



FMOH

**Expanding Access to Pediatric HIV/AIDS  
Care and Treatment in Ethiopia:  
*Challenges and Prospects***



ICAP

**Cotrimoxazole Prophylaxis:  
Implementation Strategies**

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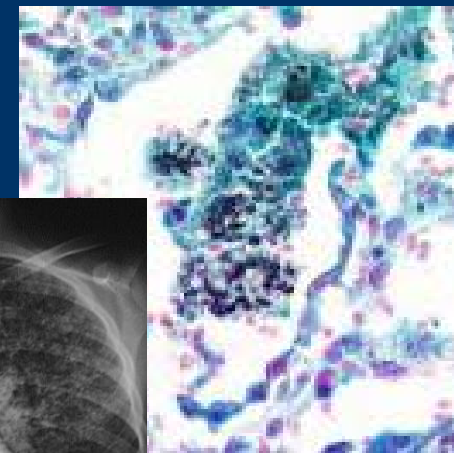
# Cotrimoxazole Prophylaxis

- Background
- The CHAP trial
- WHO recommendations
- Programmatic challenges

# Background:

## *Pneumocystis Pneumonia (PCP)*

- Studies from Africa show that 10-40% of HIV-infected children with respiratory illness have PCP infection
  - Diagnosis is challenging
  - Mortality is very high

