The Global Crisis of MDR-TB

Action #4: Revolutionize Drug Distribution, Insure Drug Quality, and Reform Regulatory Approval and Registration Policies

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Barriers and Bottlenecks

- Diagnostics
- Regimens
- Production
- Forecasting
- Financing
- Quality Assurance and Regulation
- System organization and leadership
Diagnostics and Regimens

- Point of Care Tx and rapid DST

- Combination Regimens with new drugs that are effective against XDR-TB, MDR-TB and TB, reducing the requirement for DST
 Barrier: Production

- Established pooled or aggregated procurement and flexible contracting from QA manufacturers based on forecast-driven purchasing.
- Enable producers to make larger batches based on realistic forecasting.
- A working capital fund or APC to assure up-front payment and guarantees to motivate suppliers to place full-batch orders to bring prices down;
- Revise contracting mechanisms to reduce barriers to entry deterring producers, lack of financing up-front, guarantees.
- Linking, bundling and bargaining with existing supply chains for adding SLDs for TB with larger orders malaria and HIV.
Barrier: Forecasting

• Create Functional information systems that provide reliable data on
  • pace of enrollment, consumption, and real number of patients being treated that Inform orders, lead times, production, and shipment schedules, buffers and emergency supplies
• Link SLD supply forecasting with existing systems such as HIV and malaria drug logistics and supply
• Stock-out prevention by using mHealth or IT technology for reporting from clinics, distributors and warehouses.
Barrier: Variable Quality and Regulatory Processes

- Incentives to countries, esp BRICS, to procure QA medicines,
- Countries should encourage domestic QA manufacturing of SLD and FLD
- Need for countries to establish pharmacovigilence and enforce regulations about substandard quality API and FPP.
- Bar coding or G10 coding of key parameters, drug, expiry date, batch.
- In-country training and capacity building in Supply Mgt, QA, regulation
- Regional regulatory harmonization and expediting regulatory processes
Barrier: Financing

- Innovative new sources of Financing (e.g., UNITAID, Advanced Market Commitments, AMFm – type subsidy)
- Capital Fund to enable up-front payments
- Increasing country co-payments
Barrier: The Current Organization of SLDs

- Create a new mechanism to engage private sector manufacturers, distributors, governments, donors to improve efficiency, especially for new drug combinations. e.g. distribution hubs, SMS forecasting. Ideally, a new Public Private Partnership that can function better than either alone.
- Streamline the request-to order-to purchase-to delivery process to drastically reduce delays.
- Innovative financing mechanisms, incl. split tenders to increase producers and reduce price, APC, initial guarantees, tiered pricing, AMFm negotiation and subsidy model.
- Provide strong leadership and accountability globally and in countries.
We Must Prevent This Picture