

The ACT Malaria Treatment Policy Change in Kenya

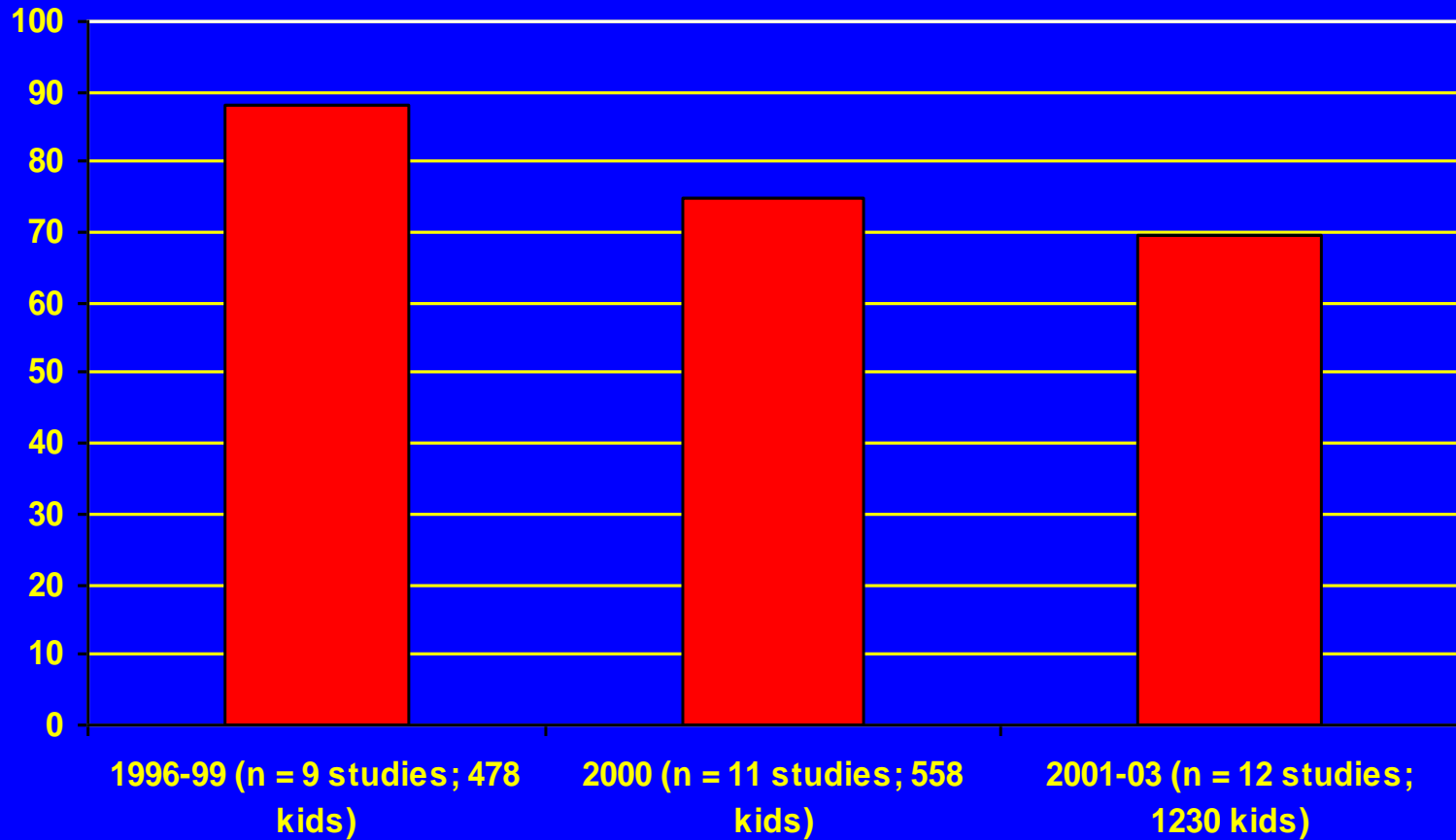
THE IMPLEMENTATION PROCESS AND CHALLENGES

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Objectives of the national Antimalarial treatment policy

- **Enable population at risk access safe, good quality, effective, affordable & acceptable antimalarial drugs**
- **Ensure rapid and long lasting clinical cure**
- **Prevent progression to severe disease**
- **Reduce the incidence of anaemia**
- **Reduce consequences of placental malaria infection**
- **Delay development of resistance to antimalarial drugs**

