Advancing the Antimicrobial Drug Quality Agenda through Coalition Building: Lessons from AMR Response

Monitoring and Improving Medicines Quality through AMR National Action Plans Side Event Alongside Prince Mahidol Awards Conference
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Outline of the Presentation

• Stakeholders for addressing substandard and falsified medicines
• Benefits of coalitions for improving medicine quality
• Examples of how coalitions can help support the Prevent, Detect, and Respond framework
• USAID/SIAPS-supported approach to building advocacy and coalitions against AMR
• Lessons learned from the USAID/SIAPS approach
• Conclusion
Stakeholders for addressing substandard and falsified medicines

- National Regulatory Authority
- National Quality Control Lab, National PV Center
- Health care providers, professional associations
- Media, journalists
- Patients and patient interest groups, CSOs
- Procurement agencies and other supply chain actors
- Customs, police, Interpol
- Public/private health facilities
- Academia and research
- WHO, donors, NGOs, INGOs, relief agencies
- Pharma industry
- Public health programs
Benefits of Coalitions for Improving the Quality of Medicines, including Antimicrobials (1)

- Common vision; improved communication; less duplication
- Sharing of expertise, experience, best practices, lessons learned, and resources
- Increased awareness, motivation, and engagement of nonspecialists such as policymakers, patient groups, and journalists
- Stronger advocacy and evidence for garnering wide support and funding for medicine quality
- Improved governance, transparency, and accountability
- Wider and coordinated efforts toward capacity building and access to quality medicines
Benefits of Coalitions for Improving the Quality of Medicines, including Antimicrobials (2)

- Multisectoral coordination to facilitate implementation of the *Prevent, Detect, and Respond* framework to improve medicine quality
- Making WHO-driven GSMS and Member State Mechanism more effective
- Drawing from and support for other initiatives (such as ICMRA, AMRH, QUAMED, WWARN, PIC/S, BREMERE, NOMCOL)
- Empowering nontraditional stakeholders, including CSOs and the public, as gatekeepers or watchdogs for medicine quality
- Support for the implementation of the overall objectives of national action plans on AMR and GHSA country roadmaps
- Greater attention to the role of substandard and falsified antimicrobials as a factor for AMR

**Prevent:** demand quality; secure supply

**Detect:** improve detection; increase reporting

**Respond:** protect public health; prevent recurrence

Local coalitions for medicine quality

GSMS - Global Surveillance and Monitoring System; ICMRA - International Coalition of Medicines Regulatory Authorities; AMRH – African Medicines Regulatory Harmonization; QUAMED – Quality Medicines for all; WWARN – Worldwide Antimalarial Resistance Network; PIC/S – Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme; BREMERE – Building Regional Expertise in Medicines Regulation, Information-sharing, Joint Investigation, and Enforcement; NOMCOL – USP’s Networks of Official Medicines Control Laboratories; CSO – Civil society organization; GHSA – Global Health Security Agenda
Subcoalitions within Larger Coalitions can Spearhead Specific Interventions

<table>
<thead>
<tr>
<th>Examples of subcoalitions</th>
<th>Examples of Specific Activities</th>
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<tbody>
<tr>
<td>Academia, health prof. associations, NHTC, NDRA, and accreditation bodies</td>
<td>Reform health prof. pre- and in-service curricula to include medicine quality topics</td>
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<td>Patient interest groups, NDRA, prof. associations, training institutes, and NGOs</td>
<td>Train and equip journalists for reporting on medicine quality issues in a fact-based and alarming but nonalarming manner</td>
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<tr>
<td>NDRA, customs, police, Interpol, pharmacovigilance (PV) center, and NGOs</td>
<td>Address the challenge of falsified medicines</td>
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<td>PV center, clinicians, academia, research bodies, NDRA, WHO, and donors</td>
<td>Strengthen evidence for the link between poor medicine quality and AMR</td>
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<tr>
<td>NDRA, WHO, donors, NGOs, and research bodies</td>
<td>Advance regional and global partnership</td>
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NHTC – National Health Training Center; NDRA – National Drug Regulatory Authority; NGO – Nongovernmental organization
Examples of How Coalitions can Support the Prevent, Detect, and Respond Framework

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<th>Action areas</th>
<th>How coalitions/subcoalitions can help</th>
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| Prevention   | • Improved knowledge and behavior in a wider group of stakeholders, leading to strengthened capacity and supply chain  
               • Better buying behaviors of patients/public – accessing antimicrobials through regulated outlets and personnel |
| Detection    | • Increased reporting of medicine quality issues from a wider group of stakeholders to regulatory authorities and WHO GSMS  
               • Timely information sharing with all key stakeholders regarding unexpected treatment failures with antibiotics (lack of efficacy) |
| Response     | • Timely and wider dissemination of alerts and recalls  
               • Coordinated, standardized, and balanced communication (alerting without alarming)  
               • More transparency and accountability due to the existence of coalition  
               • Harmonized and concerted responses to specific medicine quality issues |
The SIAPS-supported approach focuses on catalyzing coalitions and advocacy by local stakeholders to build realistic strategies to contain AMR.

