

# An Integrated Infant and Young Child Feeding and Small-Quantity Lipid-based Nutrient Supplementation Program Is Associated with Improved Gross Motor and Communication Scores of Children 6-18 Months in the Democratic Republic of Congo

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**Objective** To evaluate the impact of an infant, young child feeding practices–small-quantity lipid nutrient supplements (SQ-LNS) intervention on child development scores in children aged 6-18 months in the Katanga Province, Democratic Republic of Congo (DRC).

**Study design** We analyzed data of 2595 children from 2 health zones in a quasi-experimental design with preimplementation and postimplementation surveys to evaluate program impact on child development scores. Standard care was received in the comparison health zone and the intervention health zone received standard care plus enhanced infant, young child feeding practices with a monthly supply of 28 SQ-LNS sachets for up to 1 year. Program exposure and communication and motor domains of the Ages and Stages questionnaire were collected to assess changes in child development scores. A quasi-intent-to-treat and adjusted difference-in-difference analyses were used to quantify impact of the enhanced compared with the standard package.

**Results** In adjusted models contrasting endline with baseline, there was a greater relative increase in proportion of children with normal communication (difference-in-difference, +13.7% [95%CI, 7.9-19.6;  $P < .001$ ] and gross motor scores, +7.4% [95% CI: 1.3-13.5;  $P < .001$ ]) in the intervention vs comparison health zones. Further, in separate analyses among children of intervention health zone at endline, each additional SQ-LNS distribution was associated with +0.09 (95% CI, 0.03-0.16) z-score unit increase in gross motor scores ( $P < .01$ ).

**Conclusions** The integrated infant, young child feeding practice-SQ-LNS intervention was positively associated with larger relative improvements in measures of child communication and motor development in the Katanga province of DRC. (*J Pediatr* 2020; ■:1-10).

Poor childhood development scores are associated with poverty, malnutrition, pollutant exposure, poor health, and unstimulating home environments.<sup>1-5</sup> The first few years of life are particularly important for brain development because modest detrimental effects on this developmental processes can have life-long impact on the brain's structure and capacity.<sup>1</sup> Studies from both low- and high-resource settings indicate that cognitive and social-emotional development in early life are strong predictors of school performance and progress.<sup>2,6-10</sup>

Malnutrition is a risk factor for poor child development, particularly in low- and middle-income countries. A meta-analysis of data from 29 low- and middle-income countries showed a positive association between linear growth and child cognitive and motor development.<sup>4</sup> In terms of nutrients, protein-energy supplementation in the first 2 years of life has been shown to improve adult intellectual functioning and economic productivity.<sup>11,12</sup> Further, several micronutrients such as iron and iodine, zinc, folate, and vitamin B<sub>12</sub> have been associated with child neurocognitive and motor development.<sup>13-21</sup>

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ASQ	Ages and Stages Questionnaire
CHW	Community-based health worker
DiD	Difference-in-difference
DRC	Democratic Republic of Congo
GLMM	Generalized linear mixed model
IYCF	Infant, young child feeding practices
RCT	Randomized controlled trial
SQ-LNS	Small quantity lipid-based nutritional supplement

Randomized controlled trials (RCTs) have shown that small quantity lipid-based nutritional supplements (SQ-LNS) given to young children and/or to their mothers during pregnancy and lactation can positively impact child development scores.<sup>22-26</sup> SQ-LNS are single-serve sachets containing  $\leq 20$  g ( $\leq 120$  kcal) of a paste typically made from peanuts, sugar, vegetable fat, skim milk powder, and vitamin and mineral fortificants. RCTs in sub-Saharan Africa found positive association between SQ-LNS and child development outcomes in Burkina Faso, South Africa, and Ghana but not in Malawian children.<sup>22-24,27,28</sup> Data from Uganda, Honduras, and Malawi have also shown associations between SQ-LNS and improved child diets, in terms of adequacy, macronutrient and micronutrient content, but none looked at potential improvements in child development scores.<sup>29-31</sup> Infant, young child feeding (IYCF) practices as an intervention package may influence child development, and can include activities such as promoting active and responsive feeding. These contribute to caregiver's nurturing care and practices, which could in turn positively influence child development scores.

We are unaware of any effectiveness studies examining the associations between SQ-LNS with IYCF and child development scores in programmatic settings. We therefore evaluated the impact of an integrated enhanced IYCF-SQ-LNS program on child development scores in 2 health zones in the Democratic Republic of Congo (DRC) where the prevalence of child undernutrition is high. We hypothesized that nutrition supplementation from the SQ-LNS with enhanced IYCF practices would be associated with improved development scores in children.

