Three-Level Approach: A Risk-Based, Cost-Effective Approach to Medicines Quality Monitoring in Low- and Middle-Resource Countries

Abstract

A Risk-Based, Cost-Effective Approach to Medicines Quality Monitoring in Low- and Middle-Income Countries

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Objective of project and methodology:

The goal of this project is to evaluate a risk-based, cost-effective approach to medicines quality monitoring (MQM) in low- and middle-income countries (LMICs). This approach involves monitoring medicines quality along the supply chain and identifying areas at risk. The project is funded by USAID.

Methodology:

The project will involve the development of a risk-based, cost-effective approach to medicines quality monitoring (MQM) in low- and middle-income countries (LMICs). The approach will be tested in Cambodia and Ghana.

Introduction/Background

Challenge: Low-resource countries (LRCs) lack financial & technical resources to reduce availability of substandard and counterfeit medicines (SCM)

Proposed Tool: A risk-based, cost-effective, three-level approach to medicines quality monitoring (MQM)

Questions:

- Is it a COST-EFFECTIVE tool for LRCs to help reduce SCM availability?
- What are the requirements for success?

Operational Research Studies: Cambodia and Ghana

The Three-Level Approach

- A risk-based, cost-effective approach to monitoring medicines quality throughout the supply chain

- The Three-Level Approach: Pros & Cons

Advantages

- Capability to detect poor-quality medicines in a wide range of therapeutic treatments
- Large analysis throughput
- Minimal infrastructure requirements
- Minimal need for specialized personnel
- Low acquisition and maintenance costs

Limitations

- Inconclusive results, often due to limited experience of personnel

Three-Level Approach: Application

Case Study I: Cambodia

In the past seven years, 3,375 antimalarial and other medicines in up to 12 provinces have been sampled through routine MQM. Failure rates have fallen steadily.

Ghana (cont.)

Three-level approach to MQM yields results in first two years of operation.

- 2009: Alert citizen brought suspect Coartem® to MQM site; QC lab confirmed L2 testing—counterfeit:
  Ghana Food and Drug Board (FDB) promptly seized fakes from pharmacies and levied fines
- Note: Importance of informed patients
- 2010: SCM versions of 13 key antimalarials discovered in multiple locations across Ghana, including a public hospital. FDB organized a nationwide recall of all 13 medicines and publicly named outlets where they were sold.
- Note: Need for targeted surveillance and active enforcement of anti-counterfeiting laws

Three-Level: Requirements for Success

- Careful, risk-based selection of sentinel sites and samples
- Appropriate use of L2 analysis, leveraging of benefits and limitations
- Operational quality control laboratory
- Regulatory basis for enforcement/corrective action
- Public education mechanisms
- Collaboration between public and private sectors

Conclusion

- MQM, based on the three-level approach, enables a medicines regulatory authority to identify poor-quality medicines in a country’s supply chain, without overwhelming scarce financial, human, and technical resources.
- To sustainably reduce SCM availability, other medicines quality assurance activities will likely be required.

Acknowledgements

We would like to thank the following people for their contributions to this poster presentation:

- Victor S. Pribulda, Ph.D.
- Laura Krech, M.P.H.
- Siv Lang

Reference