

THE CHILDREN'S
INVESTMENT FUND
FOUNDATION

Prevention of Mother to Child Transmission &
Pediatric Care and Treatment

29 March 2009

Agenda

Section 1: HIV/AIDS: Problem statement

- ❑ Epidemic trends
- ❑ Need to focus on mothers and children
- ❑ Historic focus of HIV/AIDS programs

Section 2: Current landscape

- ❑ Integrated cascade of PMTCT¹ and Pediatric care and treatment interventions
- ❑ Access and coverage rates for the cascade
- ❑ Quality issues surrounding the access
- ❑ Key barriers and best practices

Section 3: CIFF's investments

- ❑ 'Big win' achieved to date
- ❑ Snapshot of current investments in PMTCT
- ❑ 'Big win' going forward
- ❑ CIFF's vision and goals
- ❑ Criteria for investment selection

AIDS Epidemic: Global summary 2007

Number of people living with HIV in 2007

Total	33 million [30 – 36 million]
Adults	30.8 million [28.2 – 34.0 million]
Women	15.5 million [14.2 – 16.9 million]
<u>Children under 15 years</u>	<u>2.0 million [1.9 – 2.3 million]</u>

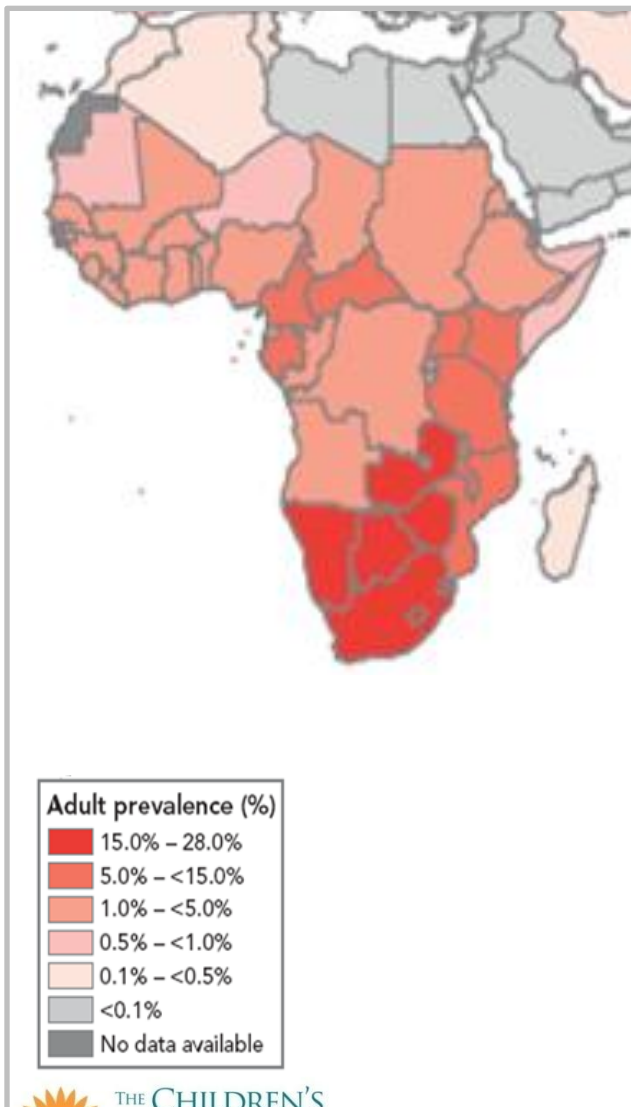
People newly infected with HIV in 2007

Total	2.7 million [2.2 – 3.2 million]
Adults	2.3 million [1.9 – 2.8 million]
<u>Children under 15 years</u>	<u>370 000 [330 000 – 410 000]</u>
<u>Children in Sub Saharan Africa</u>	<u>330 000</u> 89% of new child infections

AIDS deaths in 2007

Total	2.0 million [1.8 – 2.3 million]
Adults	1.8 million [1.6 – 2.1 million]
<u>Children under 15 years</u>	<u>270 000 [250 000 – 290 000]</u>
<u>Children in Sub Saharan Africa</u>	<u>240 000</u> 89% of new child infections

Disproportionately high child mortality due to HIV/AIDS in countries with high HIV prevalence



