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Statement

JOINT WHO/UNAIDS/UNICEF STATEMENT ON USE OF COTRIMOXAZOLE AS PROPHYLAXIS IN HIV EXPOSED AND HIV INFECTED CHILDREN

Geneva, 22 November 2004 - WHO, UNAIDS and UNICEF, guided by recent evidence, have agreed to modify as an interim the current recommendations (1) for cotrimoxazole prophylaxis in children. This is based upon recent trial data from Zambia (2).

These data and other new evidence will be reviewed in early 2005 by an expert committee convened to revise and update the recommendations for cotrimoxazole for adults and children.

Cotrimoxazole remains important even with increasing access to ART, as it use can improve survival independently of specific HIV treatment. Current recommendations suggest it should be used before children require ARVs because it may even postpone the time at which ART needs to be started.

Prophylactic dosing with cotrimoxazole for HIV infected children with any sign or symptoms suggestive of HIV is a key intervention that should be offered as part of a basic package of care to reduce morbidity and mortality.

Cotrimoxazole prophylaxis is also a crucial potentially life saving intervention that should be given to all HIV exposed children born to HIV-infected mothers, in settings where HIV infection status cannot be reliably confirmed in the first 18 months of life.

Cotrimoxazole is a widely available antibiotic that is available in syrup and solid formulations at low-cost in most settings, including resource limited settings. It is highly effective for the treatment and prevention of Pneumocystis pneumonia. In HIV infected children it also offers protection against other infections, this remains important even with increasing access to ARV treatment.

Greater advocacy for the use of cotrimoxazole prophylaxis in children is urgently required.

Who should get cotrimoxazole:

- ***All HIV exposed children*** (children born to HIV infected mothers) from 4-6 weeks of age (whether or not part of a prevention of mother-to-child transmission [PMTCT] programme)
- ***Any child identified as HIV-infected*** with any clinical signs or symptoms suggestive of HIV, regardless of age or CD4 count.

How long should cotrimoxazole be given:

Cotrimoxazole is required to be taken as follows:

- HIV exposed children – until HIV infection has been definitively ruled out AND the

mother is no longer breastfeeding

- HIV infected children - indefinitely where ARV treatment is not yet available.
- Where ARV treatment is being given- cotrimoxazole can be stopped only once clinical or immunological indicators confirm restoration of the immune system for 6 months or more (also see below). With current evidence it is not yet clear if cotrimoxazole continues to provide protection after immune restoration is achieved.

Under what circumstances should cotrimoxazole be discontinued:

- Occurrence of severe cutaneous reactions such as Stevens Johnson syndrome, renal and/or hepatic insufficiency or severe hematological toxicity.
- In an **HIV exposed child** ONLY once HIV infection has confidently been excluded;
    - For a non- breastfeeding child <18 months of age this is by negative DNA or RNA virological HIV testing
    - For a breastfed HIV exposed child < 18months – negative virological testing is only reliable if conducted 6 weeks after cessation of breastfeeding,
    - For a breastfed HIV-exposed child >18 months - negative HIV antibody testing 3 months after stopping breastfeeding
- In an **HIV- infected child**:
    - If the child is on ARV therapy, cotrimoxazole can be stopped ONLY when evidence of immune restoration has occurred. This can be assumed where the child is over 18 months of age and CD4% >15 at two measurements, at least 3 to 6 months apart. If a CD4 count is not available, cotrimoxazole should not be stopped before a full 6 months of successful adherence to ARV therapy, and then only when clinical evidence of immune restoration is present. Continuing cotrimoxazole may continue to provide benefit even once child has clinically improved.
    - If ARV therapy is not available it should not be discontinued

What doses of cotrimoxazole should be used?

- Syrup use is recommended in very young children up to 10-12 kg
- Recommended dosages of 6-8 mg/kg once daily should be used.
- Once tablets can be taken, half of a standard adult tablet crushed may be used for children up to 10kg, one whole tablet for 10-25kg, two single strength or one double strength for over 25kg (a usual single strength tablet provides Sulfamethoxazole 400 mg and trimethoprim 80 mg).
- Use weight band dosages rather than body surface area doses
- If the child is allergic to cotrimoxazole, dapsone is the best alternative

What follow- up is required?

- Assessment of tolerance and adherence: Cotrimoxazole prophylaxis should be a routine part of care of HIV infected children, and be assessed at all regular clinic visits or follow-up visits by health workers and/or other members of multidisciplinary care teams.

Initial clinic follow-up in children is suggested monthly, and then every three months, if cotrimoxazole is well tolerated.

Other operational issues

Drug supplies

- Cotrimoxazole should be prescribed by the health care providers responsible for HIV care of the child.
- Providers should ensure regular sustained supply of high quality cotrimoxazole, and ensure the child has enough supply until after the next scheduled appointment for regular monitoring or ARV related care. This should ensure doses are not missed.
- Governments need to ensure an uninterrupted drug supply for both treatment and prophylaxis is available. This requires accurately estimating programme needs and extra budgetary allocation.
- Existing drug distribution systems should be used for supply
- Private sector including industry and other medical insurance plans, should be encouraged to provide prophylaxis to families and include provision for children

Patient information

Patients need to be clear that while cotrimoxazole does not cure HIV, regular dosing is essential for protection of children from infections that are more common or more likely to occur in HIV infection. Cotrimoxazole does not replace the need for antiretroviral therapy.

Policy and programme information

It is recommended that:

- National AIDS treatment, care and support policies and strategies include provision of cotrimoxazole prophylaxis
- National ARV treatment guidelines, PMTCT guidelines, and clinical care guidelines include cotrimoxazole prophylaxis for HIV exposed and HIV infected children
- Health providers at all levels are sensitized and trained to provide cotrimoxazole prophylaxis to all HIV-exposed and HIV -infected children
- Countries should supply the cotrimoxazole for children free of charge or at subsidized rates where possible

Monitoring and evaluation

In order to monitor progress towards the delivery of comprehensive AIDS treatment, care and support, National programmes should assess the extent to which the range of HIV related care services are being implemented and set clear targets for children. Cotrimoxazole prophylaxis is an essential health intervention that needs to be included in child health services (including IMCI), PMTCT services, TB services and HIV ART treatment services (facility based and community based). Monitoring of progress towards achieving this should include:

- Monitoring the provision of cotrimoxazole prophylaxis to children and adolescents within existing care services (including, paediatric HIV care, home based care and IMCI).

- Documenting the proportion of HIV-exposed infants in PMTCT programs who receive cotrimoxazole interventions until confirmation of HIV infection status.

- National monitoring of antimicrobial resistance of pneumonia, dysentery and malaria in children is recommended because cotrimoxazole is widely used for other clinical indications.

References

1. Provisional WHO/Unaids Secretariat Recommendations Unaids On The Use Of Cotrimoxazole Prophylaxis In Adults And Children Living With HIV/Aids In Africa, accessible at: http://www.unaids.org/EN/other/functionalities/Search.asp

2. Co-trimoxazole as prophylaxis against opportunistic infections as HIV-infected Zambian children (CHAP): a chap a double-blind randomized placebo-controlled trial. Chintu C, GJ Bhat, AS Walker, V Mulenga, F Sinyinza, L Farrelly, Kagangson, A Zumla, Gillespie, A Nunn, D M Gibb Lancet 2004;364: 1865-71

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