World Health Organization

African Partnerships for Patient Safety

Local Production of Alcohol Based Hand rub Training Workshop Report

Harare, Zimbabwe

18-23 March 2013

The report on the first of its kind training workshop for English speaking countries in the African Region on the production and quality control of WHO formula alcohol based hand rub held in Harare, Zimbabwe March 18-23, 2013. The 12 Participants included selected pharmacist from African Partnerships for Patient Safety's second wave partnership hospitals and Parirenyatwa General Hospitals.

Background

Evidence from all regions of the world support the fact that hand hygiene compliance is the key for reducing hospital acquired infections. Given the lack of infrastructure in most African hospitals (lack of sinks with clean running water, soap and individual disposable towels), alcohol based handrub (ABHR) is the best solution to providing the means to hand hygiene when indicated at the point of care. However, the cost of purchasing imported ABHR is prohibitive for most hospital budgets. The cost is usually exorbitant because not being produced locally it has to be imported, with all of the cost of transportation and associated taxes. There are few places and not in each country which produce local products.

In the African Partnerships for Patient Safety (APPS) strategy for catalyzing change and improving capacity in patient safety for African hospitals, one of the greatest challenges has been that of securing an affordable available and accessible supply of ABHR. Local production is an obvious solution, but this seemingly simple solution is fraught with many challenges such as the production expertise, equipment needed to assure quality control and procuring needed amount of raw materials. Last but not least, is the simple unavailability of appropriate individual size bottles with safety caps. While the appropriate personnel is usually available at each site, without the specific training and equipment this capacity remains unused.

Hospitals need to have trained personnel and appropriate equipment to perform local production and assess its quality. This has been done in the three francophone first wave hospitals and was effective in creating points of local production of ABHR adequate for the needs of the hospital hand hygiene program and beyond.

The first wave of APPS English speaking hospitals underwent a great deal of difficulty beginning the production process, in part because of the lack of expert training and equipment. As a result there was a great delay in site production and none of the three sites are performing quality control of the final process on site. This is critical as the concentration of hydrogen peroxide must be measured within hours of final production.

The APPS five second wave English countries thus required training in ABHR production and quality control for their hospital partnership plans to advance on target.

In terms of national spread, a review of the first and second wave feedback shows that there was no greater single contribution identified than that of being able to cascade training in hand hygiene compliance in tandem with the ABHR production training to other hospitals.

Such training is also in alignment with the WHO African regional HSS work plan. Office specific expected results (OSER 10.13.3) listed the support for capacity building in Patient Safety as a priority for 2012-2013. This was in response to the general need for the strengthening of health systems through a clear identification of patient safety issues and solutions through the use of WHO guidelines.

Purpose/Objective of Workshop:

General Objective:

To increase capacity for local alcohol based handrub (ABHR) production in each of the second wave African Partnerships for Patient Safety in order to support the sustainable supply of ABHR for the activities planned in hand hygiene as the entry to reducing healthcare acquired infections in each of the APPS focal hospital, by training two selected pharmacists in the actual production and quality control of the WHO formula.

Specific Objectives:

1. To train two selected pharmacists from each hospital in the theory and practical production process of the WHO formula alcohol based handrub with confirmation through individual observed performance of production steps.

2. To train two pharmacist from each hospital in the quality control process of ABHR production from primary materials to final product with confirmation through individual

Methodology:

Each African arm of the second wave APPS partnerships and a hospital in Zimbabwe was asked to identify 2 staff members trained in practical pharmacy, willing to be trained to develop ABHR production at their hospital. Also they were to be willing to train others to do the same, once a production centre was functioning on site. These selected individuals were invited to the planned training workshop.

The workshop's training facilitator was Dr Loséni Bengaly, Doctor of Practical Hospital Pharmacy, from Mali, the WHO African Regional Lead in ABHR production training. He demonstrated the techniques and then individually tested the participants in their ability to carry out the production and quality control process independently.

Brief summary of activities:

1. Two days of focused lecture presentations of background, importance for hospital acquired infection reduction, context and theoretic basis of ABHR and of good manufacturing practices (GMP) in general.

2. Demonstration of the ABHR production process from primary materials to finished product followed by participants completing the production of two batches (200 bottles) themselves.

3. Demonstration of the ABHR quality control process from primary materials to finished product followed by each participant demonstrating the ability to complete this process.

4. Testing of participants' learning.

Agenda Daily Summary:

Day One

Opening Ceremony: After self introductions were given by participants Mistress of ceremony Dr J Hightower invited the honoured guest at the high table, to address the workshop. This session was highlighted with speeches by the WHO Representative Delegate, Dr Midzi; the MOH Director of Pharmaceutical Services, Dr A Sangoya and the Parirenyatwa General Hospitals Chief of Pharmacy, Dr D Vuragu.

