

Improving Antimalarial Drug Quality in Africa

Dr. Bernard Nahlen

Deputy Coordinator

President's Malaria initiative



President's Malaria Initiative

President's Malaria Initiative – an interagency USG initiative led by USAID with HHS/CDC as key partner



Goal: Reduce malaria-related mortality by 50% in 15 target countries

Targets: 85% coverage of vulnerable groups with 4 proven and effective interventions:

- ITNs
- IRS
- IPTp
- ACTs

Funding Levels (Additive) and Coverage

Year	Funding Level	Coverage
2006	\$30 million	3 countries
2007	\$135 million	7 countries
2008	\$300 million	15 countries
2009	\$300 million	15 countries
2010	\$500 million	15 countries
TOTAL	\$1,265 billion	

PMI Focus Countries

- **FY06: Angola, Tanzania, Uganda**
- **FY07: Rwanda, Senegal, Mozambique, and Malawi**
- **FY08: Benin, Ghana, Mali, Kenya, Liberia, Madagascar, Zambia, Ethiopia (Oromiya Region)**

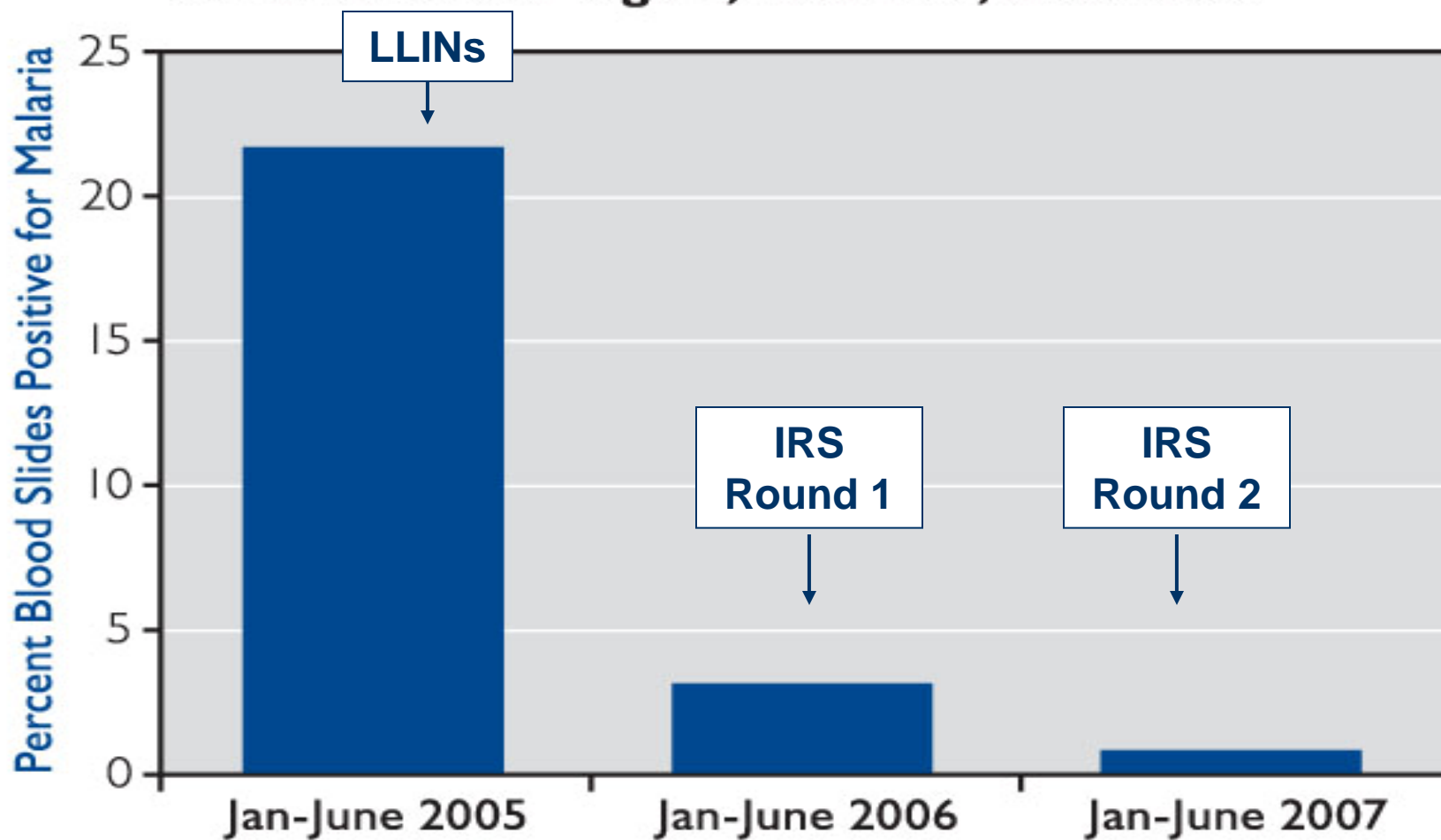
Year 2 Progress: >25 million Beneficiaries

