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Implementing a Cold-Chain System for Nutritional Assessment in Rural Uganda; Field Experiences from FtF Nutrition Innovation Lab Cohort Study

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Abstract

Objective: To elaborate on the procedures undertaken to establish blood draws and cold chain for nutrition assessments.

Setting: A total of 5,044 birth cohort households were enrolled and assessed using household questionnaires, anthropometry, and blood sampling to assess nutritional issues and exposures to environmental contaminants. The challenge was to obtain, transport, process, store, and analyze tens of thousands of serum samples obtained in sites that were often difficult to reach.

Approach: Before enrollment began, 24 healthcare facilities in the North and Southwest of Uganda were assessed for suitability as local nodes for processing and storage. Equipment needs included functional centrifuges, refrigeration, ice machines, and -20°C freezers. Other important physical infrastructure included the presence of backup power (generator or solar generated) in the event of electricity failure. Once samples were obtained, they were transported within 5 hours to the facility laboratories, where serum was separated and aliquoted into properly labelled storage tubes and then frozen.

Relevant Changes: At community level, our team visited households or small group of household members close to their homes to reduce on travel time hence contributed to high retention rates. Our immediate testing for anemia and malaria results benefited enrollees and enhanced community acceptance. By using Village Health Teams (VHTs), we could accommodate household preferences for the timing of sample collection. Our engagement with phlebotomists transformed their role from a simple service into active team members.

Lessons Learned: Our first lesson was that in our setting, the success of this nutrition biological sampling system required community engagement and acceptance. By combining an immediately actionable set of tests (for anemia and malaria), and visiting cohort households, we greatly enhanced the success of the system.

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Introduction

Since January 2008, when the first Lancet Series on maternal and child undernutrition was published, there has been a shift in the way researchers, policy makers and academicians, look at nutrition interventions especially in low developed countries. Uganda is among the 34 countries that carry 90% of the global stunting burden [Black et al 2013]. Recent data shows high rates of stunting (33%), underweight (14%), and wasting (5%) as well as anemia (87%) in children under 5 [1]. Low birth weight is common (14% < 2.5 kg), 64% of all pregnant women are anemic and 12% of adult women are underweight (body mass index < 18.5 kg/m2) reaching to 23% of women in the poorest wealth quintile [2].

While the classical methods to detect malnutrition exist as indicated above, the use of modern characterization of malnourishment requires the use of biochemical assessment to detect micronutrient deficiencies and associated disorders. Of recent, the importance of biomarkers for nutrition has gained momentum at global level and therefore no one can under-rate the importance of biomarkers in nutrition assessments. However, poor Ugandan rural households - the majority of the population-are often far from laboratories and facilities which can conduct biochemical testing.

An integrated agriculture, nutrition and health project named the Uganda Community Connector was collaboratively developed and implemented by the Government of Uganda and USAID. It aimed at improving the nutritional status of women and children through an integrated suite of interventions focused on nutrition and health; agriculture and food security [3]. The USAID Innovation Lab for Nutrition–Africa undertook a birth cohort study to assess the Uganda Community Connector and to study underlying mechanisms that link agriculture, nutrition and health. Five thousand and forty-four (5,044) birth cohort households in 16 rural locations (8 intervention, 8 control sub-counties in 12 Districts) were enrolled and assessed using detailed household questionnaires, anthropometry, and biochemical sampling to assess nutritional issues and exposures to environmental contaminants (aflatoxins). The challenge was to obtain, transport, process, store, and analyze tens of thousands of serum samples obtained in sites that were often difficult to reach and far from health facilities. While systems exist to transport vaccines and other biologics from central locations to many peripheral sites, no country-wide system existed to do the reverse. Therefore, the challenge was how to run a functional cold chain at different health facilities and maintain serum sample potency. This implies for those involved, mastering sensitivity to temperature and being adequately skilled and equipped regarding conditions of storage and transportation as well as cold chain and power supply monitoring were necessary [4, 5]. In fact, temperature control is one of the top 10 global health supply chain issues [6]. In Uganda, power supply is still a challenge to many health facilities especially in rural areas and varies from one locality to another. Hydroelectricity is the most common power source in Uganda but it is still not available in many rural health facilities. This power access challenge affects over 70% of health facilities in Uganda [7], with limited road networks further complicating access to ′off-grid′ solutions like gas and solar system. Apart from these challenges, human capacity to manage cold chain is inadequate and most often cold chain inventories do not have systems for routine data collection, which limits the existence of accountability structures and inhibits accurate and regular inventory updates [4, 7].

