based health workers include doctors, nurses/midwives, and auxiliary nurses/midwives.

[3]Adjusted DiD, %, estimates, their corresponding 95% CIs, and *P* values were obtained from GLMMs with an interaction term between health area (intervention vs. control) and time (endline vs. baseline), and cluster as a random effect. Fully adjusted multivariable models controlled for child's sex, age, and ethnicity; maternal age and education; household demographics variables; whether there was another child <5 y in the household; and malaria-positive status of index child.

[4]Adjusted PD estimated when the indicator was assessed at endline only. PD was derived as the difference in proportions indicators between the interventions to the comparison group (reference) at endline using mixed linear regressions with cluster as a random effect with adjustment for covariates. Adjusted PDs are estimated from predicted population marginals with adjustment for covariates (47).

[5]Indicator assessed at endline only.

[6]Mothers received their monthly allotment of SQ-LNS prior to endline survey date.

**TABLE 3** Nutritional status of children aged 6–18 mo from 2 health zones (control and intervention) of Katanga Province, Democratic Republic of Congo[1]

| | Control | | Intervention | | Adjusted multivariate[2] model | |
|---|---|---|---|---|---|---|
| | Baseline ($n = 638$) | Endline ($n = 653$) | Baseline ($n = 650$) | Endline ($n = 654$) | Adjusted difference in mean differences or adjusted DiD (95% CI) | $P$ |
| Continuous outcomes | | | | | | |
| LAZ | −1.51 ± 0.07 | −1.49 ± 0.07 | −1.92 ± 0.06 | −2.05 ± 0.06 | −0.11 (−0.30, 0.08)[3] | 0.26 |
| WLZ | −0.13 ± 0.04 | −0.36 ± 0.04 | −0.56 ± 0.04 | −0.71 ± 0.04 | +0.11 (−0.07, 0.28)[3] | 0.24 |
| WAZ | −0.89 ± 0.06 | −1.05 ± 0.06 | −1.47 ± 0.05 | −1.64 ± 0.05 | +0.03 (−0.15, 0.21)[3] | 0.77 |
| Hemoglobin, g/L | 11.31 ± 0.07 | 10.83 ± 0.07 | 10.13 ± 0.08 | 9.83 ± 0.08 | +0.26 (0.04, 0.48)[3] | 0.02 |
| Serum ferritin,[4] μg/L | 11.06 ± 0.96 | 14.28 ± 0.96 | 13.42 ± 0.71 | 16.53 ± 0.71 | −0.57 (−2.77, 1.63)[3] | 0.61 |
| sTfR,[4] μg/L | 9.30 ± 0.21 | 9.78 ± 0.21 | 10.34 ± 0.26 | 11.51 ± 0.25 | +0.49 (−0.36, 1.35)[3] | 0.25 |
| RBP,[4] μmol/L | 1.16 ± 0.02 | 1.2 ± 0.02 | 1.23 ± 0.02 | 1.29 ± 0.02 | +0.02 (−0.05, 0.08)[3] | 0.60 |
| Categorical outcomes | | | | | | |
| Stunting[5] | 215 (33.8) | 208 (32.1) | 328 (50.6) | 330 (50.5) | +0.0% (−7.3, 7.5)[6] | 0.98 |
| Wasting[5] | 31 (4.9) | 42 (6.5) | 62 (9.6) | 80 (12.2) | +0.7% (−3.6, 5.0)[6] | 0.75 |
| Underweight[5] | 99 (15.5) | 116 (17.9) | 203 (31.3) | 238 (36.4) | +1.8% (−4.9, 8.4)[6] | 0.60 |
| Anemia[7] | 205 (32.1) | 318 (48.7) | 421 (64.8) | 472 (72.2) | −11.0% (−18.1, −3.8)[6] | <0.01 |
| Moderate or severe anemia[7] | 68 (10.7) | 142 (22.0) | 251 (38.6) | 305 (36.7) | −6.5% (−12.8, −0.2)[6] | 0.04 |
| Serum ferritin <12 μg/L[4] | 459 (71.9) | 411 (62.9) | 356 (54.8) | 294 (45.0) | +1.7% (−5,5, 8.9)[6] | 0.64 |
| sTfR >8.3 μg/L[4] | 322 (50.5) | 276 (42.3) | 381 (58.6) | 389 (59.5) | +5.9 (−1.7, 13.5)[6] | 0.13 |
| Iron deficiency[4,8] | 504 (79.0) | 486 (74.4) | 522 (80.3) | 501 (76.6) | +0.04% (−6.1, 6.9)[6] | 0.90 |
| Iron deficiency anemia[4,8] | 169 (26.5) | 212 (32.5) | 215 (33.1) | 213 (32.6) | −5.4% (−12.5, 1.8)[6] | 0.14 |
| Vitamin A deficiency[4,9] | 26 (4.1) | 30 (4.6) | 39 (6.0) | 27 (4.1) | −2.6% (−6.0, 0.7)[6] | 0.12 |