The USAID-funded SIAPS Program and its predecessors have helped build capacity to generate coalitions to fight AMR at the—

- **Country level** in Zambia, Ethiopia, and Namibia
- **Regional level** in Africa through the Ecumenical Pharmaceutical Network (EPN)
Elements of the USAID/SIAPS-supported Approach to Building Coalitions against AMR

- Initiate the process
- Identify key issues and players
- Understand the local situation and generate feasible actions
- Mobilize support and identify a local champion group
- Monitor and evaluate
- Build and expand coalition
Coalition-building Guidebook to Jump-start the Process

• Key components
  • Identifying and engaging AMR-related stakeholders
  • Advocacy and coalition-building guidelines
  • Practical implementation examples from country- and regional-level initiatives
  • User-friendly implementation tools and templates

### Country-level Advocacy and Coalition Building

<table>
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<tr>
<th>Country</th>
<th>Activities</th>
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<tr>
<td>Zambia</td>
<td>• Mobilized key stakeholders against AMR through call-to-action meeting</td>
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<tr>
<td></td>
<td>• Revised national standard treatment guidelines (STGs)</td>
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<td></td>
<td>• Improved medicine quality assurance system</td>
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<td>• Used TV programs on AMR to educate the public</td>
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<td></td>
<td>• Incorporated AMR and RMU topics into UNZA medical curriculum</td>
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<tr>
<td>Ethiopia</td>
<td>• Mobilized key stakeholders against AMR through call-to-action meeting</td>
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<td></td>
<td>• Conducted national baseline study on AMR and developed action plan</td>
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<td></td>
<td>• Revised Medicines Formulary (2013) and STGs (2014)</td>
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<td></td>
<td>• Trained journalists, resulting in 218 media spots on AMR and RMU in 3 years</td>
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<td>• Revised National Strategy for Prevention and Containment of AMR (2015-2020)</td>
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<tr>
<td>Namibia</td>
<td>• Mobilized key stakeholders against AMR through call-to-action meeting</td>
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<td></td>
<td>• Collaborated with Namibians Against Antimicrobial Resistance and the</td>
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<td>Pharmaceutical Society of Namibia</td>
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<td></td>
<td>• Helped University of Namibia School of Pharmacy integrate AMR and RMU</td>
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<td>topics into preservice pharmacy curriculum</td>
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<td>• Helped implement HIV drug resistance early warning indicators</td>
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Regional Advocacy and Coalition Building: EPN Example

• EPN developed and distributed AMR call-to-action document in five languages

• EPN constituents in more than 12 countries carried out hundreds of AMR-related advocacy, awareness, sensitizations, surveys, trainings, and containment actions

• EPN institutionalized AMR work by prioritizing it in its 2016–2020 Strategic Plan

• Diversified funding for AMR actions
Lessons Learned (1)

- Provide initial support for stakeholder engagement to jump-start coalition action
- Focus on realistic strategies and actions that capitalize on existing initiatives and resources
- Mobilize multisector stakeholders to achieve “concerted” actions
- Identify a local champion group to lead the process and catalyze actions
- Initiate advocacy as soon as key players and issues are identified
- Ensure advocacy serves as a means to further packages of actions rather than being an end in itself
Lessons Learned (2)

- Develop **the media** as an ally for large-scale awareness and advocacy

- Frame AMR-related activities as a “**value-add**” to existing programs, NOT as a competing vertical program

- Emphasize the **continuous nature** of the AMR containment process

- Pay attention to **monitoring and evaluation**, and overall **health systems strengthening**

- Pay attention to coalition’s **institutionalization** and **funding diversification** to support sustainability

Journalists in Ethiopia join hands in solidarity to support AMR advocacy and containment, June 2012
Conclusion

- 1 in 10 medicines in LMICs are substandard or falsified, the majority of them antimicrobials
- Global attention, leadership, and evidence base regarding medicine quality are increasing – need to capitalize on this momentum
- Advocacy and coalitions are critical contributors to global objectives—
  - WHO Global Action Plan on AMR
  - Global Health Security Agenda
  - Sustainable Development Goal 3.8
- Stakeholders supporting GHSA, National Action Plans on AMR, and medicine quality have overlapping objectives and should come together and coordinate actions
- An effective approach to achieving this is via multidisciplinary and multisectoral local coalitions that help practically implement the One Health concept
- USAID/SIAPS experiences show that with initial jump-starting support, in-country stakeholders can create sustainable coalitions and advocacy to fight the common threat of AMR
- The SIAPS experience provides useful lessons for building similar coalitions to address issues related to the quality of medical commodities, including antimicrobials and diagnostics