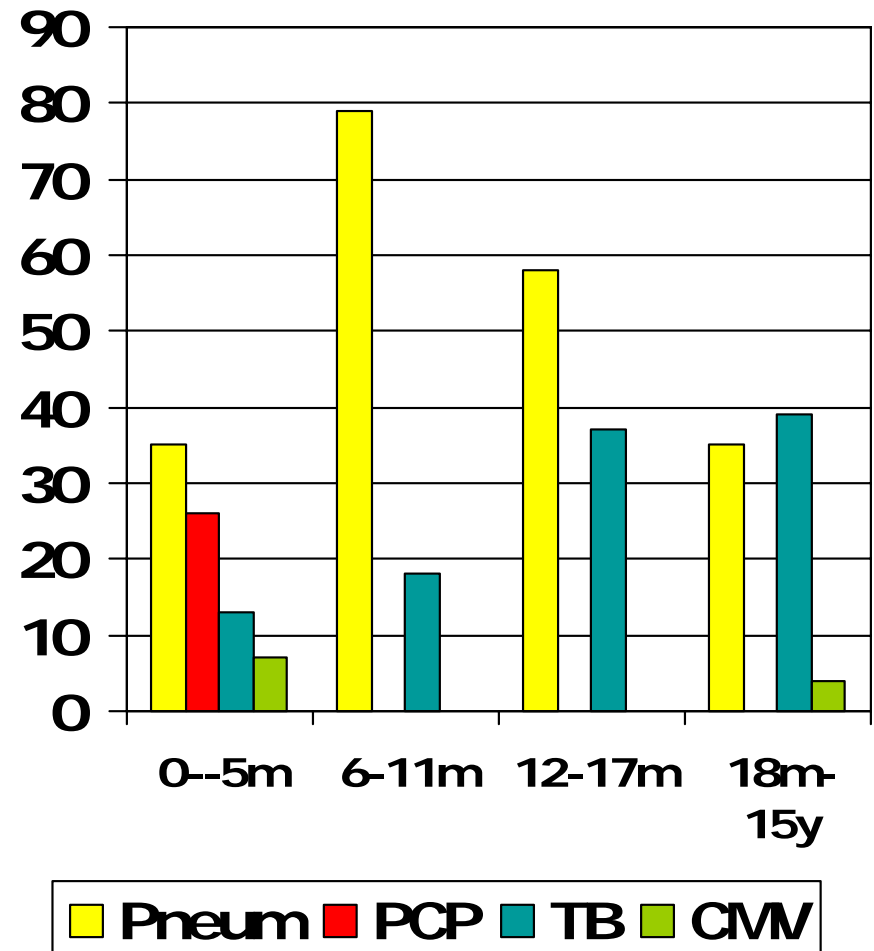
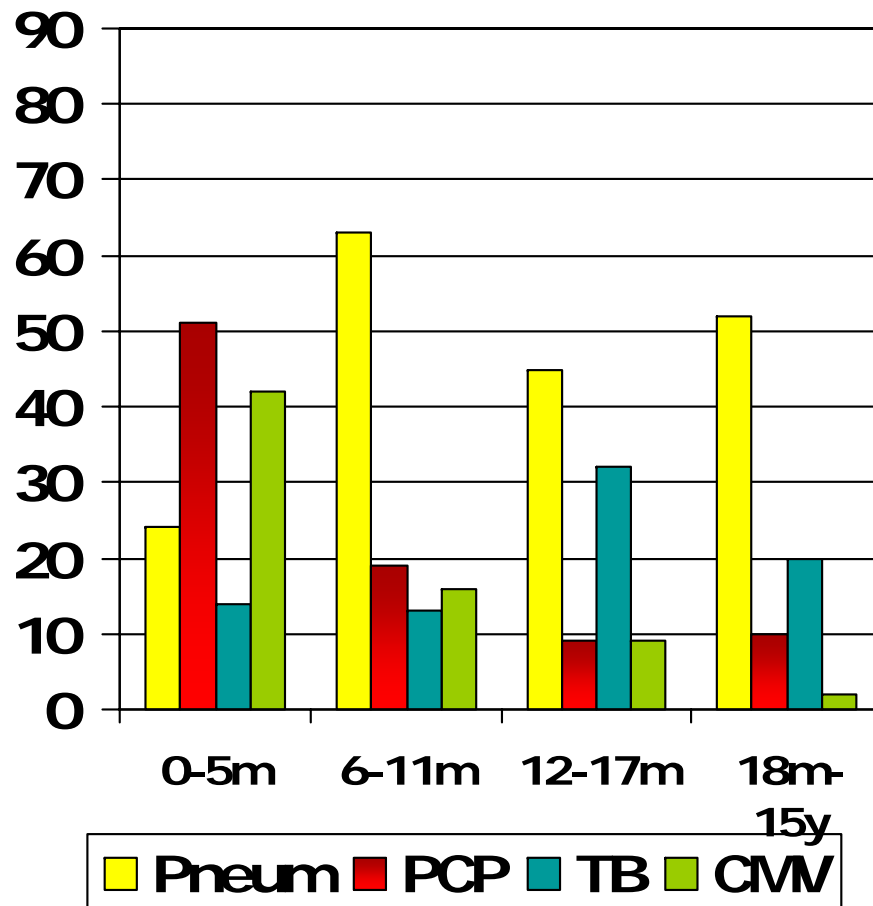