## Methods

The Programme National de Nutrition of the Ministry of Public Health and the United Nations Children's Fund-DRC piloted an integrated enhanced IYCF-with SQ-LNS intervention in Kasenga health zone in Katanga province, DRC. The government of the DRC approved the program and University of Lubumbashi School of Public Health ethics committee approved this study. From 2012 to 2015, an integrated enhanced IYCF-SQ-LNS program was implemented. Preimplementation (baseline) and postimplementation (endline) surveys were conducted in October 2011 and October 2014 in the Kasenga health zone (referred to as the intervention health zone from here on) and in Kipushi health zone (comparison health zone), which was in the same province but did not share border with the intervention health zone.

From 2012 to 2015, the comparison health zone (Kipushi) received the national standard facility-based care and IYCF counselling. The intervention health zone (Kasenga) received the standard care plus an enhanced IYCF package. This enhanced intervention package was delivered by facility-based and community-based health workers (CHWs) as detailed elsewhere.<sup>32</sup> In brief, it included facility and community-based IYCF counselling for pregnant women and mothers of children <12 months of age as well as

monthly distributions of 28 SQ-LNS sachets for children aged 6-12 months. Notably, CHWs in the intervention health zone provided extensive IYCF counselling (no enhanced IYCF counselling was given in the comparison areas). CHW also received bikes to improve their motivation and access to rural areas. The enhanced IYCF program was initiated in the intervention zone in September 2012, with the first SQ-LNS distributions occurring in May 2013. After program launch in 2012, 3 rounds of lot quality assurance survey<sup>33</sup> were carried out in all 13 health areas or posts of the Kasenga (intervention) health zone during February 2013, July 2013, and February 2014. Health areas or posts were graded on 21 program fidelity benchmark questions ranging from SQ-LNS stocks, staff training, health worker activities, distribution of SQ-LNS, and group counseling. The data were used to implement corrective action in low performing health centers based on a pass or fail grade. There was no SQ-LNS distributed in the comparison health zone.

Both the baseline and endline surveys were cross-sectional and used a 2-stage cluster sampling design. Each cluster included about 200 households. A cluster was either a village or a combination of small nearby villages. The combination of small villages into a cluster was done before sampling. Thirty clusters were randomly selected from each health zone (60 total) using probability proportional to population size from a list of all the villages in the catchment areas of the 2 health zone. The same clusters were used for the baseline and the endline surveys but different participants were selected in each survey. Sample sizes (660 children per health zone per survey) were determined for the primary outcomes of the study, namely to provide 80% power to detect a relative decrease in the prevalence of anemia and iron deficiency of 15% and 20%, respectively.

During the baseline and endline surveys, trained study enumerators asked caregivers questions pertaining to household sociodemographic characteristics and knowledge, attitudes, and behaviors relating to nutrition, IYCF, and SQ-LNS use and perception. Across both surveys, >97% of caregivers were biological mothers, and thus from here forward, they are referred to as mothers as in prior research from this program.<sup>32</sup> Different individuals participated in the baseline and endline surveys. Anthropometry (weight and length) was measured following standardized procedures.<sup>34</sup> All children were tested for malaria using a malaria antigen (HRP2/pLDH) combo rapid test kit, and if positive were given a referral to the nearest health facility.

The communication and gross motor development modules from Ages and Stages Questionnaire (ASQ), 3rd edition, were also administered in both baseline and endline surveys. The ASQ instrument was adapted for the study population and was administered to mothers. The ASQ modules were age specific. A calendar coding system was used to determine each child's age assuring that the correct module was administered to mothers of a child. There was a maximum of 6 questions per age module of the ASQ in whole months from ages 6 to 18 months. Responses were scored as 10, 5, and 0 for child does activity, does activity sometimes, and

does not do the activity, respectively, for a total ranging from 0 to 60 points. All raw development scores were standardized into z-scores based on the population distribution (mean of 0 and SD of 1) as in previous studies.<sup>25,26</sup> Verbal consent was given by each mother to participate in the baseline and endline surveys. As per ethics committee approval, when mothers verbally agreed to participate, interviewers signed the written consent form on behalf of the mothers (if illiterate) in front of an adult household member.

### Statistical Analyses

Statistical analyses were carried out in SAS (SAS Institute, Cary, North Carolina) and R (R Foundation for Statistical Computing and Graphics, Vienna, Austria). We present descriptive statistics as means (SE) for continuous variables and as percentages for categorical variables. All analyses accounted for variance owing to cluster sampling.<sup>35</sup> Statistical significance was set at  $P < .05$ .