[1]Values are means ± SEs or n (%) unless otherwise indicated. BRINDA, Biomarkers Reflecting Inflammation and Nutritional Determinants of Anemia; DiD, difference-in-difference; LAZ, length-for-age $z$ score; RBP, retinol binding protein; sTfR, soluble transferrin receptor; WAZ, weight-for-age $z$ score; WLZ, weight-for-length $z$ score.

[2]Fully adjusted multivariable models controlled for child's sex, age, and ethnicity; maternal age and education; whether the household was urban or rural; the household's primary source of income and asset tertile; whether there was another child <5 y in the household; and whether the child tested positive for malaria.

[3]For continuous outcome variables: adjusted difference in mean differences and corresponding 95% CIs and $P$ values were obtained from mixed linear regression models with an interaction term between health area (intervention vs. control) and time (endline vs. baseline) and cluster as a random effect.

[4]Biomarkers are adjusted for inflammation using the BRINDA linear regression technique described in Suchdev (48).

[5]Stunting, wasting, and underweight defined as <2 SDs for LAZ, WLZ, and WAZ, respectively.

[6]For categorical outcomes: adjusted DiD, DiD for proportions (%), their 95% CIs, and $P$ values were obtained from mixed linear models with an interaction term between health zone (intervention vs. control) and time (endline vs. baseline) and cluster as a random effect.

[7]Anemia defined as hemoglobin <11 g/dL.

[8]Iron deficiency defined as serum ferritin <12 μg/L. Iron deficiency anemia is defined as iron deficiency + anemia (hemoglobin <11 g/dL).

[9]Vitamin A deficiency defined as RBP <0.70 $\mu$mol.

integrated program, the observed associations are likely due to the combined effect of all components and not necessarily due to a single component, and the evaluation was not designed to tease out the effects of different components. Nonetheless, the findings suggest that a similar integrated approach and program delivery might be beneficial in other settings.

The integrated program was associated with a significantly lower increase in the proportion of children who suffered from anemia and consistent with data from a similar integrated health system SQ-LNS program in Peru, which saw an increased hemoglobin and reduced anemia prevalence (22). The DRC study, however, found no impact on other micronutrient status indicators, such as ID, iron deficiency, anemia, or vitamin A deficiency. This suggests that the inverse program association with anemia may be due to the interplay among program effectiveness of the other intervention components and sociodemographic and biological factors. Although it has been thought that 50% of anemia is attributable to ID in many settings (47), it is possible that anemia in this population is less likely to be due to ID. Inflammation has been shown to be related to biomarkers of iron and vitamin A. All models used inflammation corrected (34–36) SF, RBP, and sTfR data, likely reducing the role of inflammation in our interpretation. It is also possible that the observed increase in hemoglobin could be due to improvements in vitamin B-12, folate, and vitamin C status and other nutrients in the SQ-LNS formulation, which were not assessed in this evaluation.

There were marked increases in malaria prevalence across the 2 surveys and in both HZs, even though the surveys were conducted in the same season of 2011 and 2014. Malaria was assessed with qualitative rapid test kits but not by parasitic load and there could still be residual confounding, even after controlling for malaria in our models. This might also partially explain the nonsignificant ID impact. This is because malaria-positive children had higher SF concentrations relative to malaria-negative peers and could be due to iron sequestration during malaria infection (49–51). Children in the intervention HZ who received ≥3 mo of SQ-LNS distributions versus no SQ-LNS had a higher hemoglobin (adjusted mean difference:

**TABLE 4** Dose–response comparisons based on the number of times the mother received LNSs for her child, among children 8–13 mo old in the postintervention survey in the intervention health zone, Katanga Province, Democratic Republic of Congo[1]