# Lung Disease in Autopsied Zambian Children

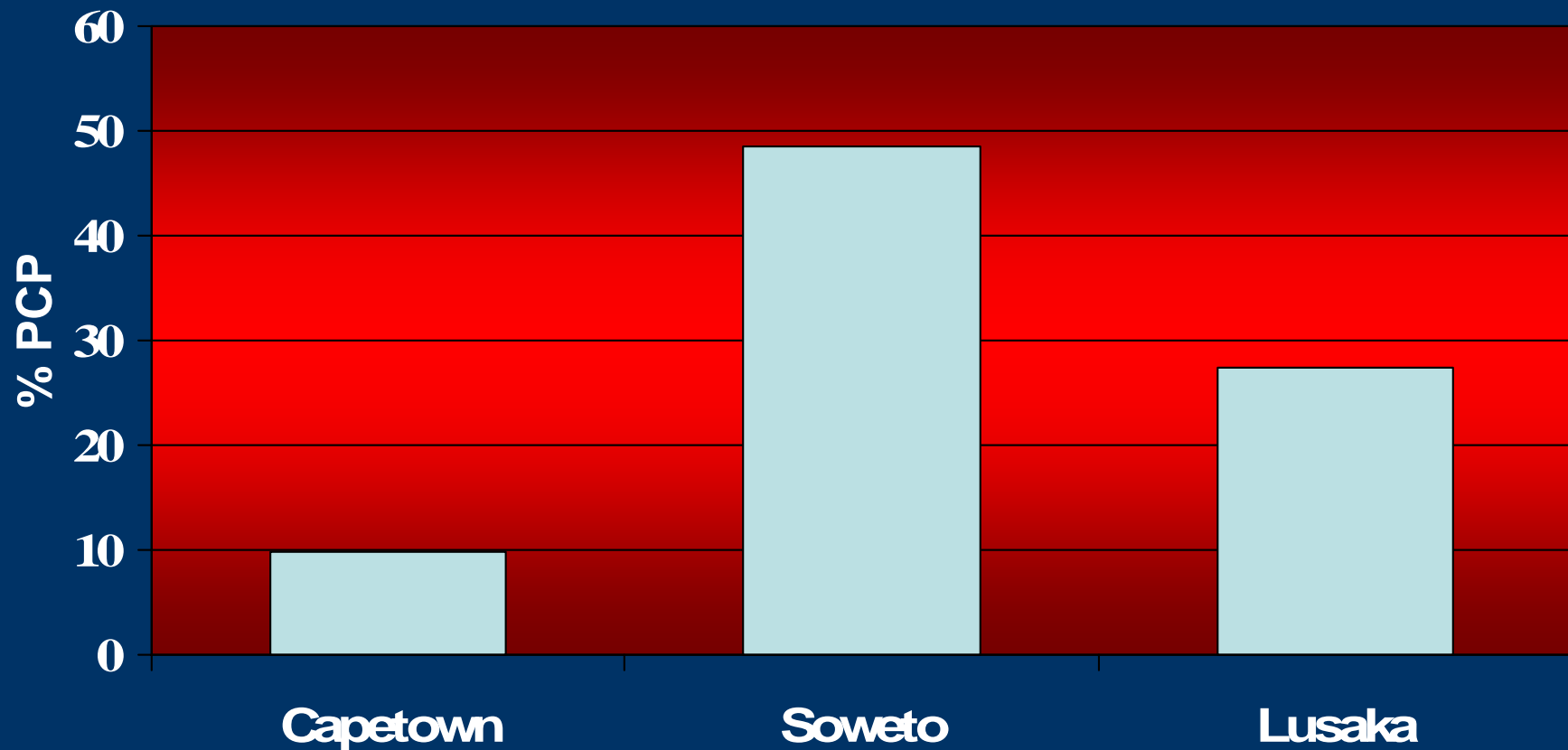
Chintu et al., Lancet 2002

HIV+

HIV-



# Diagnosis of PCP in HIV-Infected Children with Respiratory Disease



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# Why is CTX prophylaxis recommended?

PCP is:

- common
- deadly
- preventable

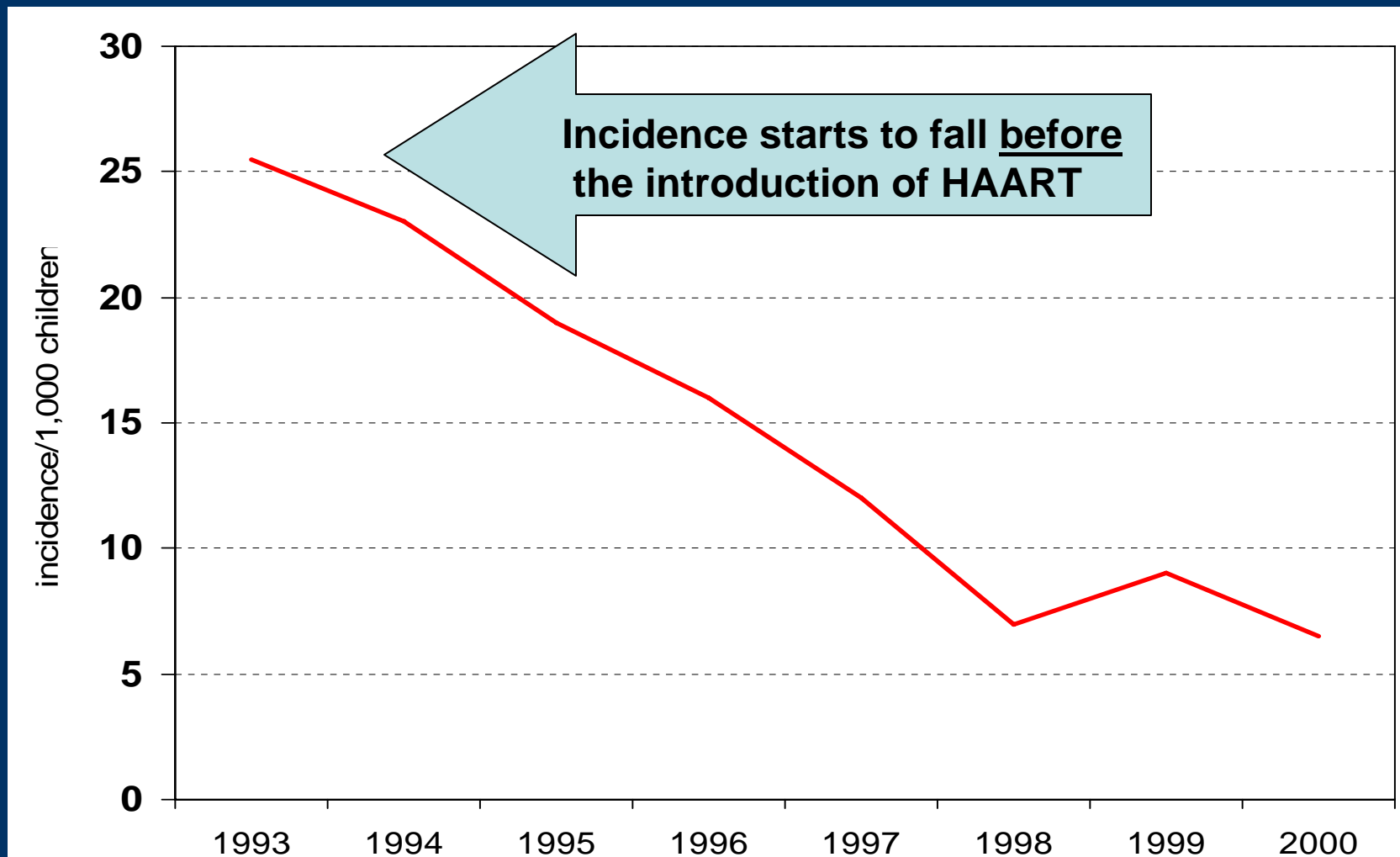


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# Why is CTX Prophylaxis Recommended?

- CTX prophylaxis also protects against infections other than PCP
  - Bacterial pneumonia
  - Diarrheal illness

# Incidence of pediatric PCP in the US



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# The CHAP Trial

## Children with HIV Antibiotic Prophylaxis

Lancet 2004; 364:1865-71

- A randomized prospective double-blind placebo-controlled trial of 541 children at University Teaching Hospital in Zambia
- HIV-positive children were randomised in a 1:1 ratio to receive daily cotrimoxazole (240mg for < 5 years; 480mg for  $\geq$  5 years) or matching placebo
- **Expanding Access to Pediatric HIV/AIDS Care and Treatment in Ethiopia: Challenges and Prospects**