- **Treatment:**
 - 11.5 million ACT treatments procured
 - Over 20,000 HWs trained
 - Over 2 million RDTs procured
- **Prevention**
 - IRS: >17 million people covered
 - ITNs: > 5 million LLINs procured
 - ITN re-treatment – 677,000 nets re-treated with insecticide
- **Malaria in pregnancy:**
 - 1.3 million IPTp treatments procured
 - over 3,000 HWs trained



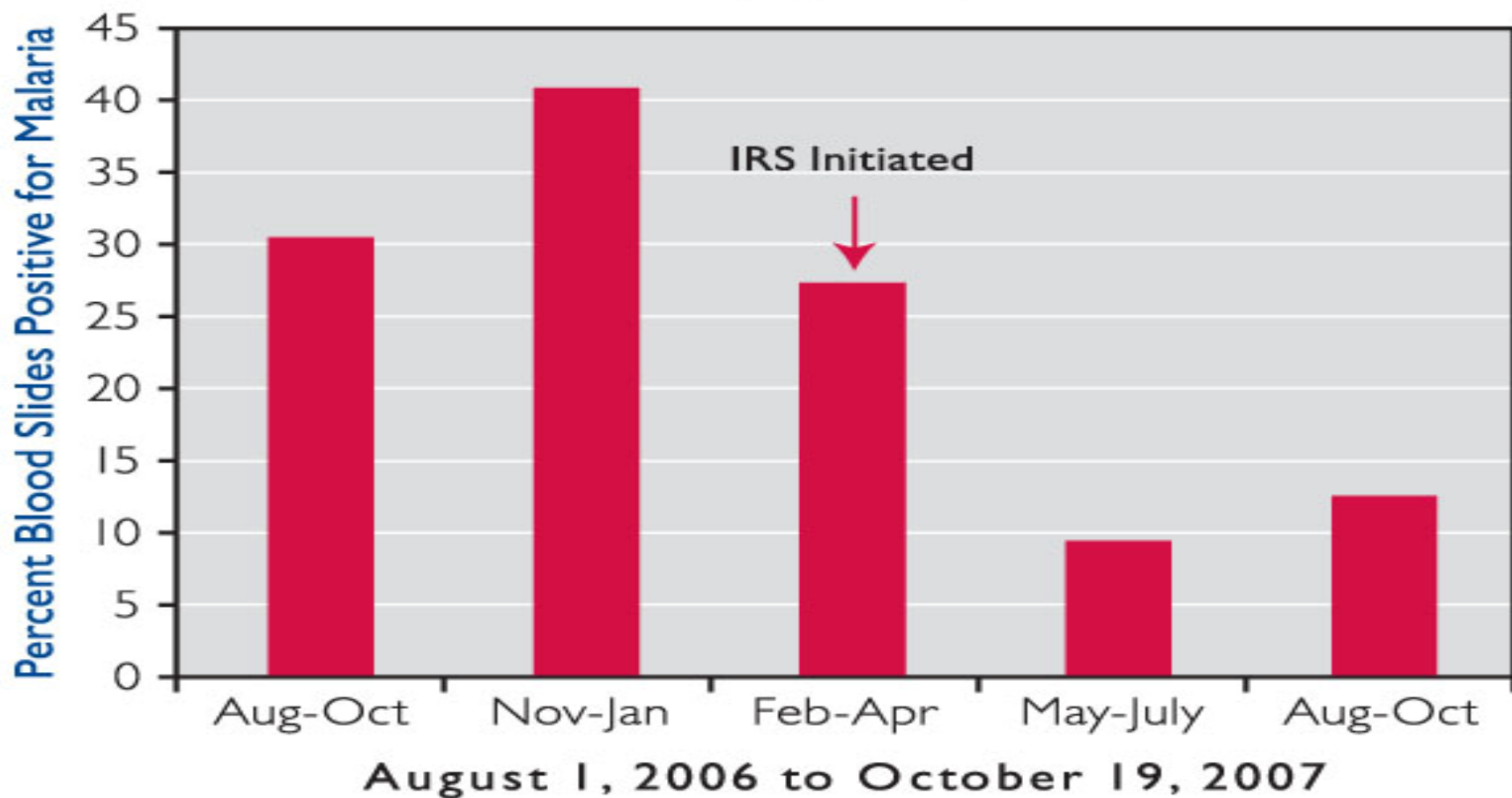
Evidence of Impact : Zanzibar

Percentage of Blood Slides Positive for Malaria in Children Under Age 2, Zanzibar, 2005-2007