| | | Received LNSs 1–2 times ($n = 136$) | | | Received LNSs of ≥3 batch distributions ($n = 80$) | | |
|---|---|---|---|---|---|---|---|
| | | | Adjusted multivariate[2] model | | | Adjusted multivariate[2] model | |
| Continuous outcomes | No LNSs (ref category) ($n = 89$) | Values | Adjusted mean difference or adjusted PD, % (95% CI) | *P* | Values | Adjusted mean difference or adjusted PD, % (95% CI) | *P* |
| Anthropometry | | | | | | | |
| LAZ | −2.17 ± 0.11 | −2.06 ± 0.12 | 0.08 (−0.24, 0.41)[3] | 0.61 | −1.99 ± 0.14 | 0.40 (0.02, 0.78)[3] | 0.04 |
| WLZ | −0.84 ± 0.11 | −0.69 ± 0.1 | 0.16 (−0.14, 0.45)[3] | 0.29 | −0.67 ± 0.11 | 0.18 (−0.16, 0.53)[3] | 0.30 |
| WAZ | −1.83 ± 0.11 | −1.67 ± 0.09 | 0.16 (−0.14, 0.46)[3] | 0.29 | −1.56 ± 0.12 | 0.37 (0.02, 0.72)[3] | 0.04 |
| Nutritional biomarkers | | | | | | | |
| Hemoglobin, g/dL | 9.37 ± 0.22 | 9.46 ± 0.16 | −0.02 (−0.43, 0.39)[3] | 0.92 | 10.2 ± 0.18 | 0.65 (0.18, 1.12)[3] | <0.01 |
| Serum ferritin,[4] μg/L | 14.15 ± 1.37 | 14.8 ± 1.45 | 1.91 (−1.83, 5.64)[3] | 0.3154 | 13.89 ± 1.3 | −0.46 (−4.79, 3.86)[3] | 0.83 |
| sTfR,[4] μg/L | 13.52 ± 0.94 | 12.25 ± 0.67 | −1.27 (−3.21, 0.68)[3] | 0.20 | 11.59 ± 0.65 | −1.71 (−3.97, 0.56)[3] | 0.14 |
| RBP,[4] μmol/L | 1.24 ± 0.04 | 1.32 ± 0.04 | 0.09 (−0.02, 0.21)[3] | 0.12 | 1.23 ± 0.04 | −0.02 (−0.15, 0.12)[3] | 0.82 |
| Nutrition indicators, *n* (%) | | | | | | | |
| Stunting[5] | 51 (57.3) | 64 (47.1) | −9.3 (−22.6, 3.9)[6] | 0.17 | 40 (50.0) | −16.7 (−32.1, −1.2)[6] | 0.03 |
| Wasting[5] | 14 (15.7) | 17 (12.5) | −3.7 (−12.7, 5.3)[6] | 0.42 | 6 (7.5) | −9.0 (−19.5, 1.6)[6] | 0.09 |
| Underweight[5] | 37 (41.6) | 46 (33.8) | −8.1 (−21.0, 4.8)[6] | 0.22 | 27 (33.8) | −14.3 (−29.4, 0.8)[6] | 0.06 |
| Anemia[7] | 70 (78.7) | 108 (79.4) | +2.5 (−8.7, 13.8)[6] | 0.66 | 52 (65.0) | −12.2 (−25.4, 0.9)[6] | 0.07 |
| Moderate or severe anemia[7] | 49 (55.1) | 73 (53.7) | −1.2 (−10.7, 13.2)[6] | 0.84 | 32 (40.0) | −12.6 (−26.5, 1.3)[6] | 0.08 |
| Serum ferritin <12 μg/L[4] | 45 (50.6) | 66 (48.5) | −3.7 (−17.3, 9.8)[6] | 0.59 | 41 (51.3) | −3.1 (−18.8, 12.6)[6] | 0.70 |
| sTfR >8.3 μg/L[4] | 56 (62.9) | 88 (64.7) | +3.2 (−9.6, 16.0)[6] | 0.629 | 52 (65.0) | +0.1 (−14.9, 15.2)[6] | 0.98 |
| Iron deficiency anemia[4,8] | 36 (40.5) | 52 (38.2) | −4.6 (−18, 8.8)[6] | 0.50 | 26 (32.5) | +7.0 (−8.6, 22.7)[6] | 0.38 |
| Vitamin A deficiency[4,9] | 8 (9.0) | 5 (3.7) | −4.9 (−11.1, 1.2)[6] | 0.1126 | 2 (2.5) | −6.2 (−13.3, 1.0)[6] | 0.08 |

[1] Values are means ± SEs unless otherwise indicated. SEs around means have taken clustering into account. Analysis is restricted to children aged 8–13 mo since children <8 mo would not have been old enough to have received LNSs of ≥3 batch distributions and children >13 mo should not have received SQ-LNS within the last month. BRINDA, Biomarkers Reflecting Inflammation and Nutritional Determinants of Anemia; DiD, difference-in-difference; GLMM, generalized mixed linear regression model; LAZ, length-for-age *z* score; LNS, lipid-nutrient supplement; PD, prevalence difference; RBP, retinol binding protein; ref, reference; SQ-LNS, small-quantity lipid-nutrient supplements; sTfR, soluble transferrin receptor; WAZ, weight-for-age *z* score; WLZ, weight-for-length *z* score.