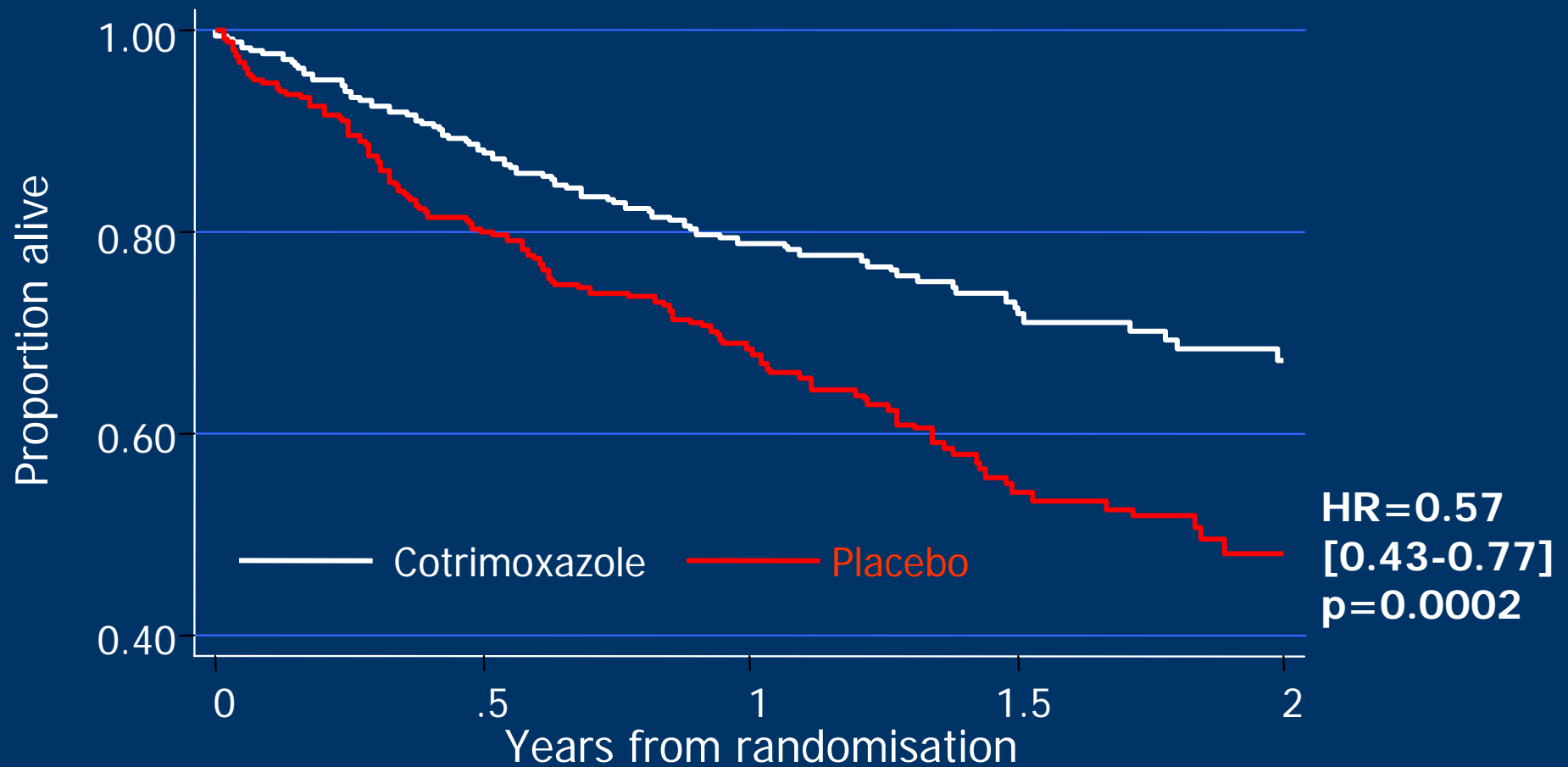
# The CHAP Trial

- Until CHAP, no trial had reported on the efficacy of CTX prophylaxis in adults or children in areas of high levels of bacterial resistance (such as Zambia)

