

# Leveraging Lean Research Principles to Engage Caregivers to Improve Child Undernutrition: a Case Example in Kolkata, India.

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## Research

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# Abstract

**Background:** For social purpose organizations (SPOs), decisions on which programs to scale are driven by information that often falls short of the gold-standard randomized control trial (RCT). This article offers a case study of how lean research, lean experimentation and lean impact principles can be leveraged by SPOs to inform strategic decision-making.

**Methods:** Through two Phases of iterative experimentation, Children International assessed the feasibility and effectiveness of at-home anthropometric evaluation [mid-upper arm circumference Z-score (MUACz) tape] and nutritional support [supplementary foods (SupF)] to influence caregiver engagement and improve children's nutritional status compared to centralized interventions. Body Mass Index Z-scores (BMIz) at baseline and completion of each Phase were collected along with semi-structured survey and focus group discussion data.

**Results:** Phase I enrolled 37 caregiver/child dyads (17 MUACz, 20 control). The group receiving MUACz tapes reported ease of use for the intervention and a trend towards improved nutrition outcomes. The findings informed the design of Phase II, which enrolled 88 caregiver/child dyads across four groups (20 control, 21 MUACz, 27 SupF, 20 MUACz + SupF). Phase II uncovered low satisfaction with supplementary food and modest overall impact of the interventions despite favorable perceptions of changes in children's overall health and higher levels of caregiver engagement addressing child nutritional needs.

**Conclusions:** Lean approaches allow SPOs to innovate within the constraints of their organizations, and provide practical platforms to co-create and test evidence-based solutions with the populations they serve. Lean process and a lean mindset allowed the team to rapidly respond with at-home nutrition implementation strategies when faced with the emerging COVID-19 pandemic. Lean approaches can provide a framework to guide teams towards new solutions even during the most unpredictable and unprecedented times.

## Background:

Social purpose organizations (SPOs) increasingly rely on quality data to support decision-making and improve program effectiveness and efficiency. In order to determine what to scale and fund, rapid feedback and evidence of positive causal impact on relevant outcomes is critical. The complexity of issues and diverse settings in which SPOs operate call for contextualized, practical approaches to meet the specific needs of constituents. While the gold standard to determine the causal impact of an intervention on an outcome is a randomized controlled trial (RCT), they come with their share of challenges for an SPO. The time and resources required to conduct RCTs can be prohibitive, particularly in resource-limited settings. RCTs are typically suited to programs that have "matured," as opposed to developing programs that are gathering data in real time so that decisions can be made quickly to improve, or pivot as needed. Practical approaches to generate valid evidence, test hypotheses and quickly innovate to meet the ever-changing needs of constituents is essential for an SPO. Lean methodology is widely used in continuous improvement and rapid development in myriad industries and has recently garnered interest from SPOs to cultivate new solutions to complex social problems.

## Lean revolution for process improvement

Emerging from the Toyota Production system in their attempt to reduce waste and improve quality in auto manufacturing, lean thinking was coined and codified in the 1980s and 1990s as a general organizational

philosophy (1). The lean startup model, developed by entrepreneurs in Silicon Valley, prioritizes rapid experimentation over execution of elaborate upfront plans, customer feedback over intuition or expertise, and iterative development of minimum viable products (MVPs) over highly polished end-products built to predetermined specifications (2). However, neither the manufacturing nor the startup model is fully applicable to the non-profit or social purpose sector. The primary differentiator is that non-profits receive funding from parties separate from those who are the beneficiaries of their products or services. Thus, the feedback loop of success—as measured by product acceptance and purchase—is obfuscated when parties with differing interests are involved. Additionally, philanthropic donors are generally risk-averse and want to see plans *a priori* and expect execution of those plans. This leaves little room for innovation, experimentation, or iteration. Other difficulties include the subjective nature of social change, longer time frames to observe favorable responses, influences of external factors (disease, conflict, economic downturns), and ethical concerns in experimenting within programs that serve vulnerable populations (3).

In a recent article, Murray and Ma present a blended framework of these two lean concepts (manufacturing and startup) as Lean Experimentation for SPOs (4). The framework is an iterative process comprised of six steps: ideation and analysis, constituent discovery, building, testing, responding to data, and scaling up (4). In *Lean Impact*, Chang collapses these six steps to three distinct stages: Inspire, Validate, Transform (3). Lean experimentation provides program implementers a feasible approach to quickly assess what works before scaling programs. At the same time, lean experimentation promotes engaging in continuous feedback with constituents to ensure that organizational efforts add value to their lives.

Further complementing the lean experimentation process, the lean research framework was developed by the MIT D-Lab and Tufts University. This framework draws on principles from lean methodology, RCTs, and human-centered design, placing the program participant or beneficiary at the center in terms of decision-making and design (5). The four principles within this framework are rigor, respect, relevance and right size. Rigor, or adhering to high standards of research methodology, borrows from RCT design and planning. Respect preserves the dignity and safety of the human beings at the center of the research. Relevance connects with lean methodology in that it addresses priority issues and values from participants, communities, and stakeholders. Right-size blends issues of sample size considerations from RCTs and ethical concerns that the research is not overly burdensome, costly, or invasive. All findings should be understandable, accessible, and inform iterative decision-making.