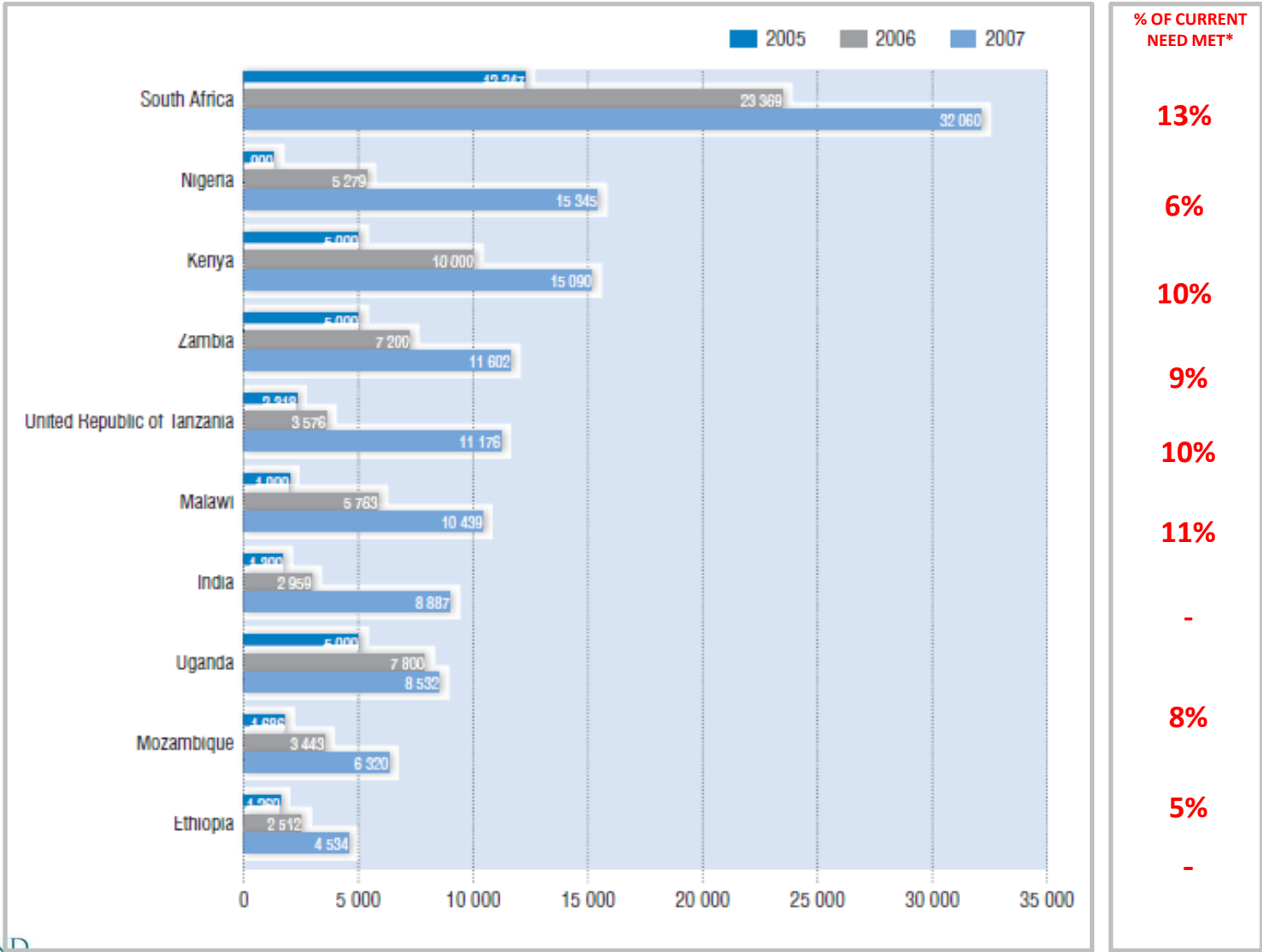
Country	Deaths among children younger than five years attributable to HIV	Numbers of children living with HIV	Adult HIV prevalence 2007
South Africa	57%	240 000	18.8%
Lesotho	56%	18 000	23.2%
Botswana	54%	14 000	24.1%
Namibia	53%	17 000	19.6%
Swaziland	47%	15 000	33.4%
Zimbabwe	41%	160 000	20.1%
TOP 6 HIGH BURDEN COUNTRIES			
OTHER COUNTRIES			
Tanzania	29%	110 000	6.5%
Kenya	15%	150 000	6.1%
Malawi	14%	91 000	14.1%
Uganda	8%	110 000	6.7%
Nigeria	5%	240 000	3.9%
Ethiopia	4%	92 000	1.4%
India	1%	70 000 ?	0.9%

PROBLEM

SCALE

Large unmet need in providing treatment to children despite recent increases in coverage

Number of children (younger than 15 years) receiving antiretroviral therapy in countries with the highest estimated number of pregnant women living with HIV



Sources: Global Progress Report 2008. CIFF analysis of unmet need based on 2007 ARV coverage as a ratio of estimated number of children living with HIV.