Approach

Household Enrollment and Enumeration

Our enrollment goal was a maximum of 322 pregnant women in each of 16 sub-counties (n=5,152). We enrolled 5,044 women in a 30-week period during 2014 and 2015. Trained cohort study enumerators visited households with pregnant women, as facilitated by local Village Health Team (VHT) personnel. After enrollment, detailed household questionnaires and anthropometry was conducted. Data was captured electronically using programmed tablets. At that juncture, households then had contact with the biological sampling system which was constructed as outlined below. When cohort women and children were visited, blood was obtained for both immediate testing and for later testing. Immediate testing included a hemoglobin measurement using a Hemocue device. We also tested for malaria using highly specific and sensitive rapid tests (RDTs). Persons with anemia were referred for medical care, and those with malaria were offered immediate treatment.

Facilities

Before enrollment began, 24 healthcare facilities in the North and Southwest of Uganda were assessed for suitability as local nodes for processing and storage. Equipment needs included functional centrifuges, refrigeration, ice machines, and -20°C freezers. Other important physical infrastructure included the presence of backup power (generator or solar generated) in the event of electricity failure. We found that many facilities with this infrastructure were supported by HIV-related programs and funding. Facilities also had to have required personnel and had to be within a reasonable distance from cohort study households (see below). Thirteen of 24 facilities met eligibility criteria. Eight facilities were chosen and Memoranda of Understanding were signed between Innovation Lab for Nutrition and the facility which outlined mutual expectations. We also required quality control such as daily checks of refrigerator and freezer temperatures. Within 2 months of study inception, 2 facilities which did not adhere to best practices for phlebotomy and processing were either replaced or consolidated with another well- functioning facility. We ended up using 4 facilities in the Southwest and 3 in Northern Uganda.

Personnel

When we visited facilities, we assessed the availability of trained phlebotomists and laboratory technicians based at the healthcare facilities. Selected individuals then received training not only in best practices relating to phlebotomy and sample processing, but also in the goals of the Innovation Lab for Nutrition cohort study and its purpose. Training also included electronic data capture. Phlebotomists travelled to cohort households by motorbike carrying cold boxes with wet ice, and obtained blood samples. Once samples were obtained they were transported within 5 hours to the facility laboratories, where serum was separated and aliquoted into properly labelled storage tubes and frozen at -20°C. Cohort mothers often asked our phlebotomists questions about the study and used them as an informal channel to reach cohort study enumerators. Phlebotomist engagement was an unexpectedly important element of our relationship with the household mothers and children.

Logistics

At the sub-county level, individual decisions were made on whether phlebotomists would visit individual households or small groups of cohort enrollees who lived close to one another. This required temporal coordination with the enumeration team that visited the cohort households before the index woman gave birth, at delivery, and then every 3 months through 1 year of age. The public motorbike 'boda-boda" transport system was efficient and cost-effective. Boda-bodas are able to traverse roads impassable to automobiles and can travel on dirt pathways where roads do not exist. At the country level, we had to transport accumulated samples from the 7 healthcare facilities to Kampala city every 3 to 4 weeks. Core study personnel travelled to the 7 'hode" sites on weekends in study vehicles containing large cold boxes with dry ice to keep the samples frozen. Dry ice was not consistently available except in Kampala and thus we essentially maintained two cold chains – one transporting dry ice to our 7 nodes, and then transporting samples from the nodes to Kampala using the same dry ice. We also purchased and distributed phlebotomy supplies (alcohol pads, needles, collection tubes, etc.) that were appropriate to children and not available in the nodal sites. Upon reaching Kampala, frozen samples were logged in and placed in a -80°C freezer (with power backup) for subsequent handling.

Relevant Changes

Our system had a number of notable features and challenges (See Table 1). First, at the community level, our team visited households or small group of household members close to their homes. We did not ask enrolled women to travel to a central facility which would have been logistically easier for us but more difficult for the households. We believe this change from usual practice contributed to very high retention rates (only 6 households out of 5,044 dropped out of the study). This has been identified by other authors as critical to retaining cohort study members [8]. Second, our immediate testing for anemia and for malaria provided a welcome result which benefited enrollees. This enhanced community acceptance of obtaining samples for later testing (which entered into the system we describe).