This article will explore the case example of incorporating principles from all three lean frameworks previously mentioned (Lean Impact, Lean Experimentation and Lean Research) to improve a nutrition program targeting caregivers and their undernourished children over age 5 in Kolkata, India.

## Malnutrition in India

Malnutrition is a complex global health issue that, to address adequately, requires innovation and contextualized solutions that involve constituents. The global response to malnutrition has resulted in significant gains spurred on, in part, by the Millennium Development Goals (MDGs) and current Sustainable Development Goals (SDGs) (6,7). Much of this effort, both in terms of programming and research, has focused on malnutrition of children under 5 years of age, with a specific focus on “the window of opportunity” (the first 1,000 days of life) due to its high correlation with morbidity and mortality (8).

There has been far less research on effective programs to address malnutrition for children over 5 years of age, even though data show additional windows of opportunity during childhood and adolescence that affect cognitive abilities, influence future success in education and employment, and mitigate adverse outcomes that extend to subsequent generations (9–12).

Children International (CI) is a nonprofit/social purpose organization providing health, education, empowerment and employment support to children and youth across 10 countries with the vision to break the cycle of poverty. Children International, Sahay operates in Kolkata, India, where there is a high prevalence of undernutrition in the urban and rural areas surrounding the city. Prevalence of underweight and thinness in school age children is particularly prevalent in South East Asia, (13) with India being home to more than 1/3 of the world's malnourished children (14). Children age 5–12 years old who are identified as moderately or severely malnourished according to the World Health Organization (WHO) growth standards (BMI Z-score, or BMIz, less than  $-2$  SD) are candidates for the nutrition rehabilitation program (15). Children who enroll in this program in Kolkata receive meal support through feeding sessions at a community center, medical checks, growth monitoring and caregiver education around healthy behaviors associated with nutrition, hygiene, and timely medical care.

Low rates of successful rehabilitation with the traditional CI program (which involve 3–5 visits/week to the community center) prompted field staff in Kolkata to assess participation and compliance. After seeking initial feedback from caregivers, it was discovered that feedings at the community center presented a burden to families who live at a distance, which adversely affected their participation. Furthermore, the community center feedings did not involve caregivers, and this diminished their motivation to engage in the rehabilitation of their child. The project team developed the following lean process to improve the nutrition program and caregiver engagement.

## **Methods:**

The aim of this study was to address the issues of convenience and caregiver engagement by using lean principles to test iterative changes to the nutrition rehabilitation program. At the same time, the team monitored anthropometric data on the children to determine whether reduced burden for, and purposeful engagement of, caregivers leads to better nutrition outcomes for their children.

Data were collected at the Jorasanko community center in the Sahay agency of Children International. The population served by this community center is primarily urban and between the ages of 2 and 19 years. Children age 5–12 years old who were identified as candidates (BMIz less than  $-2$  SD) for the nutrition rehabilitation program were invited to participate with their caregivers in the program and the study. All data were collected under a protocol that was reviewed and approved by the Institutional Review Board of Children's Mercy Hospital (IRB# 15040158).

## **Interventions**

Phase I (September–November 2018):

To address the issue of caregiver engagement, a pilot study was conducted between September 2018 and November 2018. Children enrolled in the nutrition rehabilitation program and their caregivers were eligible to participate in the study. The study was conducted in partnership with Children's Mercy Hospital, Kansas City, who developed an age- and gender-specific, easy-to-read, nutrition assessment tool based on mid-upper arm circumference Z-score (MUACz) (16,17). The caregivers in the intervention group received training on use of

MUACz tape and were then given a MUACz, along with a tracking sheet on which to monitor their child's progress over the study duration. The control group was not given the MUACz but received all the other training and benefits of the nutrition rehabilitation program. The primary outcome measure was BMI Z-score (BMIz) as determined by height, weight, age, and gender of the participants. MUACz color and measurements in mm were collected by Children International field staff at the community center and entered into a spreadsheet template. Participants' height (cm) and weight (kg) were measured at baseline in September, and again in November of 2018 at the end of the study. Semi-structured survey feedback concerning the use of the MUACz to monitor malnutrition was collected from the mothers in the treatment group at the completion of the study. The collective findings of this Phase informed the study design employed in Phase II.