## Study Exposure and Outcome

The enhanced IYCF-SQ-LNS was the key exposure variable and the main outcome of this investigation was child development scores assessed with the ASQ. Interviewers were trained to administer the ASQ to mothers in French or local language and a standardized translation was followed (ie, from French to the local languages, and vice versa). Two modules, the communication and gross motor development of the ASQ were used in this study owing to field cost and time constraints. Child development score evaluations were conducted using both continuous and categorical ASQ variables. For each metric, we also created 3 categorical ASQ indicators: (1) z-scores of  $< -2$  were considered delayed, (2)  $< -1$  to  $-2$  were in the monitor zone, and (3)  $\geq -1$  denoted normal development.<sup>36</sup> Different interviewers administered the ASQ to the mothers at their homes during the baseline and endline survey data collections.

### Program Impact Analyses

Owing to the quasiexperimental nature of this program evaluation, different mother-child dyads participated in both baseline and endline surveys. To address these population differences, a difference-in-difference (DiD) modeling approach was used.<sup>37-39</sup> We quantified the additive impact of the integrated enhanced IYCF-SQ-LNS program across the health zones in the before (2011) and after (2014) implementation periods. Program impact—the DiD effect—was calculated with generalized linear mixed models (GLMM) with cluster as random intercept. The program impact was quantified as the adjusted mean difference (with 95% CI) for continuous outcomes, and for binary outcomes it was an adjusted prevalence difference (%). Models were adjusted for potential confounding variables. In as-treated analyses, we examined the association between the number of times a mother received SQ-LNS (monthly distribution of 28 sachets) and child ASQ scores in the intervention zone in

the endline survey using mixed linear models. All multivariate predictors and/or potential confounding variables (child's sex and age; maternal age, education, and ethnicity; household's primary source of income, asset tertile, presence of another child  $< 5$  years of age, and index child malaria status) were selected a priori based on the literature.<sup>3,4,11,40-44</sup>

Finally, we conducted a health zone-specific stratified analyses with adjustment for confounding variables (of baseline and endline participants), to quantify differences in prevalence of child development score indicators across the 2 time points, separately for the intervention and the comparison health zone. In the DiD and as-treated (intervention health zone only at endline) analyses, models were built as (1) a basic DiD model that controlled only for child age and sex and (2) a fully adjusted DiD model that additionally controlled for sociodemographic factors and child malaria test positive status at both time points. Adjusted prevalence differences and DiD were calculated from estimable functions of population marginal means controlled for several potential confounding covariates.<sup>45</sup> DiD models are further adjusted for 3 additional program variables: health zone (comparison vs intervention), health area (intervention vs control), and time (endline vs baseline), interaction term between health area with time, to quantify the adjusted DiD. Prevalence difference analyses do not have site nor Site  $\times$  Time interaction as covariates. Owing to these differences, an algebraic subtraction of 2 prevalence differences will slightly differ from those estimated from the DiD model and are also subject to listwise deletion of missing covariates in full the GLMM/ANCOVA.

## Results

Study response rates ranged from 96% to 98% for each of the surveys and across health zones with sample sizes of 1295 for Kipushi health zone (comparison) and 1304 for Kasenga health zone (intervention). At baseline and follow-up, the majority (83%) of the participants in the intervention zone came from rural communities and 50% of the comparison health zone was rural (Table I). In terms of maternal characteristics, overall the mean age of mothers ranged from 27.8 to 29.2 years across surveys and locations. However, the proportion of mothers with incomplete school/no formal education was higher in Kasenga (intervention) health zone (40%-68%) than in Kipushi (comparison) (17%-28%). Child ages were comparable across the periods and health zones and averaged 11.0 to 11.8 months across the 4 surveys. The prevalence of malaria in children was significantly ( $P < .001$ ) higher at endline (October 2014) than baseline (October 2011) survey for both health zones.

Results of the (ASQ) child development and the program impact as assessed by mean difference (for continuous child development scores) and DiD analyses (for binary indicators) are shown in Table II. The integrated IYCF-SQ-LNS program was associated with a mean change of +0.40 (95%

