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AMAZON MALARIA INITIATIVE

SUCCESS STORY

COLOMBIA TAKES ROUTINE TESTING OF MALARIA MEDICINES TO THE NEXT LEVEL TO ENSURE QUALITY IN ENDEMIC AREAS

Colombia has the second largest malaria burden in Latin America and the Caribbean. The most affected populations live in the Northern and Pacific Coast regions of the country, where transmission mainly occurs in rural areas. Historically, malaria medicines obtained from public and private establishments in remote areas of Colombia have been of varying quality.

Medicine quality is important for malaria control in order to prevent further parasitic infections. Substandard or counterfeit medicines may have negative consequences such as treatment failure and the emergence of antimalarial resistance. To address this, Amazon Malaria Initiative (AMI) partners PAHO/WHO and USP have successfully championed the policy adoption of the three-level approach for medicine quality control in Colombia. This approach applies sequential and complementary levels of quality control of increasing complexity. It provides a cost-effective, fast and reliable methodology to assess large numbers of medicines in the field.

In 2006, two Colombian pharmacists attended a training for trainers in Tumeremo, Venezuela on the use and management of GPHF-Minilabs™ (minilabs) as the Level 2 equipment for field analysis of medicines in the context of the three-level approach. One pharmacist worked as an analyst at the National Institute for Surveillance of Medicines and Food Safety (INVIMA), and the other at the public health laboratory in the department of Antioquia. Colombia received a donation of two minilabs through the PAHO/

Photo Credit: USP/PQM

Laboratory analysis of artemisinin-based combination therapies (ACTs), Bogota, Colombia 2013

WHO country office. The donated minilabs were strategically placed in the regional public health laboratories of Antioquia and Valle del Cauca, as the internationally trained pharmacist from Antioquia was able to assist with the training of another pharmacist in Valle del Cauca.

To enable implementation of this approach in all of Colombia's malaria-endemic departments, additional equipment and training were needed to perform the second level of analysis in the field. In 2012, a national project of

Pan American Health Organization
World Health Organization Regional Office for the Americas
CDC Safer·Healthier·People
SIAPS Systems for Improved Access to Pharmaceuticals and Services
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the Global Fund to Fight AIDS, TB and Malaria purchased three minilabs for regional public health laboratories and USP donated two more minilabs at the request of INVIMA. The new minilabs supplemented the two that had been acquired in 2006 and allowed a total of seven departments from the national network of laboratories to perform Level 2 field tests. Through support from the Global Fund project, in collaboration with the pharmacist from the department of Antioquia, INVIMA, and PAHO/WHO, five department-level pharmacists received training on the use of the five new minilabs.

In accordance with the standardized regional protocol, the sampling of antimalarial medicines began at the municipal health institutions' pharmaceutical storage facilities, as well as at rural diagnosis and treatment centers in malaria-endemic areas. Several rounds of sampling were conducted in the departments of Antioquia, Valle del Cauca, Nariño, and Chocó using the existing minilab equipment. Subsequently, two more rounds of sampling were done with private pharmacies with collection carried out by way of simulated purchasing. The samples for the reference laboratory level of quality control were sent to INVIMA as Colombia's Official Medicine Control Laboratory (OMCL). The test results of the samples taken from public and authorized private establishments indicated that most medicines were of good quality, though several samples were expired. This finding helped diagnose a stock management problem that was subsequently corrected.

The percentage of medicines failing Level 1 and Level 2 testing in endemic areas decreased from 13% in 2007–2008 to 0% in 2009–2010. In part, this reflected a drastic reduction in the number of expired medicines in the latter period, resulting from the corrected stock management problem diagnosed through testing in the 2007–2008 period.

In 2012 and 2013, INVIMA convened meetings of the national network of departmental medicine control laboratories that were also attended by AMI partners USP and PAHO/WHO. At these meetings, the laboratories agreed to use the minilabs to monitor an additional 11 medicines with follow up tasks for doing so, including the need to strengthen INVIMA in order to develop the necessary new methodologies.

Contact:
Julie de Carvalho
Links Media, LLC
jdecarvalho@linksmedia.net
+1 301 987 5495 ext. 109

The three-level approach

The three-level approach applies sequential and complementary levels of quality control of increasing complexity, which are:

Level 1 – Visual and physical inspection

Level 2 – Rapid analytical screening tests that can be performed in the field

Level 3 – Registration methodologies that require an established lab and trained personnel

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