Workshop Presentations: Context topics, including: the history of ABHR, burden of health care-associated infections and means of their prevention and reduction, experience of production in other APPS hospitals were presented by Dr J Hightower and Dr L Bengaly. A message to the participants in the form of a slide presentation was given by Dr William Griffiths, the developer of the WHO ABHR formula. This moving presentation evoked a unanimous decision by the participants to respond to his message and each hospital sent him a reply message.

Day Two

Workshop Presentations: Good Manufacturing Practice, ABHR production and quality control theory formed the basis for presentation.

Demonstrations: A demonstration of ABHR production steps was made: 1. Label design and bottle preparation, 2. Preparation and quality control of raw materials, 3. Production of the ABHR and, 4. Bottling of ABHR. This resulted in the final collaborative production of the very first WHO formula batch (approximately 100 bottles of 100ml)

Workshop Presentations: Presentation on quality control steps for the final product was made.

Day Three

Testing: Participants' mastery of the production process was evaluated as the second batch was produced from labels to final bottled product. This resulted in the second ever WHO formula batch (approximately 100 bottles of 100ml)

Day Four

Demonstrations: A demonstration was made of quality control steps including: 1. Preparation of reagents; 2. Titration process & calculations; 3. Quality testing the final product for appropriate contents, measurable with instruments; and 4. Quality control of all aspects from testing of the raw materials to finished product. (Alcohol concentration tested with alcoholmeter & hydrogen peroxide concentration tested through a reduction titration process.)

Day Five

Testing: After the demonstration with explanation by the facilitator, each participant was required to demonstrate his/her mastery of the process by individual completion under observation.

Closing ceremony: The closing ceremony included the presentation by participants of a bottle of the finished product to the WHO Country Representative. The WR presented Certificates of Attendance to participants.

Day Six

Review of process in general discussion.

Discussion was held of plans for implementation at their hospitals and concerns about resources for implementation.

Written evaluations were completed.

Evaluations:

Participant evaluations were overwhelmingly positive in terms of scoring the facilitators' presentations and comments on the quality of the workshop. They also had constructive comments which are included in the findings and recommendations section.

Challenges Encountered:

1. Facilitator was unable to run control on raw materials before start of workshop, because of arrival date proximity to workshop start. The fact that he arrived on a Sunday when there was no access to suppliers or open offices, posed a logistics challenge.

2. There was a delay in delivery of several quality control items. The suppliers at the last minute refused to deliver the amounts requested because it would have required sending a less than full bottle. They said they would not be able to then sell the rest in an opened container. Only when we agreed to buy the entire container or minimum amount did they confirm delivery for later that day or the next morning.

3. For preparations produced by suppliers they required a minimum amount (always more than we needed for the workshop) in order to make it worth their while as far as their costs of production.

4. Two chemicals had to be returned because of an error in form.

5. One reagent ingredient arrived just an hour before it was to be used and was of questionable quality. The fact that the workshop venue did not have a working production centre posed a production venue challenged and we settled for a space adjacent to the lecture hall. It was a restricted sized space for the 12 participants.

6. The fact that each participant had to demonstrate the capacity to perform the production and the quality control with only one expert to observe posed a time restriction where a third to half of participants waited while testing was completed.

Achievements/Findings:

1. Participants proved themselves very capable of producing the WHO formula ABHR and also demonstrated full ability to complete the quality control process.

2. General plans were made for implementation in the various contexts of their hospitals and countries. Comments were unanimous in the need for supply of the 100ml bottles and other essential equipment to make this successful.

3. Participants spontaneously developed a Facebook platform to be able to support each other and share information during implementation and further follow up.

Recommendations /Action to be taken:

1. Earlier arrival of the Facilitator in future workshops (preferably two days) to allow quality control process to occur.

2. An allowance should be made in the budget for the minimum amounts required per order by requesting the pro forma invoices.

3. Workshops in the future should be at venues which have a working production centre to assure the best facilitation for working space.

4. Efforts should be made to minimize the down time for participants during testing. The options are to reduce the class size or increase the number of facilitators. In light of the need we are facing for trained producers, it is recommended that a focus be placed on grooming more facilitators for training.

5. Follow up with ABHR production implementation will need to be maintained through the two month activity reports sent by each hospital to APPS.

6. In order to assure the minimum materials/equipment not available locally, a request to be made for “production kits” to be sent to each site to include a supply of the 100ml bottles and alcoholmeter. This is a shot term solution. The long term solution might include 1. To make it worth the financial investment of a local bottle and cap producer in Africa (most likely in South Africa) to produce the bottles for sale to local ABHR producers or 2. To facilitate the procurement process from B Braun for production sites. (The needed bottles were unavailable in the plastic market/production in Zimbabwe. This has been a consistent problem for local production in every African country surveyed so far.)

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