

Advancing Medicines Quality Assurance Systems in LMICs: Celebrating 10 Years of PQM Program Achievements

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Crystal Gateway Marriott, Arlington, VA

Panel: Strengthening and building sustainable, self-reliant, medicines quality assurance systems in LMICs

Moderated by Timothy Nwogu, Principal Program Manager, PQM

Panelists

1. Alison Collins, Health Systems Advisor, USAID Office of Health Systems
2. Mojisola Adeyeye, Director General, Nigeria National Agency for Good and Drug Administration Control
3. Victor Pribluda, PQM Principal Program Manager
4. Hailu Tadeg, PQM Ethiopia Chief of Party

Mr. Timothy Nwogu: This panel will discuss strengthening and building sustainable, self-reliant medicines quality assurance systems in LMICs. It is challenging to pick the right names to discuss the scope of this work. We need to work globally to build capacity, and we need to ensure that authorities can adopt international standards. Our support has looked at medicines' pre- and post-registration activities, and we have invested heavily in workforce development.

Mr. Nwogu to Alison Collins: USAID has made significant investments in improving medicines quality assurance for more than two decades. Several approaches have been tried with countries. First, the support was reactive, like Kelly mentioned in her keynote speech on malaria medicine resistance. Then it became more targeted to build and strengthen health systems. Currently, USAID is moving toward empowering countries to become self-reliant. As the PQM Agreement Officer's Representative (AOR), can you highlight a few examples of how PQM-supported countries have worked toward sustainability and are making progress toward self-reliance?

Ms. Collins: There are a number of examples where PQM-supported countries work toward sustainability. PQM provided pivotal support from NOMCoL [Network of Official Medicines Control Laboratories] SSA to the African Medicines Quality Forum (AMQF). PQM's technical and financial support helped expand USAID's support to over 18 laboratories across sub-Saharan Africa.

The PQM collaborative learning model has also helped build capacity for laboratory staff. PQM provided specialized training to staff in laboratories in different countries and identified those who needed more training and those who could become resources to other staff. It allowed new hires to be trained by existing staff instead of by PQM staff. PQM has successfully helped countries take ownership of activities and build self-reliance.

Mr. Nwogu to Dr. Adeyeye: Nigeria is one of the PQM countries where extensive support was provided through the PQM mechanism to strengthen Nigeria's National Agency for Food and Drug Administration and Control (NAFDAC) systems, local manufacturers, and workforce to improve medicines quality assurance. What main systemic challenges did NAFDAC face with ensuring that quality and safe pharmaceutical products are available in the country? What role did PQM play to help address some of these challenges?

Dr. Adeyeye: PQM came in at the right time, when laboratories really needed to be strengthened. By the time I joined NAFDAC, there were four ISO certified laboratories in Nigeria, and a fifth laboratory was just certified this spring. That would not have been possible without PQM. When I joined 18 months ago, I saw huge gaps with equipment. PQM provided capacity-building trainings for laboratories in areas such as test scopes, competencies, quality management systems, laboratory administration, financing for use of the National Formulary (USP-NF), financing, and procurement of laboratory equipment. NAFDAC could not have done this without PQM's support.

Quality assurance is not just about testing for quality, but also about building quality around the drug approval process.

We want monitoring and evaluation to continue. Nigeria developed a GMP roadmap that led to the categorization of companies as low risk, medium risk, and high risk. Nigeria has over 200 pharmaceutical companies, 156 of which are very active. Monitoring these is a big task, and we need trained inspectors. Inspectors used to be trained differently; now we have 20 inspectors who are trained the same way.

Nigeria also now has the support needed to help combat maternal and child death, which was attributed to an oxytocin storage problem. PQM determined that 50 percent of the oxytocin was degraded. Sustaining the PQM program will help address these kinds of issues.

Mr. Nwogu to Victor Pribluda: The PQM program worked in Latin America for many years through two regional initiatives: (1) the Amazon Malaria Initiative (AMI) and (2) the South American Infectious Disease Initiative (SAIDI), and the country's Mission funding in Guatemala. What were the medicines quality assurance goals for these initiatives, and how did PQM support the Latin American region to achieve these goals?

Mr. Pribluda: From the PQM perspective, programs relied on PQM to establish and strengthen key elements of quality assurance systems. Rather than speaking about each program that benefited from PQM, let's focus on the AMI. This program covered 11 countries and lasted from 2002 to 2015. It worked through collaboration with relevant country stakeholders and a number of technical assistance partners to help national malaria control programs adopt best practices to reduce malaria morbidity and mortality in this region. The goal of PQM was to help countries ensure that their fight against malaria was effective. Any effort to reduce the burden of disease without an effective approach is worthless. PQM used a three-pronged approach to provide assistance. All approaches were aligned under the PQM Concentrate Quality Assurance Systems, which helped country laboratories attain compliance with international standards.