**Table I.** Demographic characteristics of participants in the baseline and endline surveys

Characteristics	Kipushi (comparison health zone)		Kasenga (intervention health zone)	
	Baseline (2011) (n = 639)	Endline (2014) (n = 656)	Baseline (2011) (n = 650)	Endline (2014) (n = 654)
Household				
Rural	321 (50.3)	321 (49.2)	542 (83.4)	547 (83.6)
Primary income source				
Agriculture	234 (36.6)	260 (39.5)	530 (81.5)	536 (82.0)
Not agriculture	405 (63.4)	396 (60.4)	120 (18.5)	118 (18.0)
Asset tertile*				
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)
No. of children <5 years of age				
1	135 (21.2)	147 (23.3)	178 (27.4)	221 (34.1)
≥2 children <5 years of age	503 (78.8)	483 (76.7)	472 (72.6)	427 (65.9)
Maternal				
Age, years	28.3 ± 0.25	29.2 ± 0.42	27.8 ± 0.32	27.9 ± 0.36
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)
Children (ages 6-18 months)				
Male sex	334 (52.4)	328 (50.2)	346 (53.2)	313 (47.9)
Age, months	11.75 ± 0.14	11.44 ± 0.11	11.0 ± 0.11	11.25 ± 0.13
Bemba ethnicity	75 (11.8)	87 (13.3)	600 (92.3)	592 (90.5)
Other† ethnicity	563 (88.2)	566 (86.7)	50 (7.7)	62.0 (9.5)
Positive test for malaria‡	52 (8.2)	157 (24.0)	227 (34.9)	380 (58.1)
SQ-LNS indicators				
Mother has heard of Kulabora (SQ-LNS)	-	9 (1.4)	-	627 (95.9)
Mother received SQ-LNS for her child at least once	No SQ-LNS distribution	-	-	461 (70.5)
Among mothers who received 28 SQ-LNS sachets at the last distribution (n = 421)	-	-	-	-
Child consumed all 28 sachets	-	-	-	313 (74.7)
Mean mo. of sachets consumed	-	-	-	24.7 ± 7.1

Two health zones of Katanga in the Integrated Enhanced IYCF-SQ-LNS Program, DRC.

Results are number (%) for categorical variables and mean (SE) for continuous variables.

\*Based on a principle component 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.

†Other ethnicities include Luba, Balamba, Basanga, Rund, Hembra, Tabwa, Kasai, Kaonde, and Katshowe.

‡Malaria based on rapid test kit at the time of the survey.

**Table II.** Ages and Stages Child Development Scores and Integrated Program Impact Evaluation results in the integrated enhanced IYCF-SQ-LNS program, among children 6-18 months in DRC

Continuous ASQ indicators	Comparison health zone		Intervention health zone		Program effect (DiD) analyses	
	2011 (n = 638)	2014 (n = 653)	2011 (n = 650)	2014 (n = 654)	Fully adjusted models	
	Mean ± SE	Mean ± SE	Mean ± SE	Mean ± SE	ADM, β (95% CI)*	P value
Communication z-score	0.12 ± 0.05	-0.09 ± 0.06	-0.12 ± 0.07	0.09 ± 0.05	+0.40 (0.25 to 0.55)	<.01
Gross motor z-score	0.21 ± 0.04	0.16 ± 0.06	-0.21 ± 0.04	-0.16 ± 0.04	+0.07 (-0.08 to 0.22)	.36
Categorical ASQ indicators†	No. (%)	No. (%)	No. (%)	No. (%)	% DiD (95% CI)‡	
Communication z-score ≥ -1 (normal)	544 (85.1)	512 (78.0)	520 (80.0)	570 (87.2)	+13.7 (7.9 to 19.6)	
Gross motor z-score ≥ -1 (normal)	551 (86.2)	558 (85.1)	471 (72.5)	522 (79.8)	+7.4 (1.3 to 13.5)	

\*ADM mean difference estimated from linear mixed (ANCOVA) models adjusted for child's sex and age; maternal age, education and ethnicity; and household's primary source of income (agriculture vs not agriculture), asset tertile, whether there was another child <5 years of age in the household, and whether the child tested positive for malaria. Models are further adjusted for 3 additional program variables: health zone (comparison vs intervention), time (endline vs baseline), interaction term between health area with time to quantify the adjusted DiD, and cluster as a random effect.

†Children with z-scores of ≥ -1 are considered to have normal development; children with z-scores of < -2 are considered to have developmental delays; when -2 ≤ z-score < -1, the child should be monitored.

‡DiD estimates and corresponding 95% CIs and P values were obtained from mixed linear regression model adjusted for child's sex and age; maternal age, education, and ethnicity; and household's primary source of income (agriculture vs not agriculture), asset tertile, whether there was another child <5 years of age in the household, and whether the child tested positive for malaria. Adjusted DiD was calculated from population marginals<sup>15</sup> prevalences in proportion of children with normal ASQ scores in GLMM controlling for several potential confounding factors. DiD models are further adjusted for 3 additional program variables: health zone (comparison vs intervention), health area (intervention vs control), and time (endline vs baseline), interaction term between health area with time, to quantify the adjusted DiD, and cluster as a random effect. Owing to this adjustment for additional confounding covariates, DiD estimates might slightly differ from values obtained from algebraic subtraction of difference in prevalence differences. For example, communication score: (87.2%–80.0%) – (78.0%–85.1%) ≠ +13.7%, as shown in Table II.

