Local production of alcohol-based hand rub for health facilities: A practical discussion on improving hand hygiene among health workers in Uganda

Frequently Asked Questions

The Infectious Disease Institute at Makerere University, in partnership with the US Centers for Disease Control and Prevention, undertook a project to evaluate a district-level approach to the local production of alcohol-based hand rub (ABHR) for healthcare facilities in Uganda. The goal was to produce a lowercost hand hygiene product at the district-level which would increase compliance of hand hygiene practices amongst healthcare workers. Below are Frequently Asked Questions about the project, which provide insights into the process, challenges, and lessons regarding local ABHR production for healthcare facilities. For the full webinar, presented by Project Director Dr. Mohammed Lamorde and Project Officer Maureen Kesande, see the recording <u>here</u>.

**This project was initiated prior to the COVID-19 outbreak; however, it should be noted that any alcohol-based hand sanitizers that are more than 60% alcohol content are <u>effective against SARS-CoV-2</u>.

What guidelines or formulation to produce ABHR were used for this project?

This project followed the World Health Organization (WHO) guidelines <u>"Guide to Local Production: WHO-recommended</u> Hand Rub Formulations".

Ingredients include: Ethanol 96%, Hydrogen Peroxide 3%, Glycerol 98%, Sterile distilled water.

What was the process for producing the ABHR?

This feasibility and evaluation study of local production of ABHR used a laboratory technician to produce the ABHR and an ABHR distribution coordinator. The lab technician follows the formulation in the WHO guidelines. Some standard laboratory equipment is needed to measure and mix ingredients. It takes the



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producer an hour to mix the ingredients for a single batch (20 L). This is followed by an internal quality control assessment, a 72-hour quarantine, and an external quality control test prior to product distribution to health facilities. For quality control, an alcoholometer is used to measure the alcohol concentration to ensure that meets the WHO quality control standards (75%–85% alcohol). Standard operating procedures for ABHR production targeted a concentration of 80% alcohol.

Were there challenges sourcing the ingredients? What kind of supply chain was set up?

All raw materials (96% ethanol, distilled water, 3% hydrogen peroxide and 98% glycerol) were available through the National Medical Stores. Other sources may be available, such as purchasing ethanol from sugar cane processing plants. Plasticware (1L and 60mL bottles) were procured from local suppliers. The labeled jerry cans containing 20L of ABHR, 1L pump bottles, 60ml bottles, and associated paperwork (i.e. stock card) are delivered to HCF where IPC focal person receives them. The IPC focal person is responsible for distributing the ABHR within the HCF, maintaining stock cards of refills and consumption, and ordering more ABHR. IPC focal persons were instructed to order more ABHR when there was 5L of ABHR remaining in the stored 20L jerry can. Those orders then must be reported to/monitored by the ABHR distribution coordinator to ensure accurate production each month.

What are the technical capacities required of the personnel?

The ABHR producer is a lab technician who is trained in the WHO protocol. They are responsible for making the ABHR monthly. The lab technician must know and use standard personal protective equipment (PPE) and laboratory safety practices during ABHR production. The distribution coordinator is responsible for coordinating with district-level distribution mechanisms to deliver the ABHR, training IPC focal people at healthcare facilities in how to refill containers and monitor use of ABHR, and ensuring monthly reporting of ABHR use to inform the next month's production requirements.

What are the physical space requirements for production?

ABHR production requires an air-conditioned or well-ventilated and spacious unit for production with a fire extinguisher, as well as air-conditioned or well-ventilated storage facilities that are lockable and secure for storage of raw materials and finished ABHR. Careful planning of space requirements for storing each round of ABHR production should be taken to ensure safe and sufficient storage. National safety guidelines and local legal requirements must be adhered to regarding the storage of ingredients and the final product. At the health facility, the ABHR is kept within the store (i.e., in a lockable place) in cool conditions.

What is the shelf life of the ABHR product?

According to the WHO guidelines, samples of ABHR stored in a tropical climate without air conditioning or special ventilation still met the WHO optimal quality parameters up to 19 months after production. There may be some variations depending on local storage temperatures and humidity, however, longevity is also dependent on the ABHR being stored according to the recommended guidelines in the WHO protocol for ABHR production. In our study, all ABHR tested in the HCFs that had been there for about four months still met the WHO optimal quality parameters (alcohol content 75%–85%).

What size were the batches (in liters)?

In our experience, ABHR was made in 20L batches (using the WHO-recommended ABHR Formulation) and distributed in 20L jerry cans because this quantity was sufficient to last multiple months at the largest of healthcare facilities. However, the production protocol can be adapted to smaller jerry can sizes (e.g., 10L or 5L), if required.