Table 1: Responses to technical and logistical challenges encountered when implementing Nutrition cold chain system in Uganda 2013-2015

Challenge	**Reason**	**Response to challenge**
Poor community perception on phlebotomy especially from mothers who had just delivered and from infants	That health workers take a lot of blood yet the mothers experienced hemorrhage at birth. Husbands when at home question this and even refuse them to participate.	Ongoing re-consenting of study participants, mobilization and sensitization of mothers and the community by study team and VHTs days before blood drawing and Male involvement in the process was helpful
Difficulty of drawing blood from infants	Veins are not visible, crying by the babies lead to the mothers (parents) decline blood draw for their children.	Provided training to Study Phlebotomist and lab technicians on use of the butterfly needles that are less painful because the butterfly needle is a smaller needle gauge (23 gauge is a standard) and suitable for children since their veins are small. Had to come up with timetable to draw blood, encouraging mothers to cover their babies to keep warm, also incentivizing mothers with the hygiene related items for their time like a bar of soap and a jerrycan as approved by the Makerere Institutional Review Board and Uganda National Council for Science and Technology.
Samples for children not enough	Insufficient blood result into sample hemolysis.	Unlike the initial implementation of blood draw in children, phlebotomist have gained experience in drawing sufficient blood from children.
Transport difficulty	Some areas are far and can take over 1 hour on the road on boda-boda (motor-bike), poor terrain and distances between households, compounded by poor and impassable roads and poor and hilly terrain.	Travelling early to study sites, mobilizing women prior to the blood draw visit and having extra ice packs were very useful.

Lack of enough storage of blood samples at health facilities	Some sites have limited space to store samples because health facility freezers are shared i.e. between different research institutions and the health facility.	Core study Personnel had to move to the field frequently and repatriate samples to Central Lab at Makerere University. Clear sample pick -up schedules per site were adhered too to ensure optimal utilization of the available storage space in the lab including procuring one extra freezer for a health facility.
Perception of mothers on blood testing; expecting more than the study can offer	The mothers expect results from other tests such as HIV which the Nutrition Lab Proto-col was not set to perform.	Test results for detecting Anemia (Blood Hemoglobin) and Malaria were provided to enrolled women immediately. Treatment and referrals of serious cases were made as per study protocol. All other tests or conditions that the study could not offer were referred to the nearest health facilities for medical attention.
Wet Ice packs melting while still in the field	Because of taking long in the field and temperatures go as high as 40° melt the ice packs.	Prior arrangements were made whereby participants were notified and followed up to have timely blood draws and minimized any possible delays. The study team strove to make sure that they did not take more than 3-4 hours in the field.
Hemolysis of blood samples	Due to long distances and time from health facility to field site and back.	Team started using butterfly needles among the infants helped. Repeating blood draws to enrolled participants with hemolyzed was done.

Third, because of our engagement with the VHTs we were able to accommodate household preferences for the timing of sample collection. Last, engaging the phlebotomists transformed their role from a simple service into active team members.

We used local boda-boda transportation systems. This provided income to small businesses at the community level [9] but also proved to be efficient in rural communities because of a poor road network. The health facilities we used derived benefits relating to the training, quality control, and financial support which helped them to maintain critical infrastructure used for healthcare delivery such as supplies and equipment. This was of mutual benefit. Had we had to set up a separate system that did not leverage healthcare facility resources, our task would have been far more difficult.

Challenges

Challenges were many. Some households were nearly impossible to reach during the rainy season. Healthcare facilities had difficulties with power and personnel had, at times, to reorient their attitudes. We had to adjust how samples were transported from the field to reduce hemolysis by using enhanced cushioning inside the cold boxes. Culturally, blood taking is resisted by many parents [10] in many societies same in the study communities. Our use of the local boda-boda system, devotion to training and quality, and engagement with the communities eased these challenges. In addition, we had to maintain a strict schedule of pickups from the 7 healthcare facilities as their freezer space was limited.

Lessons Learned

Our first lesson was that in our setting, the success of this nutrition biological sampling system required community engagement and acceptance. By combining an immediately actionable set of tests (for anemia and malaria) and visiting cohort households, increased the demand for blood drawing and this greatly enhanced the success of the system and retention of study subjects.

These elements, in combination with engagement of healthcare facilities, in a whole-systems approach are very different from a top-down, center-to-periphery orientation often seen with vaccine delivery cold-chain system. Therefore, to maintain a nutrition cold chain system, one has got to have strong engagements with community so that they are part and parcel of the whole process.

Our second lesson was that collaborating with local healthcare facilities was paramount. They not only had required equipment, they also employed locally knowledgeable personnel who truly became team members. This is important because when the health care system is cooperating and becomes part and parcel of the whole process, they are able to do mobilization, processing, centrifuging and storage of the samples. For Uganda's case, the district and health managements were committed and supportive, health workers and phlebotomists were very effective in drawing blood and processing the samples on time. Working with health workers was very helpful; because they are professionals, known and respectable in their communities. VHTs were instrumental in mobilization and sensitization.

Lastly, we discovered that our idea that our system would be a reversed cold chain vaccine delivery system was far too simple. We had to maintain cold chain (dry ice in one direction, samples cooled by dry ice in the other) in two directions as well as deliver a cold chain to the household level, far beyond the usual local healthcare facility level.

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