CI, 0.25-0.55) in the fully adjusted model. For binary outcomes, the program (adjusted DiD, %) was associated with an adjusted +13.7 (95% CI, 7.9-19.7) percentage point increase in children with normal ASQ communication scores in the full model. Similarly, we observed significant impact for normal ASQ gross motor development with an adjusted DiD of +7.4 percentage points (95% CI, 1.3-13.5). We note that, owing to this adjustment for additional confounding covariates, DiD estimates might slightly differ from values obtained from algebraic subtraction of difference in prevalence differences. For example, communication score: [(87.2%–80.0%) – (78.0%–85.1%)] ≠ +13.7% (Table II).

The results of the as treated-analyses describing the dose-response associations between SQ-LNS distribution and ASQ scores in the intervention health zone in the endline survey are shown in Table III. Overall, each reported additional SQ-LNS distribution of 28 sachets received was associated with a 0.06 (95% CI, 0.00-0.12) z-score unit increase in continuous communication child development score and +0.09 (95% CI, 0.02-0.15) in gross motor scores, respectively, in the basic model. The association remained significant with adjustment for additional demographic variables and malaria for gross motor z-scores unit increase:  $\beta = +0.09$  (95% CI, 0.03-0.16); however, the communication results were no longer statistically significant  $\beta = +0.06$  (95% CI, –0.01 to 0.12) z-score units.

With respect to the binary ASQ indicators (Table III), each additional SQ-LNS monthly distribution received by the mother was also associated with an 18% decrease in the odds of monitor or delayed gross motor development (child development z-score <–1) in the fully adjusted binary logistic model (OR, 0.82; 95% CI, 0.69-0.97). Similarly, each SQ-LNS distribution was associated with a 19% reduction in odds of monitor or delayed communication development (OR, 0.81; 95% CI, 0.67-0.99; from the basic model). In the fully adjusted model

however, this association became nonsignificant (OR, 0.83; 95% CI, 0.67-1.02).

The Figure displays adjusted prevalence difference (%) of the ASQ indicators by child age categories and by health zone as estimated from GLMM controlling for potential confounding factors. The prevalence difference for each child ASQ indicator was calculated from pooled and child age-stratified analyses within each health zone following an intention-to-treat approach. At endline relative baseline (Figure A and C), there was a greater improvement in children with normal gross motor and communication child development scores in the intervention than the comparison health zone in the pooled analyses (+9.0% vs +0.4 % motor; +8.5% vs –5.1% communication scores). This pattern was consistent in the child age stratified analyses, and for both ASQ indicators (Figure B and D), with improvements strengthening with age especially for communication scores, in the intervention zone.

## Discussion

Findings from this quasiexperimental effectiveness evaluation demonstrated that an integrated IYCF-SQ-LNS program conducted in 1 health zone in the DRC was associated with improved child development scores among children ages 6-18 months of age as compared with a comparison health zone. At endline relative to baseline, there was a relatively greater positive change in the proportion of children with normal communication and gross motor z-scores (z-score of >–1) when the children from the intervention group are compared with those from the comparison health zone. As-treated analyses of the endline data (intervention health zone) indicated that each additional SQ-LNS distribution (of 28 sachets) received was associated with improvements in child gross motor scores after adjusting for potential confounders in the fully adjusted models. Finally, a health zone-

**Table III.** Associations between SQ-LNS distributions received and Ages and Stages Child Development Scores at the endline survey in Kasenga Health Zone (intervention), among children 6-18 months of age, DRC

Variables	Mean ± SE or no. (%) (n = 653)	Regression estimates			
		Adjusted for child's sex and age only (basic model)		Adjusted for sociodemographic characteristics (fully adjusted model)*	
<b>Continuous Outcomes</b>		$B^{\dagger}$ (95% CI)	<i>P</i> value	$B^*$ (95% CI)	<i>P</i> value
Communication z-score	0.09 ± 0.05	+0.06 (0.00 <sup>‡</sup> to 0.12)	.05	±0.06 (–0.01 to 0.12)	.08
Gross Motor z-score	–0.16 ± 0.04	+0.09 (0.02 to 0.15)	.01	±0.09 (0.03 to 0.16)	.01
<b>Categorical outcomes (binary logistic models)</b>		$OR^{\S}$ (95% CI)	<i>P</i> value	$OR^{\S}$ (95% CI)	<i>P</i> value
Communication (Z-score <–1 vs ≥–1) <sup>¶</sup> (monitor or delayed)	83 (12.7)	0.81 (0.67 to 0.99)	.04	0.83 (0.67 to 1.02)	.08
Communication (Z-score <–2 vs ≥–2) <sup>¶</sup> (delayed)	12 (1.8)	0.75 (0.47 to 1.20)	.23	Won't converge**	–
Gross Motor (Z-score <–1 vs ≥–1) <sup>¶</sup> (monitor or delayed)	131 (20.1)	0.83 (0.70 to 0.98)	.03	0.82 (0.69 to 0.97)	.02
Gross Motor (Z-score <–2 vs ≥–2) <sup>¶</sup> (delayed)	34 (5.2)	0.76 (0.57 to 0.99)	.05	0.76 (0.57 to 1.01)	.06