Phase II (May-December 2019):

This second phase of the study aimed to assess the issue of convenience and engagement by offering an in-home supplementary food (SupF) versus the traditional program. Eligible participants were randomized into one of four treatment groups in a quasi-experimental design: traditional program with community center feeding sessions (control), traditional program with the use of the MUACz to monitor child at home (MUACz), Supplement-based program (SupF), or Supplement-based program with the use of the MUACz at home to monitor child progress (MUACz + SupF). Supplementary food used in this study, Nutrimix, was produced by the Child In Need Institute (CINI) (West Bengal, India). Each 500 gram pack of this food consists of 400 grams of roasted wheat and 100 grams of mung bean yielding 70 grams of protein and 700 kilocalories of energy (18). As in Phase I, all caregivers randomized to receive the MUACz were trained how to use and interpret readings when measuring their child. The project team collected data and calculated BMIzs for children in all groups at baseline and checked in with mothers and children at pre-specified intervals every 2.5 months for 7.5 months for a total of four time points. At each point, the project team also received feedback and made adjustments based on that feedback. Thus, Phase II involved three iterations. All groups received nutrition education sessions.

At the conclusion of Phase II, semi-structured survey feedback concerning the use of the MUACz and the supplementary food were collected from respective groups, along with focus group discussions (FGDs) conducted at the community center with each of the four experimental groups: MUACz, SupF, MUACz + SupF and the control group.

### **Statistical analysis**

Descriptive statistics (Mean, Standard Deviation) were used to describe demographic and anthropometric characteristics. Continuous variables are reported with the median and interquartile range. Categorical variables are reported as percentage and counts represented by each level.

Anthropometric Z-Scores (BMI, height-for-age, weight-for-age) were calculated for participants using the World Health Organization's (WHO) Child Growth Standards macro in R (19). BMIzs were categorized into 7 risk categories based on standard deviation intervals derived from the WHO 2007 growth standards (see Table 1).

Table 1  
Z-score risk category ranges for the study

Risk category	Z-score range
Severely malnourished	$Z < -3$
Moderately malnourished	$-3 \leq Z < -2$
At risk of underweight	$-2 \leq Z < -1$
Normal	$-1 \leq Z < 1$
At risk of overweight	$1 \leq Z < 2$
Overweight	$2 \leq Z < 3$
Obese	$Z \geq 3$

The linear mixed model framework was utilized to determine if there was an association between BMI<sub>z</sub> and treatment group, controlling for demographic characteristics of participants. A random intercept was included for each participant to account for within-subject correlation. General linear hypothesis tests were designed to test trends between treatment groups. Multiple-testing correction was applied using the single-step method (20). An alpha-level of 0.05 was used to determine statistical significance for all tests. The statistical package R was used to conduct the analysis (version 3.5.2).

## Results:

### Phase I

A total of 37 families who were participating in the nutrition program participated in this study; seventeen were randomly assigned to the MUAC<sub>z</sub> group and twenty were assigned as controls. All 17 MUAC<sub>z</sub> participants completed the study; 18 of 20 controls completed. While no statistically significant difference in covariates between the groups was observed, the small sample size makes the subtle differences between groups difficult to detect with statistical tests (see Table 2).

Table 2  
Phase I Comparison across groups

	<b>Control (N = 20)</b>	<b>MUACz (N = 17)</b>	<b>P-value</b>
<b>Completed Program</b>	18 (90%)	17 (100%)	0.49
<b>Age</b>	10.1 (9.3–10.9)	9.5 (7.9–11.0)	0.50
<b>Baseline BMI Z-score</b>	-2.7 (-3.0 - -2.2)	-2.4 (-3.0 - -1.9)	0.43
<b>Gender</b>			0.52
Male	7 (35%)	8 (47%)	
Female	13 (65%)	9 (53%)	
<b>Stunting</b>	8 (45%)	6 (35%)	0.99

### Phase I Qualitative Feedback

In terms of ease of use, 88.0% of the respondents in the treated group said the MUACz tape was “Very easy” or “Somewhat easy” to use, and the remaining 12.0% responded “Neither easy nor difficult.” No one expressed that they found the MUACz tape difficult to use. All respondents answered that it was either “Somewhat easy” (47%) or “Very easy” (53%) to understand nutrition risk using the tape. The vast majority of respondents in Phase I said the tape was “Very helpful” in making decisions for intervention (88.0%), and the remaining 12.0% said it was “Somewhat helpful.” All respondents preferred the tape to other methods for monitoring nutritional status (namely, a ruler for height and a scale for weight). Respondents varied in their descriptions of how the use of the MUACz tape affected the care they provided for their child. Nine of 17 reported changes including increased motivation, attention, and effort in rehabilitation of their child. One mother mentioned that the tape increased her level of worry in the progress of her child. A few mentioned changes to their daily routine concerning childcare and meal consumption. Only two mothers reported no effect of MUACz tape usage on how they cared for their child. Of the 9 mothers who reported childcare changes, all said that the change was helpful. They reported seeing value in these changes because it would improve the current and future health of their child. One mother mentioned that she was also using the MUACz tape to monitor other children in the home that were not enrolled in the program.

### Phase I Quantitative Anthropometric Results

Of the participants who had both pre and post measurements completed, 31% of the MUACz group (4/17) improved their categorical risk status, compared with 11% (2/18) in the control group. After adjusting for age and gender, there was not a significant association between treatment group and change in BMIz ( $P = 0.76$ ). However, the model did indicate that the MUACz group experienced slightly more improvement in BMIz, after covariate adjustment.

