Malaria – Update on prevention, diagnosis and treatment

IPC meeting
30-31 May 2013
WHO, Geneva, Switzerland

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Outline

- Malaria Prevention
  - Policy update: Intermittent Preventive Treatment in pregnancy

- Malaria Diagnosis
  - Updated WHO Selection criteria for procurement of RDTs
  - French translation of Universal Access manual

- Malaria Treatment - antimalarial medicines
  - Prequalified medicines and semi-synthetic raw material
  - Oral artemisinin-based monotherapies and resistance
WHO evidence review:
Meta-analysis of 7 trials evaluating IPTp-SP showed that 3 or more doses of IPTp-SP were associated with more benefits than 2 doses of IPTp-SP. There were no differences in serious adverse events between the two groups.

Expected benefits:
- IPTp-SP prevents the adverse consequences of malaria on maternal and fetal outcomes, such as placental infection, clinical malaria, maternal anaemia, fetal anaemia, low birth weight and neonatal mortality.
- IPTp-SP has recently been shown to be highly cost-effective for both prevention of maternal malaria and reduction of neonatal mortality in areas with moderate or high malaria transmission.
- Despite the spread of SP resistance, IPTp-SP continues to provide significant benefit, resulting in protection against both neonatal mortality (protective efficacy 18%) and low birth weight (21% reduction in LBW) under routine program conditions.

October 2012 - Malaria Policy Advisory Committee (MPAC):
Policy brief for the implementation of IPTp-SP

All possible efforts should be made to increase access to IPTp-SP in all areas with moderate to high malaria transmission in Africa, as part of antenatal care services. WHO recommends a schedule of at least four antenatal care visits during pregnancy.

- ... starting as early as possible in the second trimester...
- ... all pregnant women at each scheduled antenatal care visit...
- ... until the time of delivery, provided that the doses are given at least one month apart...
- ... ideally administered as directly observed therapy (DOT)...
- ... either on an empty stomach or with food...

- SP should not be administered to women receiving co-trimoxazole prophylaxis due to a higher risk of adverse events.
- Folic acid at a daily dose equal or above 5mg should not be given together with SP as this counteracts its efficacy as an antimalarial.

The full document is available at: http://www.who.int/entity/malaria/publications/atoz/Policy_brief_IPTp-SP_implementation_11april2013.pdf.pdf
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Malaria diagnosis
Updates and translations

- Round 4 product performance testing results:
  Updated information note on recommended selection criteria for procurement of malaria rapid diagnostic tests (RDTs)

  English: http://www.who.int/entity/malaria/publications/atoz/rdt_selection_criteria_en.pdf

- French translation available:
  Accès universel aux tests diagnostiques du paludisme

  French: http://www.who.int/iris/bitstream/10665/78877/1/9789242502091_fre.pdf
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Fixed-dose combinations (FDCs)

- artemether/ lumefantrine: Ajanta, Cipla, Ipca, Novartis
- artemether/ lumefantrine dispersibles: Ajanta [Dec 2012], Novartis
- artesunate/ amodiaquine: Sanofi, Guilin [Nov 2012], Ipca [Jun 2012]
- artesunate/ mefloquine: DNDi/Cipla [Sept 2012]

Co-Blisters (Co-B)

- artesunate + amodiaquine: Cipla, Guilin, Ipca, Strides
- artesunate + sulfadoxine/ pyrimethamine: Guilin [May 2012]

Injectables

- AS powder for injection: Guilin (60mg, 30mg and 120mg [May 2012])
First semi-synthetic artemisinin
Accepted by the WHO Prequalification Programme

- **2004**: Project start. Partnership for semi-synthetic artemisinin:
  - Led by One World Health, PATH's Drug Development Programme, with funding from BMGF
  - University of California Berkeley, Amyris, Sanofi

- **April 2013**: Launch of large-scale production (Sanofi, Italy)
  - Strengthen artemisinin supply, by obtaining more stable prices and ensuring greater availability => steady and affordable supply of high-quality artemisinin
  - Sanofi production plans (no-profit, no-loss): 35 tons in 2013, and by 2014 yearly 50-60 tons

- **May 2013**: WHO PQP announces "acceptability…
  …of first source of non-plant-derived artemisinin, manufactured by Sanofi, for use in the manufacture of APIs or FPPs submitted to WHO for PQ, or that have already been WHO PQed."
Oral artemisinin-based monotherapies
National Drug Regulatory Authorities

National Drug Regulatory Authorities:
13/78 (17%) still allow oral monotherapies
(last updated 20.05.2013)

13 countries still allowing the marketing of oral artemisinin-based monotherapy medicines by WHO Region
(last updated on 27.05.2013)

- Angola
- Bolivia
- Cape Verde
- Colombia
- Equatorial Guinea
- Gambia
- Myanmar
- Papua New Guinea
- Sao Tome and Principe
- Somalia
- Swaziland
- Timor Leste
- Vanuatu

Risk of development of resistance
Oral artemisinin-based monotherapies
Manufacturing companies

Manufacturing sites/place of registration of 30 producers of oral artemisinin-based monotherapies (last update 27.05.2013)
Current status of resistance

N ENGL J MED 361; 5, July 2009: → 2013:

Artemisinin Resistance in Plasmodium falciparum Malaria

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Sites where suspected or confirmed artemisinin resistance has been detected
Thank you