\*Full multivariable models adjust for child's sex, age and ethnicity, maternal age, and education; whether the household was urban or rural, the household's primary source (agriculture vs not agriculture) of income and asset tertile, whether there was another child <5 years of age in the household.

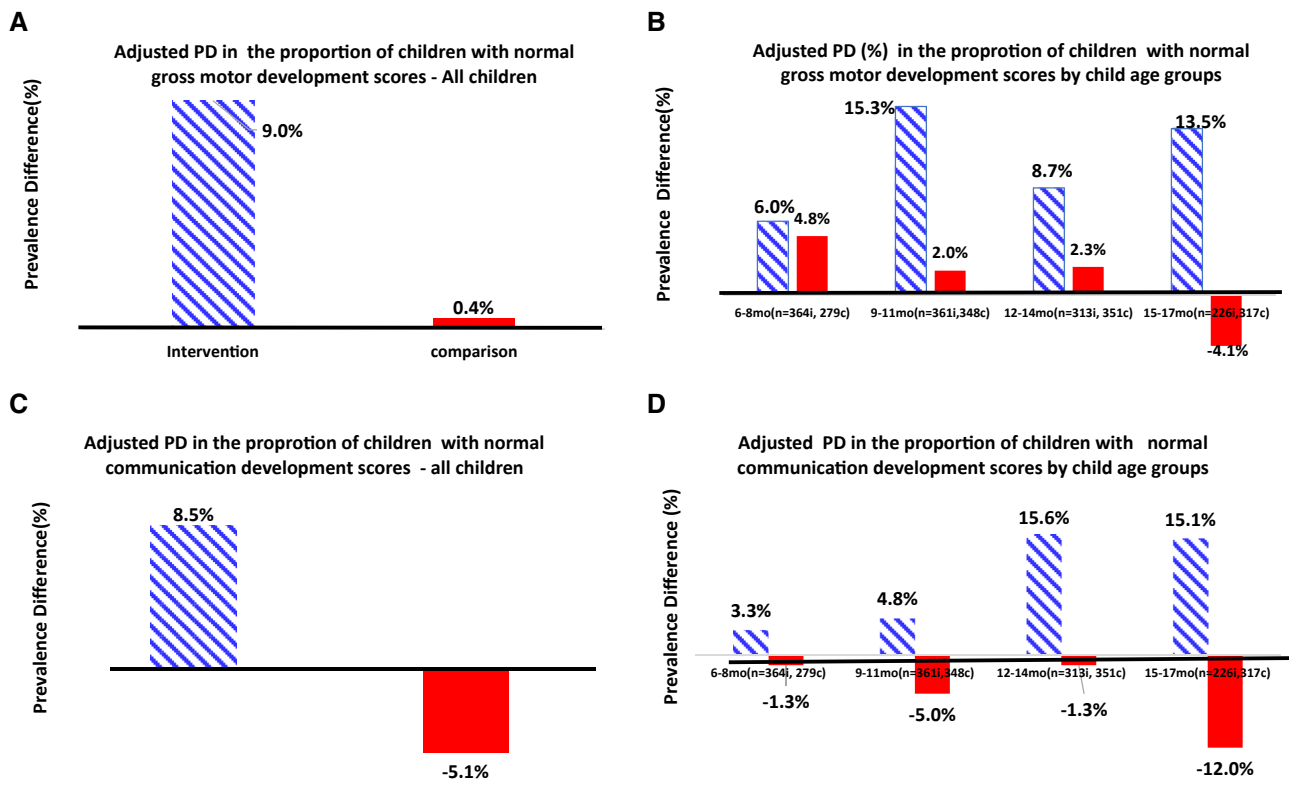
<sup>†</sup>Beta, 95% CI and *P* value were obtained from a linear mixed regression model with cluster as a random effect.

