CIDA 6107 Project

'Reaching the Hard to reach' Study Protocol

Helen Keller International

Feasibility study on Reaching Children at 6 months with Vitamin A Supplementation

Principal Investigator: Christina Nyhus, PhD, MPH
Co-Investigators: Generose Mulokozi, PhD (Tanzania Food and Nutrition Center)
Dafrossa Lymo, MD (Expanded Program on Immunizations)

Other Investigators: Margaret Benjamin, MPH

Institutions:
Helen Keller International
Tanzania Food and Nutrition Centre
Ministry of Health/ Expanded Program on Immunizations

Acronyms

DHS	Demographic Health Survey
EPI	Expanded Program on Immunization
IYCF	Infant and Young Child Feeding
IYCN	Infant and Young Child Nutrition
MOHSW	Ministry of Health and Social Welfare
RCH	Reproductive and Child Health
TFNC	Tanzania Food and Nutrition Centre
VAS	Vitamin A Supplementation

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Summary

'Reaching Children at 6 months with Vitamin A supplementation is a health-facility level randomized control study to investigate the feasibility and effectiveness of incorporating a 6-month contact point into Tanzania's current Expanded Program on Immunizations schedule (EPI) in order to improve infant health outcomes. This new contact point, at a critical time in child development, would ensure earliest protection with Vitamin A Supplementation (VAS), and is ideal timing for interventions to improve Infant and Young Children Feeding (IYCF) such as targeted counseling and micronutrient supplementation, as it coincides with the transition to complementary foods. The results of the study will provide the Tanzanian Ministry of Health with evidence on the feasibility and effectiveness of integrating the delivery of two or more child survival interventions at an official 6-month contact point in the national vaccination program. The findings of the research will be generalizable to other countries working to integrate child health packages into broader programmatic initiatives

1. Background

Stunting and micronutrient deficiencies are known to have a lasting and detrimental effect on child development. The high rates of stunting are alarming and have resulted in a new focus among donors in Tanzania to reduce low stature in future initiatives, including USAID's Feed the Future initiation in Tanzania. Evidence to help guide future programs aimed at reducing stunting will be sought and the proposed operations research has direct relevance in determining the feasibility and effectiveness of integrating delivery of vitamin A with other child survival interventions to reduce child mortality and decrease the incidence of stunting.

To address micronutrient deficiencies, Vitamin A supplementation (VAS) to children aged 6 to 59 months has been identified as the most effective development intervention by the 2008 Copenhagen Consensus[i]. Studies indicate that twice yearly vitamin A supplementation results in an estimated 23% reduction in under-five mortality[ii]. The United Republic of Tanzania has been providing twice-yearly mass vitamin A supplementation to children under 5 since 2001 with coverage rates consistently maintained over 90%. This success has been validated by studies that indicate that the recent reductions in child mortality in Tanzania can be attributed in part to the high coverage of VAS[iii].

In Tanzania, VAS is also provided routinely through the Expanded Program on Immunization (EPI) from health clinics and routine outreach. The current EPI schedule has established contact points for children at 1, 2, 3 months and again at 9, 15 and 21 months. According to WHO and Tanzanian VAS guidelines, the first dose of supplemental vitamin A is recommended once a child reaches 6 months (100,000 IU)[iv]. Therefore, through the EPI

program, vitamin A supplementation is first provided at 9 months, at the time of measles vaccination. Through EPI, VAS is able to reach an estimated 88% of children at 9 months of age[v].

However, it is critical that a child is supplemented as early as possible with vitamin A. Evidence indicates that mortality rates decline appreciably with each month of life[vi]; therefore VAS protection has the greatest benefit at 6 months of age, when VAS is first recommended. This is supported by research, which shows mortality reduction impact with VAS at different age intervals (see References, Figure 1)[vii].

Unfortunately, despite the twice-yearly events and the EPI provision, only 1 in 6 children (or 17% of eligible children) are reached by VAS at the earliest possible age. This is because national VAS campaigns, the only current mechanism for reaching a child at the age of 6 month, offer the supplement only twice a year in June and December. Since this blanket supplementation occurs during only two months of the year, it reaches only one-sixth of all 6-month old children. Currently through routine services, a VAS-eligible child won't appear for a visit until he/she is 9 months old. This means that even in an ideal situation, if a child is able to come to the health clinic for a measles vaccination at the desired 9 month of age, she is still left unprotected for 3 months.