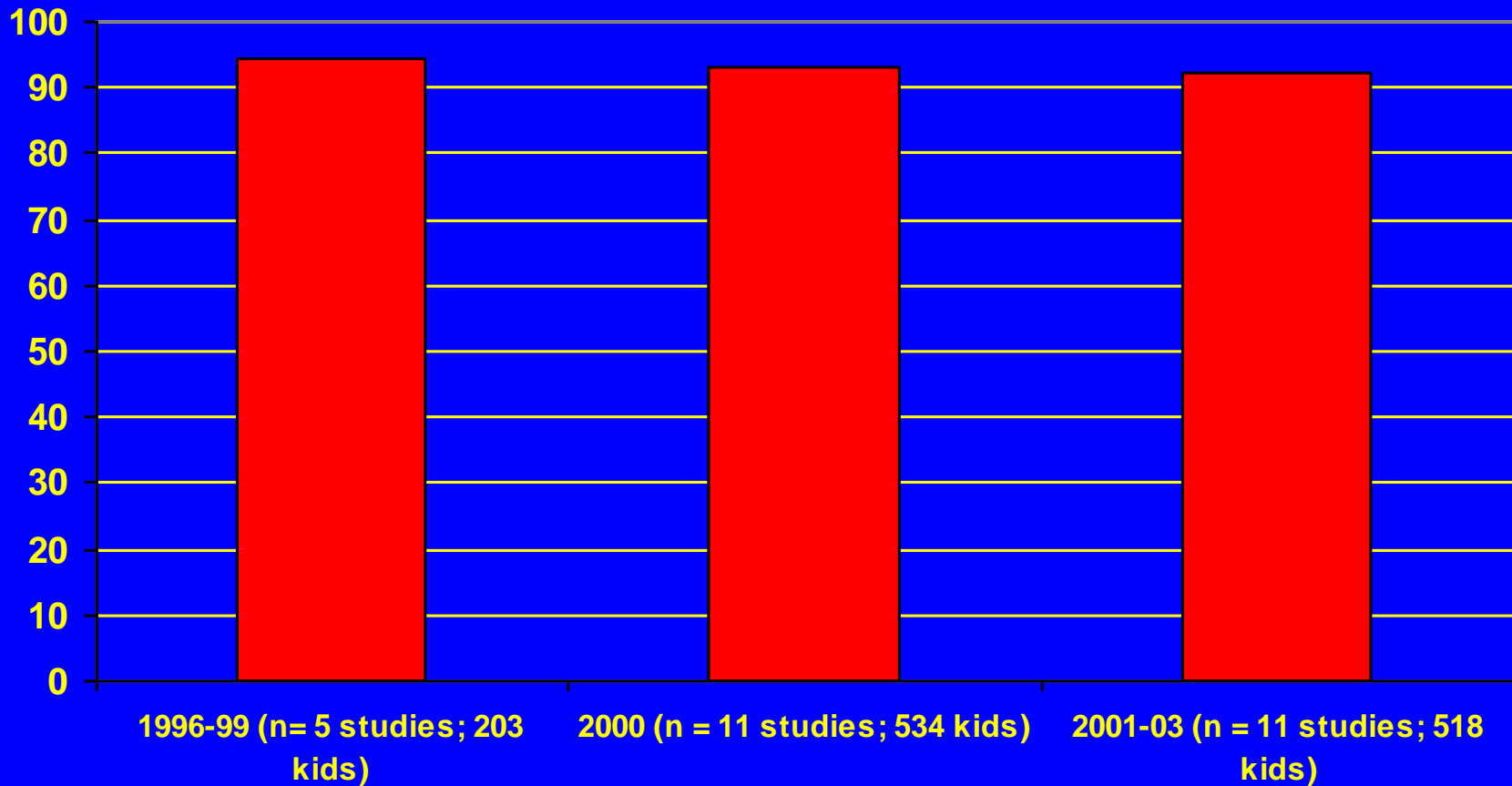
SP ACPR (%) day 14 from 32 studies in Kenya



SP study Failures $\geq 25\%$

- 1996-1999 **1/9** studies ACPR $< 75\%$
- 2000 **6/11** studies ACPR $< 75\%$
- 2001-2003 **7/12** studies ACPR $< 75\%$
- Day 14 to day 28 ACPR:
 - Bondo 62% vs. **35%**
 - Kibwezi 83% vs. **48%**