<sup>‡</sup>Lower CL nonzero, but rounds to zero with 2 decimal points.

<sup>§</sup>OR, 95% CI, and *P* value were obtained from a GLMM with the logit link, binomial distribution and cluster as a random effect.

<sup>¶</sup>Children with a communication or motor of <–2 Z are considered to have a developmental delay. Children with a communication or motor z-score of <–1 but ≥–2 should be monitored.

\*\*Owing to the limited number of cases, the fully adjusted multivariable model does not converge.



**Figure.** Adjusted baseline–endline prevalence differences (%) in proportion of children with ASQ normal child development scores, among children ages 6–18 months of age in DRC.

specific stratified analyses also indicated that the intervention health zone was associated with a greater prevalence difference (%) of children with normal child development scores (both communication and gross motor) at endline relative to baseline than children in the comparison health zone. Age-stratified analyses also indicated similar trends, with intervention health zone registering relatively larger improvements in normal child development scores across child age groups (than comparison health zone) at endline relative to baseline.

Studies have shown that higher ASQ scores in early life are associated with higher IQ at ages 5 and 6 years and children who suffer from developmental delays are likely to become less productive adults because they have fewer years of schooling and reduced learning per year of school.<sup>2,46,47</sup> In the current program, the intervention was associated with a reduced prevalence of developmental delays and higher proportion of children with normal child development scores, which could translate into long-term benefits, including human capital formation.<sup>44</sup>

RCT of SQ-LNS provided to mothers during pregnancy and lactation and/or to children directly from 6 to 23 months of age have had inconsistent effects on child development score outcomes.<sup>22–26</sup> For instance, although SQ-LNS delivered via mother–child dyads or to children in a RCT setting were not associated with child development score outcomes in Malawian children, similar trials showed positive association in Bangladesh (positive effects on motor and language

development), in Burkina Faso (positive effects on motor, language, and social development) and Ghana (positive effect on motor development only), and South Africa (positive effect on motor development).<sup>22,24,28,48,49</sup> Data from integrated IYCF-SQ-LNS programs and their impact on child development score outcomes are limited. However, integrated IYCF-SQ-LNS programs could improve child development through pathways external to SQ-LNS, including promotion of active and responsive feeding, which are also associated with child growth, health, and nutrition status, and that could in turn impact child development.<sup>50,51</sup> Such a program will be important, given that certain IYCF components like exclusive breastfeeding are positively associated with cognition and child development.<sup>52,53</sup> The positive impact observed in children from the DRC suggests that integrated IYCF-SQ-LNS (and similar) programs may potentially be a viable and effective platform for improving child development scores.

Among children of the intervention health zone, each additional SQ-LNS distribution of 28 sachets received by mothers was associated with higher child ASQ scores for both communication and gross motor outcomes in dose–response models (adjusted for child sex and age only); however, only gross motor outcomes remained significant in the fully adjusted models. In the current program, there were some weaknesses identified in implementation fidelity through the lot quality assurance survey rounds, such as SQ-LNS stock-out at the health zone level. Although receipt

of SQ-LNS allotment could be a proxy for program intensity, it is unclear how such program bottlenecks (as identified in the lot quality assurance survey rounds) could have impacted observed associations between child ASQ scores and SQ-LNS sachets received. Nonetheless, these findings underscore the importance of program fidelity (from supply and demand sides) in achieving potential associations between IYCF-SQ-LNS and child development scores. Because this is an integrated program, it is difficult to disentangle whether associations between the number of SQ-LNS distributions and child development scores were driven by impacts of IYCF with SQ-LNS or whether the number of SQ-LNS distributions received was a proxy for high program exposure, or a synergy of these multiple factors.

Other features of the program that could have contributed to improve child ASQ scores could be the maternal time investment in attending the enhanced IYCF (ie, provided by facility-based nurses and community outreach-based services by CHW) counseling sessions. Mothers who had participated in IYCF counseling sessions were encouraged to increase infant's and children's opportunities for child–adult and child–child social interactions. This may stimulate both communication and gross motor development milestones, as noted in an expert committee report.<sup>54</sup> A large body of evidence has consistently emphasized the role of nurturing care and stimulating environments on early child development in different population settings (eg, adoption studies, trials, foster care).<sup>55,56</sup> Studies in Indonesia and Jamaica have demonstrated beneficial effects of combined stimulation and nutrition supplementation on child psychosocial development.<sup>57,58</sup> A *Lancet* early child development expert committee emphasized the potential of combined health and nutrition programs, coupled with stimulating environments on child development.<sup>44</sup> The positive associations between an integrated IYCF-SQ-LNS program on child development scores among children from the DRC further highlights the importance of incorporating child development assessments in integrated programs effectiveness evaluations.