## Phase II

The encouraging trend in the anthropometric data, coupled with positive feedback about the ease of use and understanding of the MUACz, guided the design of the study in Phase II. The project team invited all 140 caregivers of children who were eligible to participate from the Jorasanko community center and 88 chose to participate.

Working parents were less likely to participate in the study and in the nutrition program in general. Demographics and baseline nutritional status of Phase II participating children are presented in Table 3. No significant differences were observed between groups in terms of age, gender, language spoken, baseline BMIz, or caregiver participation in the nutrition education sessions. The prevalence of stunting and having younger siblings approached statistical significance between groups; over half (55%) of the MUACz + SupF group had younger siblings, whereas only 15% of the traditional program group did. Stunting was also more likely in the two MUACz groups (MUACz with traditional program and MUACz + SupF).

Table 3  
Phase II Demographic characteristics across groups

	<b>Traditional (N = 20)</b>	<b>MUACz (N = 21)</b>	<b>SupF (N = 27)</b>	<b>SupF + MUACz (N = 20)</b>	<b>P- value</b>
<b>Completed Program</b>	20 (100%)	21 (100%)	25 (93%)	19 (95%)	0.99
<b>Age</b>	10.1 (8.9– 10.6)	11.3 (9.8 to 11.8)	9.8 (9.4 to 11.3)	10.5 (10.2 to 11.3)	0.18
<b>Gender</b>					0.90
Male	9 (45%)	9 (43%)	14 (52%)	11 (55%)	
Female	11 (55%)	12 (57%)	13 (48%)	9 (45%)	
<b>Language</b>					0.38
Bengali	2 (10%)	3 (14%)	4 (15%)	0 (0%)	
Hindu	17 (75%)	18 (86%)	20 (74%)	18 (90%)	
Urdu	1 (5%)	0 (0%)	3 (11%)	0 (0%)	
<b>Younger Siblings</b>	3 (15%)	6 (29%)	8 (30%)	11 (55%)	0.06
<b>Attended Caregiver Education</b>	13 (65%)	12 (57%)	16 (59%)	13 (65%)	0.94
<b>Baseline BMIz</b>	-2.2 (-2.7 to -2.0)	-2.2 (-2.7 to -1.9)	-2.5 (-2.8 to -2.3)	-2.2 (-2.7 to -1.9)	0.30
<b>Stunting</b>	5 (25%)	14 (67%)	10 (37%)	13 (65%)	0.06

### Adjustments Made During Phase II

This longer Phase included predetermined checkpoints with caregivers every 2.5 months, which resulted in three iterations over the 7.5 month long study. During the first check in, SupF and MUACz + SupF groups shared children’s dissatisfaction with the nutritional supplement, which resulted in project team connecting with CINI to offer additional flavors and suggestions for preparation to caregivers. In the second check in a refresher training was provided on using MUACz and the tracking card per caregivers’ request.

### Phase II Qualitative Feedback: MUACz Tape

In Phase II, 85.0% (34/40) of the participants given the MUACz used it to monitor their child's nutritional status throughout the study. Of those users, 53.0% of participants reported that it was "Very easy" or "Somewhat easy" to use. Only 82.3% of all participants in Phase II said it was "Very easy" or "Somewhat easy" to understand nutritional risk with the tape compared to 100% of participants in Phase I. Half of the caregivers (50.0%) in Phase II reported making decisions or changes concerning care for their child based on the MUACz and tracking sheet. Few participants reported dissatisfaction with the program and use of the MUACz (2.9%). Among the difficulties listed were that the tape was difficult to use, was misplaced, and parental absence during training or study period.

#### Phase II Qualitative Feedback: SupF

All participants in Phase II who completed the study in the SupF or MUACz + SupF groups completed a survey about their experiences using the SupF at home. These surveys elucidated some tolerance and dissatisfaction issues with SupF. Although 100% of the participants in the SupF and MUACz + SupF groups who completed the study had consumed the SupF powder, there was a significant association between reported level of child's satisfaction with the SupF and study group ( $P=0.04$ ), with MUACz + SupF caregivers reporting much higher levels of dissatisfaction (65.0% vs 33.3%). Caregivers of children in the SupF group reported their children were "neither satisfied nor dissatisfied" more often than MUACz + SupF (29.6% vs 0.0%). While not significant, MUACz + SupF caregivers reported using the SupF only a few times during the study period compared to the SupF group (35.0% vs 11.1%, respectively). Dissatisfaction was significantly associated with lower frequency of use ( $P<0.001$ ), as well as higher rates of rejection of the supplement ( $P<0.001$ ). No caregivers reported difficulty in preparing the SupF, and 91.5% reported that it was "Very easy." Age, preparation, and group were not significantly associated with supplementary food dissatisfaction; however, 80.0% of those who were dissatisfied with the SupF were taking it either at breakfast or as an evening snack. As dinner is typically eaten later and is the biggest meal of the day in the community, these two times would typically represent the longest fasting periods of the day, hence a potentially empty stomach.