AQ ACPR (%) day 14 from 27 studies in Kenya



AQ study Failures $\geq 25\%$

- One study in 2001 ACPR $< 75\%$
- Day 14 to day 28 ACPR:
 - Bondo 98% vs 87%
 - Kibwezi 87% vs 62%

Makanga *et al.*
ART-LUM (Coartem) studies –
Kilifi (under 5 y)

- Efficacy ACPR day 14 - **100%** (n =92)
- Efficacy ACPR day 28 - **92%**

- Effectiveness ACPR day 14 - **98%** (n =85)
- Effectiveness ACPR day 28 - **92%**

POLICY- Which drugs?

- 1.Uncomplicated Malaria—6 dose regimen of artemether-lumefantrine
- 2nd Line— Oral Quinine-7 day course
- Severe – Parental quinine- 7 day course
- Malaria prevention in pregnancy (IPT)—SP
- Case management in Pregnancy-Quinine in all trimesters and artemether-lumefantrine may be used in 2nd and 3rd trimesters.
- Pre-referral management of severe malaria- Quinine, artesunate suppositories and IM artemether

Chemoprophylaxis

- Long term residence-Proguanil (Paludrine)-1 week before & 4 weeks after.
- Mefloquine- 3 weeks before& 4 weeks after, Doxycycline- 100mg OD during stay and 4 weeks after (not children and pregnant women)
- Long term visitors advised to carry a treatment dose of coartem in case they cant access medical care

Diagnostics

- **Need for parasitological diagnosis for older children and adults**
- **Introduction of Rapid Diagnostic Kits (RDTs) and interpretation of results in the different epidemiological settings**
- **QA/QC of microscopy and RDTs**
- **Prescriber habits**

MOH Concerns and constraints

- **Sustainability- assurance of GFATM commitment over 5 year period**
- **Budgetary commitment- yet to be included in the MTEF**
- **Cost differential in public vs private sectors**

Key specific issues

- **Limited data available on safety of ACTs in young infants (use of coartem <5kgs)**
- **Lack of adequate safety and efficacy data on drug combinations in pregnant women (safety of lumefantrine in pregnancy)**
- **Improving systems of forecasting of drug needs**
- **Strengthening the management and drug supply system (procurement, distribution and use) according to the specificities of the new drugs (shorter shelf life and the course-of-therapy packs)**
- **Complex treatment schedules poses challenge for ensuring compliance**
- **Need for more friendly paediatric formulations**

Key specific issues contd.

- **Complexity of regimens for treatment near the home**
 - **Use of ACTs at community level**
 - **Engaging and sustaining communities**
 - **Improving malaria diagnosis at community level**
 - **Involvement of the private sector**

Challenges

- **Artemether-lumefantrine (Coartem®), patented and single-source**
- **All other ACTs: multi-source products, generally off-patent generics, available as individual products to be co-administered (preferably in course-of-therapy blister packs).**
- **Market not primed - few manufacturers, limited experience with manufacturing and packaging of artemisinin derivatives (highly hygroscopic), API linked to natural plant production**
- **Relatively new products on the international market – limited country experience in regulation and procurement**

Malaria Case-Management

Challenges

Only 11% of children **access** antimalarial drugs within 48 hours



Making new drugs available as close to home as possible

Sustainable financing of new expensive antimalarial drugs

NO

YES



Current status

- **Nationwide implementation started in July 2006**
- **9,000/17,000 core health workers trained**
- **12.2 million treatment doses**
- **30% of doses issued to mission HF**
- ❖ **Advocacy and communication campaign ongoing**

Monitoring and evaluation

- **Monitoring the Policy Change (The system)-key actions and clear deadlines**
- **Framework for monitoring the implementation of the new drug policy developed**
- **Monitoring Availability and Quality of all ACTs on the market**
- **Post-market surveillance to eliminate sub-standard drugs from the market,**
- **Prescribing and dispensing habits and dosage compliance**
- **Therapeutic efficacy testing of ACTs: Conduct routine monitoring of Artemether- Lumefantrine, other potential ACTs and quinine**
- **Pharmacovigilance (adverse drug reaction monitoring).**
- **HMIS of malaria morbidity and mortality data**

CHEERS!