Reaching children at their 6- month birthday with VAS is likely to be most effectively accomplished by establishing an official 6- month visit within the national EPI (Expanded Program for Immunizations). The investigators suggest that by having an official contact point with mothers and children in between the currently scheduled EPI visits of 3 and 9 months, infants and young children can be reached with essential services during a critical development window in their lives. These include not only VAS but also counseling on complementary feeding; catch up vaccinations, as well as any other relevant services available to mothers and children in the facility (family planning, growth monitoring, etc.) A 6-month visit with an emphasis on nutrition services and counseling could therefore be an important addition to the current EPI schedule[1].

Using the 6-month contact point as the delivery platform, the study will measure the following:

- Age at first dose of vitamin A supplement
- Effectiveness of nutrition counseling on nutrition behaviors

Rationale

[1] Reaching children through growth monitoring programs (GMP)can be an option to reach children at 6 months with VAS. However, although routine monthly growth monitoring is policy in the Tanzania MOHSW/RCH guidelines, it is not consistently practiced in most clinics, and where it is practiced, attendance is generally poor. Such anecdotal and observational evidence suggests that many caretakers are less likely to bring their child for growth monitoring when it does not coincide with a vaccination schedule or provision of some other services. And unfortunately even when GMP does occur at 6 months, it is not current practice to provide a preventive dose of VAS even though the policy states that supplementations should begin at this age.

Currently Tanzania's Vitamin A supplementation program is in a transition phase. With reduced donor funding for VAS and significant steps made in the institutionalization of the program, the Ministry of Health is advocating for combining the twice-yearly campaigns with the routine (EPI) schedule to create a more sustainable approach to VAS provision. Strengthening the role of routine services is central to sustainability. A long term vision held by many of the vitamin A stakeholders in Tanzania is to ensure coverage to children under 1 year of age through routine services and then switch to mass supplementation for children older than >1, which coincides with the deworming target groups. This long term plan will ensure coverage at 6 months, attendance to health visits at 6 months and 12 months, and simplify twice yearly supplementation to be just for children above 12 months of age, therefore requiring 200,000 IU to be uniformly provided and lessen the confusion with supply management of 100,000 IU to temporary campaign posts. However, it is not yet clear if coverage rates through routine services will match those currently seen in twice yearly campaigns for 6-11 month olds. This study will provide important evidence and lessons learned in-country on the feasibility of one approach to harmonization of routine VAS and the twice-yearly VAS campaigns.

A comprehensive approach on complementary feeding is among the most effective interventions that can significantly reduce stunting during the first two years of life. Tanzania DHS (2010) indicates prevalence of stunting to be unacceptably high, at 44%.[viii] Often foods traditionally prepared by Tanzanian families for infants and young children are of low nutritional quality, particularly for critical micronutrients such as iron and zinc[ix]. In addition, only 91% of all children 6-9 months are actually consuming complementary foods according to the DHS 2010. A 6-month visit is an opportune time to provide caregivers with IYCF counseling as it marks the onset of complementary feeding.

2. Objectives

Developing effective programming to reach children at 6 months of age with vitamin A supplements has been identified by the Global Alliance for Vitamin A as a priority area for vitamin A efforts[x]. However, it is important for the feasibility of this approach to be tested in Tanzania, and for challenges to be identified and addressed before it can be adopted and scaled up to a national level. A 6-month contact point can also be highly beneficial in reaching children at a critical stage of development, where the switch to complementary foods is accompanied by increased risks of infection and undernutrition. Unfortunately, compliance with a new 6-month visit cannot be guaranteed. In order to ensure both mother and the health system can absorb this additional health contact point, evidence needs to show sufficient attendance and increased coverage rates.

The overall objective of this study is to generate results which will be able to inform Tanzanian Ministry of Health & Social Welfare (MOHSW) on the feasibility of adding a six-month contact point to the national routine service schedule and the effectiveness of reaching children with proven, life-saving nutrition interventions as early as possible.

The primary objectives of this project are to determine:

(1) The age at first dose of vitamin A in comparison to current practices (quantitative); and
(2) How new contact point will be accepted by both caretakers and health care workers (qualitative)

This study is not testing the efficacy of vitamin A at 6 months as this is already a globally recognized policy that has been well-examined for its impact in many settings. Rather, this is an operational research project to **test a novel delivery mechanism and platform** for the first dose of VAS and from that, an ideal package of nutrition services to be delivered at a critical age in an infant's life. In summary, this study tests the feasibility of adding an official routine health visit at 6-months of age and the optimal combination of child survival interventions delivered through this channel, that will have maximum impact on infant and young child nutrition.