#### Phase II Quantitative Anthropometric Data

The interaction term between time and group was only marginally significant ( $\chi_9 = 15.58, P = 0.08$ ). However, the results of the general linear hypothesis testing showed that on average the MUACz + SupF group experienced a change in BMIz 0.52 standard deviations higher when compared to the SupF at the end of the study (95% CI: (0.10, 0.96);  $|Z|=3.31, P = 0.01$ ). The MUACz + SupF compared to the MUACz with traditional program was marginally higher by 0.40 standard deviations, but not statistically significant (95% CI: (-0.03, 0.85);  $|Z|=2.49, P = 0.06$ ). The SupF group was the only group that displayed statistically significant, unexpected decrease in BMIz after controlling for other covariates, exhibiting a BMIz - 0.38 standard deviations lower in December than in May 2019 (95% CI: (-0.67, -0.08);  $|Z|=3.46, P = 0.005$ ).

Height-for-age Z-scores were examined *a posteriori* to determine whether disproportionate gains in height relative to weight over the study period may have contributed to the BMI findings. However, there was no significant difference between MUACz + SupF and the SupF group in terms of change in height-for-age Z-scores ( $|Z|=0.02, P \approx 1.00$ ). Thus, an accelerated gain in height without commensurate weight gain is unlikely to explain the observed differences in BMIz for MUACz + SupF and the SupF groups

#### Focus Group Discussions at End of Phase II

Four focus groups were conducted, one per experiment group, with a minimum of 8–9 enrolled mothers in each group. Discussions were audio recorded with verbal consent and later transcribed. Themes were identified through in-vivo coding. Two additional coders reviewed the results in order to ensure quality of the emerging themes.

While quantitative measurement did not reflect significant gains in nutritional status across groups, FGDs revealed that mothers in the intervention groups (i.e. MUACz, SupF, MUACz + SupF ) perceived changes in their children's health after the study. These included increase in height and weight, fewer illnesses, and improvements in overall appearance.

*"Nowadays my child doesn't get ill frequently"* – Respondent, MUACz + SupF Group

*"My child used to be very weak earlier, after having the powder from last few months, she now feels strong"* – Respondent, SupF Group

Additional caregiver observations for children in the MUACz + SupF group included improvement in academic activities.

*"She is now regular in her school and tuitions. Earlier she used to be irregular"* - Respondent, MUACz + SupF Group

A few respondents across the groups however mentioned they were not aware of or did not notice improvement in child's health after this experiment.

During the FGDs, almost all the mothers in MUACz and MUACz + SupF group reported use of MUACz tape at least twice in the last seven and a half months. When asked about the reasons of not using the tape every month, responses included forgetfulness and lack of time due to other household activities. A few mentioned difficulties in recalling the proper usage of the tape; however, several noted that their children assisted when they forgot the process.

*"Children are fast learner they remember everything quickly"* - Respondent from MUACz group

In comparison to height and weight measurement at the center, the majority of respondent cited convenience with immediate feedback, and the ability to monitor other children at home were cited as a benefit of the MUACz.

*It is better, we can easily measure at home anytime, and we do not have to come to the center repeatedly.* – Respondent, MUACz Group

*"We can measure for other siblings as they don't get their height weight measured in the center"* - Respondent, MUACz + SupF Group

Nearly all mothers were able to confidently state the meaning of the different colors in regard to nutritional status

*"Yes, colors are easy, red means bad, orange means medium and green means good, we have to reach to green color"*- Respondent, MUACz Group

Almost everyone tracked the progress using the tracking card; the colors on the card helped caregivers to visualize the progress or decline. Children helped their mothers to record the date of measurement on the tracking card.

During the FGD, mothers shared that majority of the children consumed the supplementary food only once or twice during the duration of the study. Few had completed the whole packet of supplementary food over the 7.5 month period. The reasons shared by the respondents were disliking the taste and flavor of the SupF. In addition, one month of festival during the study period may have contributed to some of the children inconsistently consuming the SupF.

Dissatisfaction with taste was reported in both the SupF and MUACz + SupF groups. However, all the mothers were aware of the importance of the supplementary food and tried their best to encourage the child to consume it, using different preparations such as with water, milk, homemade bread, or pulses.

*"My child did not intake the powder hence no progress was seen on the tracking card"*- Respondent MUACz + SupF Group

The use of the supplemental tracking cards was less than that of the MUACz tracking cards in the MUACz groups. Reasons stated were mainly around frequency; the nutritional supplement tracking card required daily reporting, whereas MUACz tracking card was only required once a month. Often, tracking cards were misplaced, or damaged, as the paper quality was inadequate to sustain storage impacts.