We interpret these study findings considering several limitations. The study was nonblinded and ASQ development assessment was by maternal report; thus, biased reporting is possible among mothers in the intervention (and who received SQ-LNS, and IYCF counselling) relative to mothers in the control health zone and is a limitation. An overarching aim of this program was also to improve mother's adherence and acceptability of SQ-LNS combined with enhanced IYCF practices in a real-life setting in rural DRC.<sup>59</sup> Hence, it was difficult to blind certain program components as it was not intended to be an experimental design. Steps were taken to ensure program evaluation rigor. Different trained interviewers collected the endline survey data. Additionally, many other components of the evaluation were based on mothers' perceptions, which were also not different across the 2 health zones.<sup>59</sup> Nonetheless, the program was also associated with biologic improvements in child biomarkers (hemoglobin) and growth indicators (unpublished manuscript under review) and in IYCF practices, suggesting that any

maternal recall biases associated with nonblinding may not have been enough to wipe away observed program impact.<sup>32</sup> Future studies could explore how to overcome this limitation in other settings.

We are not able to assess program impact on the whole battery of ASQ scores because only 2 (gross motor and communication) of the 6 ASQ modules were administered in both surveys owing to cost and time constraints.<sup>36</sup> The serial cross-sectional nature of the data did not enable us to ascertain temporal sequence because these findings only capture clustering or associations among study variables and do not imply causality. We controlled for some of the differential population cohort changes that might have occurred over time. However, we could not statistically control for factors, such as changes in the healthcare system, staffing, local employment/industry, and other demographic shifts—all of which could have influenced the results of this evaluation.

After the baseline survey in 2011, a mine was reopened in Kipushi (comparison health zone) that might have improved the economic status of many families. However, the resumption of this mining activity could have also potentially exposed children in the control health zone to metal environmental pollutants and we could not adjust for this factor in our models. Nonetheless, the extent and mechanisms by which neurotoxic metals might have impacted child ASQ motor and communication scores in this health zone is unclear, but it is noteworthy as heavy metal exposure (from both large-scale and artisanal mining), has been previously shown to be associated with cognition and neuromotor impairments in children in certain parts of the DRC.<sup>60,61</sup> It was decided a priori that different mother–child dyads would be sampled in both evaluation surveys (2011 and 2014). This decision was based on several factors. The baseline children had aged out of the intervention target ranges by endline survey (>2 years later) and would have been challenging to track down the same mother–child dyads. Further, because children have received all their key health services, mothers are less likely to return to the health centers for child wellness visits given the that some families might be transient. This quasiexperimental was not ideal relative to a prospective cohort for example, in this community-based evaluation. The use of GLMMs helped our interpretations as the program was implemented in health facilities (ie, clusters), and they were treated as units of analysis with mother–child dyads nested within each of the health clusters (same clusters used for baseline and endline surveys). Because GLMMs quantifies average unit effects, it facilitated interpretations on an average mother–child dyad that used the services of the health centers over the time of observation. Future studies and intervention programs could address some of these concerns although considerations should be given a balance between mother's decreased use of age-sensitive health services that are provided at these community health centers (eg, well-child growth monitoring and immunizations) as their infants get older vs effective implementation duration.

There are several strengths of this evaluation. They include the availability of the ASQ data, and little to minimal spillover of intervention effects, because the 2 health zones were not geographically connected. Data came from a representative sample of children in the catchment area of both health zones which afforded robust sample size and statistical power for the evaluation objectives. Another strength is that certain components of the program were nonexistent before roll-out (eg, the SQ-LNS supplement was not available in the catchment area before this intervention). Thus, using DiD models with serial data from health zones at different time points enabled us to account for trend changes likely owing to the intervention, beyond secular changes. Further, prevalence difference analyses (Figure) indicated that the intervention health zone at endline had greater (prevalence difference) improvements in gross motor development scores relative to its own baseline and more so across age than in comparison health zone. For communication scores, the comparison health zone saw a decrease in scores relative to the intervention health zone. This evidence suggests that the overall DiD impact estimates observed are driven by a combination of improved scores (for gross motor) and for communication via potential prevention of decreasing scores plus improved scores, especially with age. Even though there were implementation challenges, improvements in child development scores suggest that the potential program impact may be stronger with improved intervention fidelity.

An integrated IYCF-SQ-LNS intervention program was positively associated with relatively larger positive change in the proportion of children with normal communication and gross motor z-scores. Program effectiveness evaluations that also include child development score assessments should be examined in different settings. ■

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