3. Project Design and Implementation Plan

The proposed study will be a health facility-based randomized control trial. All children of 14-weeks of age and up who will attend the health facilities where the study will be taking place will be considered eligible. Caretakers will have to provide informed consent to enroll. Eligible and consented children will be enrolled at their 14-week EPI visit (DTP 3) and caretakers will be asked to return to the clinic at 6 months for additional services. It will be explained to the caretakers that vitamin A and nutrition counseling services will be provided at the new 6 month visit.

The arms of the study are:

Arm A: VAS and Complementary Feeding counseling
Arm B: Control

Six facilities operating under the MOHSW's Reproductive and Child Health (RCH) program in one health district will be included in the study. All interventions will be delivered at the proposed 6-month contact point.

Standard of care will be provided at the routine visits according to policy, including in the control arm. This also means that if any child in the control arm appears for a 6 month growth monitoring visit, it is expected that some IYCF counseling may be conducted at the facility, and perhaps other interventions, which will be recorded. Targeted IYCF counseling, what will be tested in this protocol, means that the messages provided will be specific to the needs of a child at 6 months of age. The study will use the already-existing national IYCF counseling materials, specifically the job aid/counseling card for messages directed to mothers with children starting at 6 months of age. Although the materials exist and trainings on IYCF have been conducted across Tanzania, nutrition counseling services are often neglected in understaffed clinics with high attendance. 2-day refresher training on targeted IYCF will be conducted with facilities in Arm B.

It is proposed that the study will take place in Sengerema district in Mwanza Region. This district is selected as the site for this study for the follow reasons;

- The district is one where HKI is beginning engagement with a new project (not yet started) and has staff on the ground to assist with supervision
- The district is average and representative of other districts in Tanzania with respect to VAS coverage
- The district has a fast growing population therefore enrollment numbers will be easily met within the study period

The implementation and data collection portions of the study are expected to take place over a 12 month period. Children will be enrolled at their 3 month/14-weeks visit and remain enrolled in the study until their 12-month EPI visit. Basic demographic information on mothers and children will be collected at the enrollment visit. At enrollment, the mothers/children in the intervention group will be asked to return to the clinic at 6 months of age to receive vitamin A plus nutrition counseling for their child.

In the intervention facilities, VAS will be provided at a child's 6-month visit, along with complementary feeding counseling. At the end of the visit, data will be collected from the child health card on VAS receipt as well as knowledge acquisition from the nutrition counseling session.

At the 9 month visit, measles will be provided in both intervention and control facilities as is current standard of care. In both intervention and control facilities, data collected will include age at receipt of measles, age at receipt of VAS (if the child did not come in for the 6 month visit), and a few indicators on behaviors related to complementary feeding.

Finally, at the 12 month visit a second dose of VAS will be given. Final data from the child health card will be recorded on the study forms and the child will graduate from the study. On a weekly basis in both intervention and control facilities, exit interviews with health workers will ascertain perceptions on work load.

As the design of this study rests on the introduction of a new contact point into the child health schedule, collaboration with the Expanded Program in Immunization, within the Ministry of Health and Social Welfare, is crucial to the design, implementation and application of potential recommendations resulting from this study. The EPI is also instrumental in providing any revisions to the current child health card which would need to be amended should a 6 month visit be introduced into policy in Tanzania.

Six data enumerators, 1 for each facility will be oriented on the study protocol, reporting forms and data collection. They will be responsible for collecting data at the various visits on the reporting forms and monitoring through observation the activities at the health facilities. Health workers at specific clinics will receive detailed training on the study protocol. All health workers in the intervention facilities will receive refresher training on appropriate nutrition counseling techniques and on vitamin A capsule administration, as needed. The national materials developed for counseling of complementary feeding from 6

months onwards will be used. All trainings will be conducted by the appropriate personnel from the Tanzania Food and Nutrition Centre (MoHSW).

As the primary objective of the study is to understand the feasibility of this intervention to be continued and brought to scale through the health system, the study design is attempting to use existing structures and personnel in every way possible. Therefore supplies needed for implementation will flow through regular channels as much as possible (IEC materials, VAC supplies, etc.). IEC materials for nutrition counseling exist in the local Swahili language and were recently revised. All RCH clinics participating in the trial will be provided sufficient, updated copies of these materials by the Tanzania Food and Nutrition Center.