# The CHAP trial

- The trial was stopped early by the DSMB
- The use of CTX
  - Decreased mortality by 43 %
  - Decreased hospitalizations by 23 %
  - Did not increase adverse drug effects

# Death by time at risk: overall



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# Main causes of death

(Definitive in brackets)

	CTX N = 74	Placebo N = 112
Tuberculosis	1 (1)	4 (1)
<b>Pneumonia/empyema</b>	<b>16 (4)</b>	<b>34 (5)</b>
Septicaemia	3 (1)	2 (0)
Meningitis/encephalitis	7 (1)	8 (0)
<b>Diarrhoea/gastro</b>	<b>21 (2)</b>	<b>22 (7)</b>
Malnutrition	6 (2)	6 (2)
Malaria	2 (0)	2 (1)
Anaemia	2	3
Other	6 (4)	11 (7)
unknown	10	20

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# CHAP Summary

- Daily CTX was highly effective in preventing death and hospital admissions in HIV-infected children aged 1-14 years in an area of high antibiotic resistance
  - Across all ages
  - Across range of CD4 percent
  - Over more than 12 months
- Zambian MOH will change policy on provision of CTX to HIV-infected children

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# WHO / UNAIDS / UNICEF

**“Greater advocacy for the use of cotrimoxazole prophylaxis in children is urgently needed.”**

- Joint statement on use of cotrimoxazole as prophylaxis in HIV exposed and HIV infected children (11/04)

# Which infants and children should receive CTX prophylaxis?

- Which HIV-exposed infants should receive CTX?
- Which HIV-infected infants and children should receive CTX?

# HIV-exposed infants

- All HIV-exposed infants should receive CTX
  - e.g., all infants born to women known to be HIV-infected
- Starting at 4-6 weeks of age
- Until no longer breast feeding and HIV has been definitively excluded

# **HIV-exposed infants**

- Why provide CTX prophylaxis to infants whose HIV status is unknown?
  - PCP presents and kills early (3-6 months)
  - HIV is often diagnosed late (15-18 months)
  - CTX is safe and effective
- If you wait for a definitive diagnosis of HIV, you will lose the opportunity to save many lives

# HIV-infected infants and children

CTX prophylaxis is indicated for:

- all HIV-infected infants < 12 months of age
- HIV-infected children  $\geq$  12 months with:
  - Clinical features suggestive of HIV/AIDS
  - Prior *Pneumocystis* infection
  - Evidence of immune dysfunction
    - CD4 < 15%
    - In children 1-5 years, total CD4 < 500
    - In children 5+ years, total CD4 < 200

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# Programmatic Challenges

Programmatic barriers vary from site to site:

- Identification of HIV-exposed infants
- Coordination of care between ANC & MCH
- Altering pediatric visit schedules
- Medical records and documentation
- Access to pediatric formulations of CTX

## Identification of HIV-exposed infants

- When an infant is seen at a maternal child health clinic (or other site of care), how will the clinician know that s/he is HIV-exposed?
- Is the mother's HIV status routinely documented in the infant's medical records?
- If not, how can prophylactic CTX be systematically provided?

## Altering visit schedules & protocols

- Are HIV-exposed infants seen more frequently than other infants?
- Are HIV-exposed infants assessed differently than other infants?
- Are the parents/caretakers of HIV-exposed infants counseled differently than other parents?

If not, why not?

## Access to Cotrimoxazole

- Does the pharmacy have a reliable and consistent supply of cotrimoxazole?
- Are pediatric formulations (suspension and single-strength tablets) available?
- Are pediatric dosing guidelines available to the correct staff?
- Is patient education material available to support parents and caretakers?

If not, why not?

# In conclusion: Pediatric CTX Prophylaxis

- ✓ Safe and well tolerated
- ✓ Extremely effective
- ✓ Inexpensive
- ✓ Relatively simple
- ✓ Strongly recommended
- ✓ **SAVES LIVES**