PQM also introduced the risk-based post-marketing surveillance approach and began fostering South-to-South collaborations. We know this program will not be around forever, and there are a number of countries that have strong quality assurance systems, so we wanted to foster collaboration between those countries. Three laboratories in the region attained compliance with international standards.

Establishing a screening methodology resulted in two accomplishments:

1. Enzyme-Linked Immunosorbent Assay (ELISA) testing was adopted by Peru and added to the guidelines. Peru took ownership of their approach (national quality control center) and developed their own training materials in collaboration with international regulatory agencies. They established 3-year workshop cycles to create a national quality control network to support their lab and reduce burden on the lab.
2. We fostered South-to-South collaborations. In 2014, we convened a workshop of all Latin American and Caribbean countries, obtaining full commitment from regulatory authorities to create a mechanism for South-to-South collaboration. Immediately after the workshop, participants established who could help who. The region as a whole had all the requirements, but not a single country had all of them, so the need for South-to-South collaboration was critical. The awareness about the need was clear.

Mr. Nwogu to Hailu Tadege: PQM has worked with the Ethiopian Food, Medicine and Health Care Administration and Control Authority (EFMHACA) for close to 10 years, and both parties have collaborated in many activities to achieve key EFMHACA milestones and goals. Very briefly, can you describe the main achievements, in your view, that have helped EFMHACA advance to where it is today, as one of the strong medicines regulatory authorities (MRAs) in the Intergovernmental Authority on Development (IGAD) region?

Mr. Tadege: There are three main achievements:

1. After EFMHACA secured the accreditation, it was confident in its results. Success is not just the accreditation, but what comes after the accreditation. EFMHACA took about 100 regulatory actions as a result of post-marketing surveillance, and this prevented the distribution of 17 million substandard condoms.
2. Regulatory workforce development: PQM provided training to more than 1,500 experts. Training experts will not resolve the issues entirely. Now, we are launching a post-master's program in regulatory access. The success story is that we are ensuring sustainability in the regulatory workforce and learning from the experts. We helped EFMHACA develop about 200 standard operating procedures. EFMHACA will continue to provide high-quality work, even without PQM's technical assistance.
3. PQM has also helped reduce the wait time in the drug approval process by 80 percent, from 107 weeks to 22 weeks.

Mr. Nwogu: What would you consider the critical lessons learned from PQM's work in Ethiopia?

Mr. Tadege: Working in siloed interventions that focus on one technical area of medicine regulation does not help build quality assurance in countries.

Mr. Nwogu to Ms. Collins: From a USAID perspective, where do you see priorities moving forward to improve the quality of medicines and medical products globally?

Ms. Collins: Although USAID has been invested in this area for decades, there remain many challenges. Some of the future areas of focus include:

1. Impact of poor-quality medicines on the increasing spread of antimicrobial resistance (AMR), including medical product quality considerations in the context of country efforts to expand health coverage.
2. Resource optimization and the need to reduce waste; poor-quality medicines undermine trust in the system and waste more resources.
3. Fostering regional harmonization to introduce efficient product entry into countries, sharing standardized information and global collaboration
4. Including medical products to expand self-reliance, strengthening the application of good governance principles, supporting regular in-country quality assurance activities, and using limited health resources efficiently.

Questions from the Audience

Javier Guzman, audience participant, to panelists: What is PQM's experience in making the case for stronger regulatory authorities, with the office of the Presidency and the Ministry of Finance to guarantee more resources?

Dr. Adeyeye: It is extremely important for governments to partner with international partners. Nigeria's government is realizing the need for a strong regulatory system. The government is supporting us to expand laboratory strengthening. It is important for countries to contribute because it translates into sustainability.

Mr. Tadeg: In Ethiopia the importance of regulatory authority became very evident. The government decided to allocate resources and to reorganize the system, so it is more fit for purpose. The scope of EFMHACA is now focused just on medicines and food, and the narrower scope now has enough resources. Most recently, WHO and PQM helped provide training to people in Ethiopia. The training was fully funded by the Ethiopia government.

Farouk Umaru, USP PQM Principal Program Manager, to Dr. Adeyeye: Beyond Nigeria, we have other countries that are less structured in terms of regulatory systems. What is your office doing to help other countries have the same success as Nigeria?

Dr. Adeyeye: Africa has six economic communities. I am a believer in strengthening younger regulatory agencies in Africa, and now we are focusing on helping younger regulatory agencies. If any regulatory agency is weaker than another, we are all weak. Nigeria has five neighboring countries. If we do not strengthen those systems, we will continue to have infiltration of substandard and falsified medicines. We have porous borders, and AMQF became what it is now through PQM.

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PANEL

Strengthening & Building

Sustainable, Self-reliant Quality Assurance Systems

PQM CLOSE-OUT EVENT

moderator
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