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

- 1996-99 (n = 9 studies; 478 kids)
- 2000 (n = 11 studies; 558 kids)
- 2001-03 (n = 12 studies; 1230 kids)
SP study Failures $\geq 25\%$

- 1996-1999 $\frac{1}{9}$ studies ACR $< 75\%$

- 2000 $\frac{6}{11}$ studies ACPR $< 75\%$

- 2001-2003 $\frac{7}{12}$ 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

- 1996-99 (n= 5 studies; 203 kids)
- 2000 (n = 11 studies; 534 kids)
- 2001-03 (n = 11 studies; 518 kids)
AQ study Failures >= 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
2. 2nd Line—Oral Quinine-7 day course
3. Severe—Parenteral quinidine-7 day course
4. Malaria prevention in pregnancy (IPT)—SP
5. Case management in Pregnancy—Quinine in all trimesters and artemether-lumefantrine may be used in 2nd and 3rd trimesters.
6. 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 can't 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!