The level of care and decisions at the household level were higher among the MUACz and SupF groups. The range of care and decisions on child stated by the mothers were providing timely food to the children, preventing them from eating unhealthy street food, preparing interesting food items with vegetables, which they learned from education sessions, or incorporating one egg daily into the child's diet.

Many reported consulting doctors, inquiring about vitamin tablets and health drinks to support the growth of child. Communicating with outside medical professionals about their child's health suggests increased knowledge, engagement, and agency in the care of their child.

*"I have visited the CI clinic many times and asked the doctor to give vitamin tablets to my child but the doctor did not provided any tablet and asked me to feed homemade food"* - Mother, MUACz Group

*"... I have also visited and asked the doctor to write in the prescription some health drinks which will increase height of my child"* - Mothers, MUACz Group

## **Discussion:**

Historically, Children International has provided standard nutrition rehabilitation support based on global best practice for treatment of acute malnutrition in infants and children (21), which included feeding centers within the community, education sessions for caregivers, and follow-up support. In the past, caregivers played a more passive role in this program, and systematic feedback was not part of the process. This case study used lean approaches to integrate caregivers into the design and implementation of new program modalities, and to make decisions based on results and feedback in Kolkata, India (Fig. 1). By having frequent touch-points with the families, implementers were able to adjust the approach of the nutrition program to better meet needs of caregivers and their malnourished children in this less-studied group aged 5 to 12 years.

THINK BIG/INSPIRE

The lean experimentation cycle (4) begins with ideation and constituent discovery—big ideas that are inspired by the needs and values of constituents (3). Teams are encouraged to generate ideas and seek feedback from constituents about what problems are most relevant before moving forward with designing solutions. While the program team started with the bigger goal of achieving better results around nutrition, caregivers expressed concerns about the opportunity costs of traveling to a center for feeding multiple times throughout the week. This led the team to develop a more convenient version of the program, which by necessity, required actively engaged caregivers in the recovery process of their children.

At this ideation and feedback stage, Respect is critical to create an enabling environment where all parties feel free to express ideas and concern, understand what to expect, and offer consent to participate in the process (5).

#### START SMALL/VALIDATE

Once a big goal or vision is identified, the process of lean experimentation must be developed to work towards the bigger goal by testing and learning at a small scale (3,4). The team used MIT's Lean research (5) principles of Rigor by randomizing participants into one of the treatment groups or the control group to be able to make comparisons and effectively test hypotheses, along with the Right Size to ensure that manageable sample sizes were determined and study participation would result in minimal burden to those participating. The design and management of the experiments involved both internal and external resources; the Monitoring, Evaluation, and Learning coordinator in Kolkata, Health and Nutrition officers, the inventor of the MUACz, and a statistician. Data collection tools such as excel and Google forms, which can be accessed for free, were procured to ensure appropriate management of data. The application of appropriate statistical analyses required statistical software along with someone trained to use it. The statistical software R was used for this study, which is free and opensource. While the project team had an in-house statistician, local university partners or other research institutions can provide expertise to organizations that do not have the internal capacity through collaborative research agreements to control costs.

The first iteration of experimentation started with a small sample of mothers and an abbreviated timeline of 2 months. Testing specifically the MUACz with a group of 17 mothers gave the implementing team the ability to quickly assess feasibility and interest for this engagement tool. While nutritional gains observed during this short time were not expected to be statistically significant, feedback through surveys demonstrated that the tool was easy to use and positively changed the way that caregivers provided support to their children. This information supported a second Phase of experimentation.

The second Phase increased the sample size, timeline, and number of program components to be tested based on the information gathered in Phase I. During this iteration, the implementing team had two check-ins with families where they received feedback and made adjustments based on that information, such as expanding available flavors for the supplemental food and reinforcing training on the MUACz use and tracking. Despite the potential confounding nature of these adjustments, the team felt it necessary to address the issues raised by the participants.

During the test and validate phase of the lean process learning to pivot is key. Results from the second Phase brought into question the effectiveness of the supplementary food for the target age group (5–12 years old). While Nutrimix had been acceptable for children under the age of 5 in rural areas (18), there were compliance and tolerance issues among older children residing in more urban areas. While we observed BMIzs trending toward

improvement the change was not significant for children whose mother had the MUACz during the 7.5-month period. However, the FGD findings showed that mothers who used the tape reported satisfaction and ownership of their child's recovery process, a critical first-step during rehabilitation. A few mothers even noticed differences such as their child appearing healthier and improved academic performance. Similar subjective observations arose from the MUACz + SupF group who were more interested and attentive during the experiment because they received supplements and the measuring tape together and were able to identify and correlate the changes in their child's health with the MUACz and tracking card. However, the SupF respondents were not able to easily relate the intake and progress or decline of a child's status easily as they were still dependent on the CI community center to determine progress or decline.

Through this study, engaging caregivers was critical to gain buy-in and insights on effective program approaches. Providing formal space for participants to respond between experimental iterations through verbal feedback, surveys and FGDs allowed the program team to triangulate results and adapt quickly. The team incorporated Lean Research's principle "Respect" by ensuring that participants' interests and concerns were at the center of the design (5).