The investigators will be involved in overall management of the study including: training of health workers on the interventions, supervision of implementation, monitoring the study, and evaluation of the impact of the interventions. Initial study planning with partners will include outlining a program impact pathway to ensure all potential confounders to outcomes seen will be understood in the context of other programs and interventions ongoing in the area. National, regional and district level health officials will be involved, including the EPI program staff in the Ministry of Health and Social Welfare.

4. Evaluation

The following data will be collected throughout the course of the study:

Table 1: Study Visit and Data Collection Schedule

At **enrollment (3 months/14 weeks)** the following data will be collected: General questionnaire with socio demographic data and contact information
At **6 months** the intervention (VAS and CF counseling) will be provided and the following data will be collected: Via Health Card: Age at receipt of VAS, age, weight, height Via Exit Interview with Caretaker: reasons for attendance, infant feeding knowledge
At **9 months**, when children return for measles vaccination the following data will be collected: Via health card: age of receipt of VAS, age at receipt of measles, age, weight, height Via Exit Interview with Caretaker: Infant feeding knowledge and behaviors
At **12 months** the following data will be collected: Via Health Card: Age at receipt of 2nd routine dose of VAS, review of RCH card to determine if vitamin A provided through twice-yearly event since last visit (age of receipt of twice yearly VAS), age, weight, height Via Exit Interview with Caretaker: infant feeding knowledge

Data enumerators will be collecting all data for the study. Data that are routinely collected on health visits will be collected as usual in client health files, with these data transcribed onto study forms for data collection. Because we will be collecting information to try to harmonize the twice-yearly and routine VAS provision, the nursing staff will need to collect information on the receipt of VAS through the twice-yearly provision. It is not common practice to indicate VAS coverage on the RCH card during mass campaigns, but in the facilities of interest, mothers will be notified to bring their cards to the campaign. Health staff in the study will be engaged with the campaign and should be able to identify children enrolled in the study, so in case cards are not brought in, the staff can indicate receipt of VAS in the records.

It is the hypothesis of the investigators that the creation of an earlier contact point for supplementation of Vitamin A will reduce the average age at first receipt of VAS from an anticipated 9 months to something closer to 6 months. However, current data on age at first dose is not available since date of receipt is not currently indicated on the health card at the measles visit. Therefore these data will be collected through the facilities in the control arm. Age at first receipt of VAS from the twice yearly events should also be considered. Current coverage of 6-month old children who receive supplementation through twice yearly events is estimated at 14% based on the fact that under best circumstances only 17% of 6 months olds are reached by twice yearly events at 80% coverage rates. Estimates in each arm will be calculated as the average age (in months to one decimal point) of receipt of the first dose of VA supplement. A sample size estimate was calculated based on the need to detect a difference of 3 months between average age of first dose of VAS between the control and intervention group (estimated at 6.5 and 9.5 months with a SD of 3 months), and a sample of only 36 children is needed. However, in order to enroll enough children in different types of facilities to determine the feasibility of implementation of this VAS protocol, we will increase the sample size. Six facilities will be selected (4 intervention and 2 controls) with enrollment of 50 children into each facility.

Analysis across groups will include differences across control and intervention arm at various ages as well as differences in changes within a group (difference within differences analysis). Compilation and analysis of collected data will be done by members of the research team.

5. Sustainability and Potential for Scaling-Up

The proposed study builds on Tanzania's successful vitamin A supplementation program to test the feasibility and effectiveness of providing VAS at 6 months of age, and harmonizing routine and campaign VAS schedules, both areas of current interest for VAS programs globally. The crucial inclusion of EPI personnel from the central ministry and health center personnel at each stage in the planning and testing of this approach will allow for continued refinement and implementation of the new contact point, following the study period. Additionally, the IYCF counseling interventions already exist in Tanzania, thus tools are already in place and designed for the Tanzanian context. The proposed new contact

point would be another way of strengthening the nutrition counseling work that is already underway by the MoHSW and TFNC.

There have been various discussions over the last few years on the VAS program in Tanzania. Therefore MOH colleagues in the EPI unit have been sensitized to the need for a 6-month contact to reach children with VAS. EPI has stated they are willing to take on the new health contact point and they were actively engaged with developing this proposal. They agree that that having hard evidence from this study would be useful as they amend their health visit schedule and will help them to justify this shift to the MOHSW.

The MOHSW Reproductive and Child Health Unit is keen to strengthen routine VAS in place of the campaign approach, so again evidence which shows a feasible and viable way to reach children through routine health visits will facilitate the amendment to the schedule. The long-term approach of reaching all children through routine services is a vision for 20 years down the road when health facilities can effectively reach >80% of children. A 'medium' term (perhaps the next 10-15 years) VAS approach in Tanzania could be to reach children <1 through routine VAS and reserve campaigns to reach children >1 (and children <1 missed by routine VAS). We see this transition as still strengthening routine services without compromising on VAS coverage.