[2] Fully adjusted multivariable models controlled for child's sex, age, and ethnicity; maternal age and education; whether the household was urban or rural; the household's primary source of income and asset tertile; whether there was another child <5 y in the household; and whether the child tested positive for malaria infection.

[3] For continuous outcome variables: adjusted mean differences and 95% CIs were obtained from GLMMs with cluster as a random effect.

[4] Biomarkers are adjusted for inflammation using the BRINDA linear regression technique described in references 34–36.

[5] Stunting, wasting, and underweight defined as <2 SDs for LAZ, WLZ, and WAZ, respectively.

[6] Adjusted PDs are estimated from mixed models for binary outcome with the identity link and cluster as a random effect and using no SQ-LNS as a referent category. Adjusted PDs are estimated from predicted population marginals with adjustment for covariates (47) but not from algebraic subtraction. Adjusted PD and adjusted mean difference estimates might not approximate values obtained from algebraic subtraction of crude prevalences and are subject to missing covariates in the GLMM.

[7] Anemia defined as hemoglobin <11 g/dL; moderate or severe anemia as hemoglobin <10 g/dL.

[8] Iron deficiency is defined as serum ferritin <12 μg/L. Iron deficiency anemia is defined as iron deficiency + anemia (hemoglobin <11 g/dL).

[9] Vitamin A deficiency is defined as RBP <0.70 μmol.

+0.65 g/dL) and lower stunting (adjusted PD: −16.7%) in the as-treated-analyses. This suggests that the IYCF–SQ-LNS program can achieve impact in settings like the DRC, but low program intensity/adherence might have been a major bottleneck to biological impact, as was noted elsewhere in a Gambian RCT (52). For example, at endline, >44% of mothers in the intervention HZ reported they received information on breastfeeding from a CHW and counseling on child feeding from a CHW (≤0.5% did so for each in the comparison HZ).

Strengths of this study include use of a comparison group and DiD analysis in a context where it was not possible to carry out a prospective, longitudinal study of mother–child pairs. Both surveys were conducted at similar times of the year, alleviating the potential role of seasonality. We were unable to assess fidelity or quality of other program components such as WASH, counseling messages, or maternal contacts with the health services. Clinical outcomes and morbidity data were not assessed in this work and might be a potential limitation. However, the possibility that improvements in hemoglobin concentrations or anemia reductions could impact functional outcomes is plausible in this DRC sample of young children. The evaluation design involved repeated cross-sectional surveys, so we are unable to tease out cohort or demographic differences or a temporal sequence of events. We could not directly assess and statistically account for SQ-LNS intake/adherence and implementation difficulties due to security issues. Children aged ≥6 mo or those for whom complementary feeding was delayed would not have been exposed to the SQ-LNS component. In anticipation of these recruitment challenges in identifying enough children, it was decided a priori that children aged 12–18 mo would also be sampled, and this might have affected the effective dosing duration received by certain groups of children. As child age was adjusted for in our models, it is less likely this sampling frame might have systematically biased our findings. If anything, it would have led to a dilution of overall impact because some children would not have consumed SQ-LNS for several (≤6) months prior to the endline data collection. An LQAS was conducted in the intervention HZ as part of routine program monitoring. Even though it was not an additional intervention we do recognize that it was higher intensity and included additional resources than standard monitoring practice. A mine was reopened in Kipushi (control HZ) between baseline and

endline, which may potentially have contributed to changes in the economic status of families, but we are unable to statistically control for these potential confounders and any impact they might have (e.g., food availability, household food insecurity, environmental conditions) in the catchment area.

Maternal recall bias of breastfeeding practices could be a limitation, but it is possible that this would have occurred similarly in both HZs. We are unsure if recall bias had any impact on observed associations and, if so, the potential direction. Although we attempted to adjust using multivariate models with key sociodemographic characteristics and for several other potential confounding factors, residual confounding is still possible.

In conclusion, the integrated IYCF–SQ-LNS program implemented through the public health care platform in an intervention zone of 1 province of the DRC was associated with a significantly smaller increase in anemia and smaller declines in hemoglobin, but there was no effect on anthropometric indicators. Children aged 8–13 mo in the intervention zone who received ≥3 mo of SQ-LNS distributions had higher LAZ, WAZ, and hemoglobin and a lower prevalence of stunting compared with those who did not, highlighting the importance of program adherence and biological impact. Future research could consider exploration of contextual tools that could maximize coverage and intake adherence in programs integrating an IYCF–SQ-LNS intervention.

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