These findings align with "Constituent Voice," a methodology developed by Keystone Accountability (22). This methodology works to improve relationships between implementers and participants through a feedback loop, which can create trust and buy in where it may not already exist. Constituent Voice and the lean approaches highlighted in this case study reinforce the importance of incorporating constituent feedback in order to develop effective and relevant programs and services that add value to constituents' lives. In order to ensure this is part of any process donors must be informed and provide flexible systems that allow for adjustments and pivots based on feedback and the ever-changing needs of constituents and contexts.

#### SEEK IMPACT/TRANSFORM:

After finding what works, solutions should be scaled and monitored to have greater reach (3,4). This study highlights through a combination of staff observations, survey results and FGDs that when caregivers are provided resources to support their child's nutritional recovery (Supplementary Food and/or MUACz tape to monitor growth) and actively engage in the design and strategy, their perceptions of their capacity to improve their child's health increases. Caregivers as a result sought out new solutions and alternatives to program components when they did not work as planned.

In light of the Covid-19 pandemic announced in March of 2020, the United Nation's World Food program predicted that 265 million people could face acute food insecurity by the end of the year (23).

This health care crisis provided challenges and opportunities for our case study and program. There was an urgent need to scale an approach to support families in terms of nutrition during the pandemic. Because the team was in the process of designing Phase III through lean approaches, they were able to adapt quickly. This experiment that sought to find solutions within the home became a fortuitous aspect of this work as shelter-in-place orders were issued. Locally, this resulted in a plan to scale up the MUACz for nearly 500 mothers in the Kolkata nutrition program. This will provide an opportunity to monitor the growth of children at home during shelter-in-place orders. The need for home-administered supplemental nutrition was also critical. Due to feedback about the negative response of children to Nutrimix, teams elected to provide food baskets as an alternative for families.

What was learned locally in Kolkata has transformed into global opportunities. Organizationally, due to the acceptance and feasibility of MUACz use at home by caregivers in Kolkata, other countries where CI operates in Asia, Africa and Latin America will be incorporating this tool as a way to monitor malnourished children's growth from afar and support their healthy recovery. Nutritional Support is increasingly a priority as food insecurity and unemployment continue to rise.

In addition to the tangible results from this case study that are being scaled, there has been a mindset shift that has transformed the way SPO teams think about and approach their work within the community. CI has invested in creating a learning culture that praises inquiry, lean experimentation, constituent feedback, and a growth mindset (24). This adaptability has allowed CI to adjust its course to meet the ever-changing needs of the population during these unprecedented times. When there is no playbook, as is the case for the pandemic, lean approaches can provide a process to guide teams towards new solutions even during the most unpredictable times. This requires buy-in from both leaders and donors to provide the ability to transform programs and communities.

#### Study limitations:

Due to the nature of this study and the desire to keep it lean, the researchers acknowledge the following limitations. First, lean experimentation may result in abbreviated program durations that are insufficient to observe the effects of nutritional rehabilitation efforts in undernourished school-age children, and/or the proposed program delivery methods are unable to achieve the desired results.

Small sample sizes with insufficient statistical power likely also played a role. There was not strong evidence of an independent effect of using the MUACz to monitor progress, but avoiding the nutritional supplement seemed to result in higher gains in BMIz. This could be due to over-reliance on Nutrimix to contribute sufficient calories. The MUACz + SupF group also had a higher percentage of families with younger siblings, so SupF may also have been diverted as a supplement for the siblings thus resulting in lower consumption of the supplement in that group.

Another limitation could be that the nutritional supplement used in this study are not as effective in older children or in non-critical rehabilitation, or that over-reliance on the supplement may be detrimental to rehabilitation efforts. In the former case, a different nutritional supplement could be piloted; in the later, education for caregivers could be enhanced in future studies. Finally, those who were randomized but did not participate may have introduced bias into our findings if their approach to caring for their children differed fundamentally from those who did participate.

## Conclusions:

Research on effective programming for malnourished children over 5 and their caregivers is limited. Lean approaches provide opportunities to engage constituents in a meaningful way with program implementers to find new solutions. These processes provide a framework to quickly test hypotheses and assumptions through comparison studies and iterate or pivot when an intervention does not achieve the desired results. These processes provided a framework to engage stakeholders to iterate and improve a nutrition program in Kolkata, India for malnourished children over five. This work has also led to an organizational systems and mindset shift within Children International.

The pandemic has further emphasized the importance for organizations, particularly those for social purpose, to have the mindset and processes in place to bring the voices of their constituents to the table to radically innovate

by thinking big, testing small and seeking impact (3).