What quality control mechanisms did you put in place?

Following production, the ABHR producer uses an alcoholometer to perform internal quality control assessment to ensure a 75–85% alcohol content per WHO guidelines. The batch is then quarantined for 72 hours. After the 72 hours, an external quality control assessment, identical to the internal quality control assessment, is done by an external, district level official (e.g., the district health officer or designee) prior to distributing the ABHR. Based on our experience, it is best to have the internal and external quality control assessments take place at different locations so that there is no communication or potential bias between the internal and external quality control process. If the alcohol concentration at the external quality check was 75–85%, then the product was distributed to health facilities.

What was the mechanism for distributing ABHR to the healthcare facilities?

During our evaluation, we distributed ABHR with hired cars. This model was expensive and not sustainable cost-wise in the long-term. Integration of ABHR jerry can distribution into existing supply chains is something that should be taken into consideration prior to implementation at the district level. Similarly, monitoring ABHR use at the facility was challenging due to all the duties the IPC focal person was required to do. Within our project, the distribution coordinator used the hired cars to check on ABHR consumption monthly at each facility. Given that hiring cars is not sustainable, integrating monitoring of ABHR levels at care points into existing reporting or requisition structures at the healthcare facility and district level should be considered before implementation and carefully implemented to avoid overstocks and understocks.

What kind of dispensers do you use within the HCF and where are they located? (on person, on wall, tables, etc.)

We used free standing, 1L pump bottles at each patient care point. We considered putting these 1L bottles in wall-mounted cages that could be locked to prevent theft. However, the wall mounted cages available in Uganda did not fit the 1L bottles that we were using. When the HCF first received the ABHR, the IPC focal person filled ABHR in the 1L pump bottles and placed them at each patient care point. The IPC focal person would then monitor the bottles and refill them as needed using the 20L jerrycan from the store and noting refills on the ABHR stock card. The IPC focal person was also responsible for signing out 60mL bottles for individual staff use. The 1L bottles, as well as all ABHR supplies, were locked in the storeroom when not in use.

How was the consumption of ABHR monitored and how are data utilized?

At the highest level, ABHR consumption was monitored by tracking when healthcare facilities requested a new 20L jerry can of ABHR. Additionally, the study coordinator visited healthcare facilities every month to monitor the amount of ABHR left in the 20L jerry can and the approximate amount remaining in each of the 1L pump bottles at the patient care points. We are using the data to estimate how much ABHR is used in different sizes of HCF. However, ABHR consumption varies widely and is driven primarily by patient volume and healthcare worker behavior and can vary over time.

Others have taken a decentralized approach to ABHR production (i.e., producing ABHR within a single facility for only that facility). Why did you decide on a centralized approach and what have been the benefits and challenges of that method for this project?

An individual facility producing ABHR for itself is feasible for large regional and national referral hospitals, which are able to order their own supplies for production, while smaller HCF only receive standard consignments of essential drugs from the National Medical Stores. Additionally, this production is very challenging for resource-constrained, geographically-isolated, small healthcare facilities. District-based production (ABHR production at a single HCF for the entire district) allows for smaller HCF, which lack the space for a designated production unit and rarely have the cadre to support production, to receive ABHR regularly.

What were the costs associated with ABHR production at the district-level?

Initially, there are several laboratory supplies needed to produce ABHR (e.g., measuring cylinders and jugs, funnels, buckets, table, personal protective equipment, cleaning supplies, etc.). We estimate a one-time cost of \$550 USD to purchase all these production start-up materials in Uganda. Next, there are raw materials and packaging for producing the ABHR. For the first production of ABHR, each liter costs approximately \$4 USD. Because we distribute 20L jerry cans and reuse the 1L pump bottles, the cost of 1L of ABHR after the initial production and distribution can be as low as \$2 USD. These estimates are specific to this project and prices may vary in different regions or countries.

Did you find improved hand hygiene compliance through the ABHR project?

Facilities that received ABHR had higher levels of hand hygiene compliance before and after patient contact than at baseline when they did not have access to ABHR. Increases in compliance from baseline to midpoint may have decreased slightly at endpoint. While improvements were observed, hand hygiene before patient contact remains low. Unfortunately, external complications prevented a direct intervention/control comparison of healthcare facilities with access to ABHR vs. facilities that did not have ABHR, which prevented a complete evaluation of causality.

The <u>Infectious Diseases Institute</u> (IDI), established within Makerere University, is a Ugandan not-forprofit organization which aims to strengthen health systems in Africa, with a strong emphasis on infectious diseases through research and capacity development. For questions about this project, please contact Maureen Kesande: <u>mkesande@idi.co.ug</u>.