Throughout most of Africa, VAS is provided through routine services at the 9 month contact point of the EPI schedule. Few countries have been able to effectively provide VAS at 6 months, although there have been some initiatives to examine strategies. Testing the feasibility of a 6 month contact point in Tanzanian routine EPI services would also allow the twice-yearly Vitamin A campaigns to be streamlined to provision just of children 12-59 months of age, which coincides with the campaign's target population for de-worming, reducing health worker workload, supply management issues (capsules of VA for children 6-11 months of age differ from those provided to 12-59 months of age) and coverage calculation errors through incorrect age. A 6-month visit will also allow for the earliest available provision of nutrition education as complementary feeding starts.

Appendix 1: Project Timeline

Activities	Task Included	2011						2012											
		J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D
PREPARATION																			
	Presentation of Study Plan to Partners				x														
	Selection and engagement of participant health facilities				x														
	Hiring of Study Coordinator				x														
	Training of Health workers on intervention bundles					X													
	Development of Data Collection tools					X													
	Testing of Data Collection tools					X													
	Development of Monitoring tools					X													
	Testing of Monitoring tools					X													
	Design and Establishment of Monitoring Report Flow					x													
	Revision/adaptation of IYCF and family planning counseling materials (if needed)					x	x												
	Printing of counseling materials					x	x												
ENROLLMENT PERIOD	Distribution of materials and tools to health facilities					x													
	Active enrollment of participants						x	x											
	Expected closing of enrollment period							x											
STUDY PERIOD	Active Data Collection					x	x	x	x	x	x	x	x	x	x	x			
	Supervision and monitoring visits by Study coordinator to health facilities					X			x			x			x				
	Reports due from Study Coordinator to Principal Investigator				x	x	x	x	x	x	x	x	x	x	x	x			
	Midway report								x	x	x								
	Closing of Study Period																	x	

DATA HANDLING	Collation of Data																			
	Analysis																		x	x
	Report Writing																			x

Appendix 2: References

[i] Along with zinc supplementation (www.copenhagenconsensus.com)

[ii] Beaton GH, Martorell R, Aronson KJ, Edmonston B, McCabe G, Ross AC, et al. Effectiveness of vitamin A supplementation in the control of young child morbidity and mortality in developing countries. ACC/SCN State-of-the-Art Series: Nutrition Policy Discussion Paper No. 13. Geneva: The United Nations, 1993

Figure 1: Potential of Lives Saved through Vitamin A Supplementation at different age intervals (source: Beaton 1993)

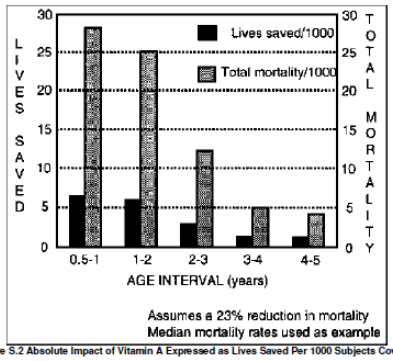

Figure S.2 Absolute Impact of Vitamin A Expressed as Lives Saved Per 1000 Subjects Covered

[iii] Masanja, H et al.(2008) Child survival gains in Tanzania: analysis of data from demographic and health surveys. The Lancet 12 April 2008: 6736(08) p 60562-70.

[iv] World Health Organization (1997). Vitamin A supplements: a guide to their use in the treatment of vitamin A deficiency and xerophthalmia. 2nd edition

[v] Latest EPI data from 2007 report.

[vi] Ross & Burkhalter (2007) When Do Infants Die? Analysis of Pooled DHS Data from 67 Countries, AED/Linkages unpublished paper

[vii] Beaton GH, Martorell R, Aronson KJ, Edmonston B, McCabe G, Ross AC, et al. Effectiveness of vitamin A supplementation in the control of young child morbidity and mortality in developing countries. ACC/SCN State-of-the-Art Series: Nutrition Policy Discussion Paper No. 13. Geneva: The United Nations, 1993

[viii] Adjusted from 38% NCHS Reference Standard to the new WHO Growth Standards

[ix] Household Budget Survey analysis for nutrient intake, World Bank, informal

[x] Consensus statement, GAVA meeting March 2009 Dakar, Senegal

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