Evidence of Impact : Uganda

Percentage of Blood Slides Positive for Malaria, Kihhi Health Center, Uganda, 2006-2007



Challenges to Scaling Up Access to Antimalarial Drugs

1. Complex Regulatory Landscape for Antimalarial Drugs

- Lack of incentives for manufacturers to seek FDA or SRA approval
 - malaria is not endemic in developed countries
 - so, there is no market
- Only one ACT (artemether-lumefantrine) has been approved by an SRA (Swiss Medic)
- Only two brands of artesunate-amodiaquine have been approved by WHO Pre-qualification project
- Several other lifesaving drugs lack any regulatory approval status
 - pre-referral severe malaria drugs
 - other ACT combinations

Challenges to Scaling Up Access to Antimalarial Drugs

2. Ensuring Access to High Quality Antimalarial Treatment at the Country Level



- **Public Sector**

- Quality of antimalarial drugs can be controlled to a certain extent through the procurement selection and drug quality testing process
- Weak supply chains and distribution systems, e.g. poor storage, exposure to humidity and heat, and transport issues

- **Private Sector**

- Very difficult to regulate drugs in the private sector
- Most countries do not allow OTC purchase of ACTs in private shops

Challenges to Scaling Up Access to Antimalarial Drugs

3. Strengthening Diagnostics, Case Management, and Use

- Recent study in Kenya: despite ACTs being in stock on the day of the survey, only 28% of 866 children were prescribed ACTs according to national guidelines¹
 - Need to improve health worker diagnostic skills, training and adherence to ACT treatment recommendations
 - Lack of knowledge or demand for ACT treatment in communities

¹ Why don't health workers prescribe ACT? A qualitative study of factors affecting the prescription of artemether-lumefantrine *Malaria Journal* 2008, 7:29 doi:10.1186/1475-2875-7-29

PMI Approach to Scaling Up Access to High Quality Antimalarials—Principles

- Comprehensive, holistic approach
- Close partnership with host government
 - national malaria control programs
 - national drug regulatory authorities
- Partnership and coordination with international partners
 - Global Fund
 - World Bank
 - WHO
 - UNICEF

PMI Approach to Scaling Up Access to High Quality Antimalarials— Procurement and Selection of Drugs

- All PMI drug procurements comply with applicable statutes and regulations
- Drugs with FDA or SRA approval status are preferred, if recommended and available
- But most antimalarial drugs do not meet this criteria
 - So, PMI reviews each drug procurement request on a case by case basis to assess the evidence for quality



PMI Approach to Scaling Up Access to High Quality Antimalarials— Procurement and Selection of Drugs

- In addition, PMI requires
 - Confirmation of SRA approval, WHO Prequalification status, WHO/UNICEF interim malaria drug supplier list, or prequalified wholesalers (for generic multi-source drugs)
 - Consistency with WHO treatment recommendations
 - Consistency with national treatment guidelines
 - Confirmation of satisfactory GMP inspection by WHO, US FDA, or SRA
 - Quality testing of drugs procured with PMI funds prior to shipment to countries

PMI Approach to Scaling Up Access to High Quality Antimalarials— In-Country Support

- Strengthening all aspects of the pharmaceutical supply chain, including
 - storage
 - transportation
 - inventory
 - logistics information systems.
- Support to national regulatory authorities to improve drug quality through
 - post-market surveillance
 - regulation
 - enforcement
 - in-country drug testing
- Working with host governments to develop and implement strategies for increasing access to high quality ACTs through the private sector (Tanzania, Rwanda)





PMI Approach to Scaling Up Access to High Quality Antimalarials— Diagnostics and Case Management

- Strengthening and expanding access to quality malaria diagnostics
 - microscopy
 - RDTs
- Supporting roll out of malaria case management training and supervision to public and private HWs
- Introduction of community and home-based management of malaria through trained CHWs



Conclusions

- Urgent attention to drug quality issues is critical to saving lives and successfully achieving global treatment targets
- A comprehensive, holistic, systematic approach is required to support access to effective malaria treatment
- Donors and host governments need to collaborate on an ongoing basis to develop a coordinated, harmonized approach
- Strengthening capacity for appropriate regulation, quality assurance testing, and enforcement is critical
- More attention should be focused on improving access to quality malaria diagnosis and case management through the private sector and through CHWs
- Need to strengthen malaria diagnosis to decrease inappropriate use of antimalarial drugs



The middle-aged American man buying fake Viagra from a fraudulent on-line pharmacy has the FDA to look after his interests; the poor African mother unknowingly buying fake malaria medicine in single doses for her baby is more deserving of protection, but receives none.

Roger Bate