## List Of Abbreviations:

Body Mass Index Z-score (BMIz)

Children International (CI)

Focus Group Discussion (FGD)

Mid-Upper Arm Circumference Z score (MUACz)

Millennium Development Goals (MDG)

Moderate Acute Malnutrition (MAM)

Minimum viable products (MVPs)

Randomized controlled trial (RCT)

Severe Acute Malnutrition (SAM)

Social purpose organization (SOP)

Supplementary Food (SupF)

Sustainable Development Goals (SDG)

Weight for Height (WH)

World Health Organization (WHO)

## Declarations:

### *Ethics Approval*

This study was conducted under a protocol that was reviewed and approved by the Institutional Review Board of Children's Mercy Hospital (IRB# 15040158).

### *Consent for Publication*

Not applicable to this research article.

### *Availability of Data and Materials*

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request. Information regarding the MUACz and instructions for use are also available upon request.

### *Competing Interests*

KM, MAM, RB and NM have no competing interests. As the inventor of the MUACz, SAR reports that a U.S. patent 10,238,317 has been issued to her employer.

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### *Author's Contributions*

All authors contributed to the concept and design of the study along with development of the data collection tools. KM produced the initial draft of the manuscript. MAM, RB, NM and SAR were involved in data analysis. RB and NM were responsible for implementing the study. SAR facilitated procurement of the MUACz. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work

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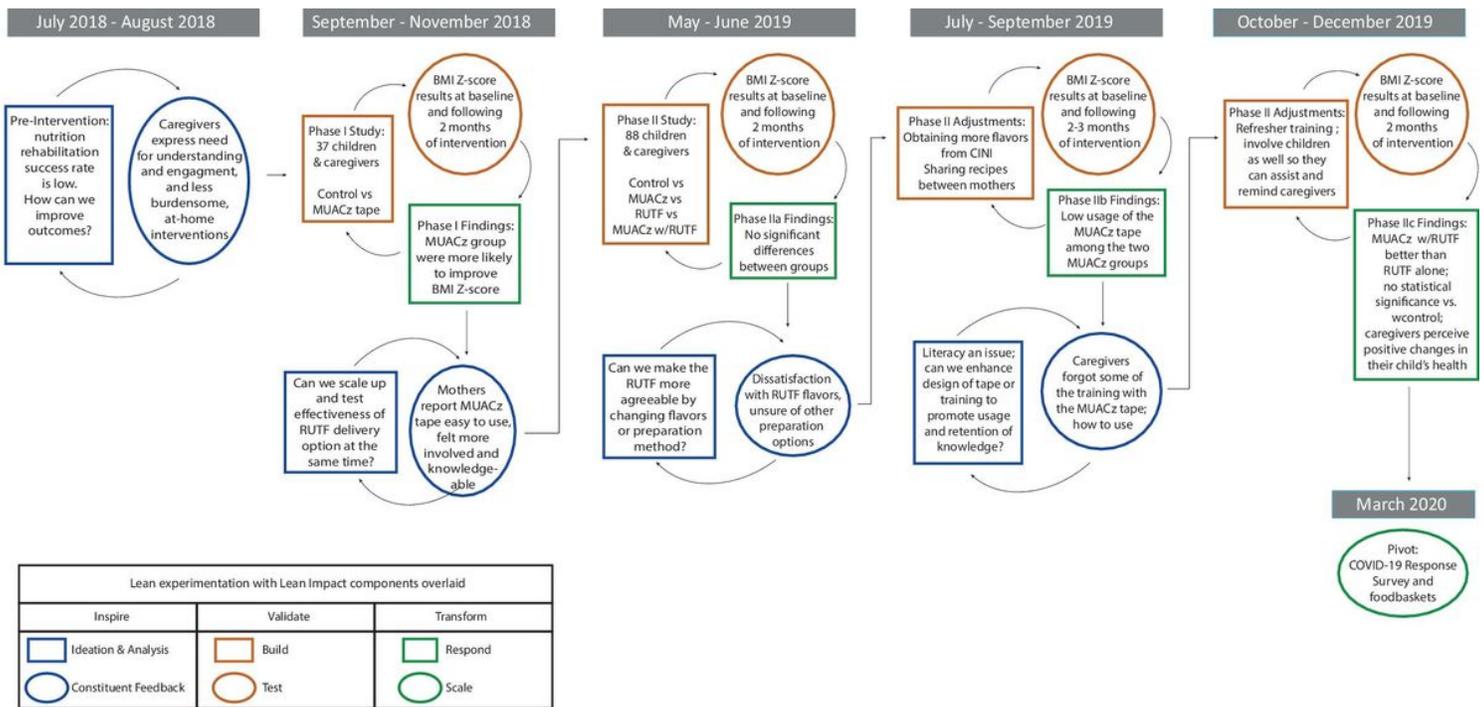
Not applicable

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## Figures



**Figure 1**

The lean process carried out by the team consisting of two phases with multiple iterations. Each iteration incorporated feedback aiming to engage caregivers through a mixture of interventions within a nutrition rehabilitation program. Across the top of the figure is the timeline of the iterations. The bottom of the figure displays a key that represents the overlay of the lean experimentation process with the lean impact framework employed in this study. The colors and shapes relate to specific iterative steps within the two frameworks.