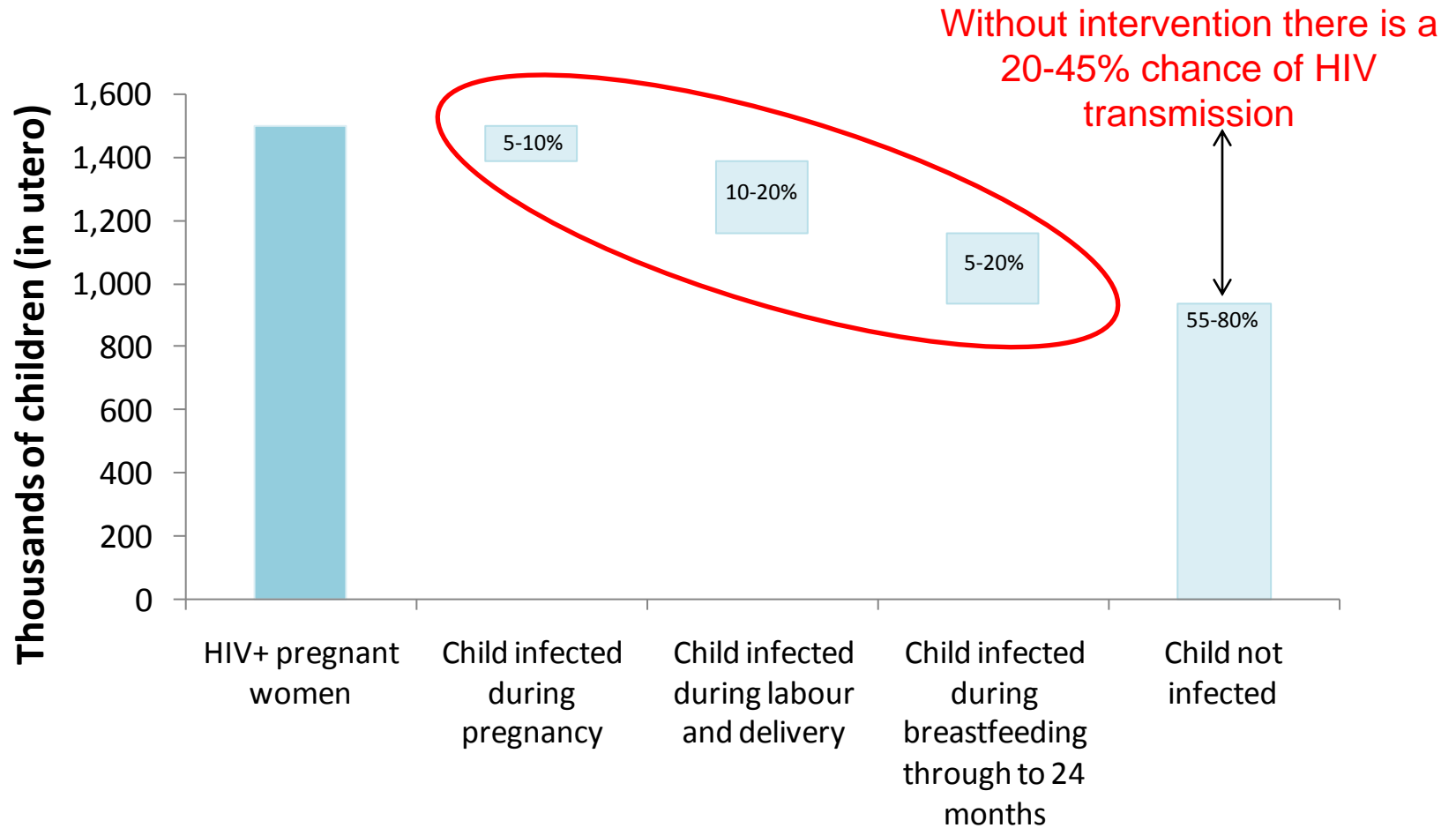
* With adoption and implementation of WHO 2008 guidelines for early initiation of treatment in infants, the estimate of number of children requiring treatment are likely to grow rapidly. Therefore, the actual need met in the top 10 high burden countries is significantly lower than what is estimated here.

90% of children got infected from their mothers during pregnancy, birth and post delivery

Rank	Country	Estimated number of pregnant women living with HIV*
1	South Africa	220 000
2	Nigeria	190 000
3	Tanzania	100 000
4	Mozambique	97 000
5	Uganda	78 000
6	Kenya	76 000
7	Zambia	76 000
8	Malawi	73 000
9	Ethiopia	66 000
10	India	64 000
11	Zimbabwe	52 000
12	DRC	38 000
13	Cameroon	34 000
14	Cote d'Ivoire	28 000
15	Sudan	18 000
16	Angola	18 000
17	Chad	18 000
18	Ghana	14 000
19	Swaziland	13 000
20	Lesotho	13 000

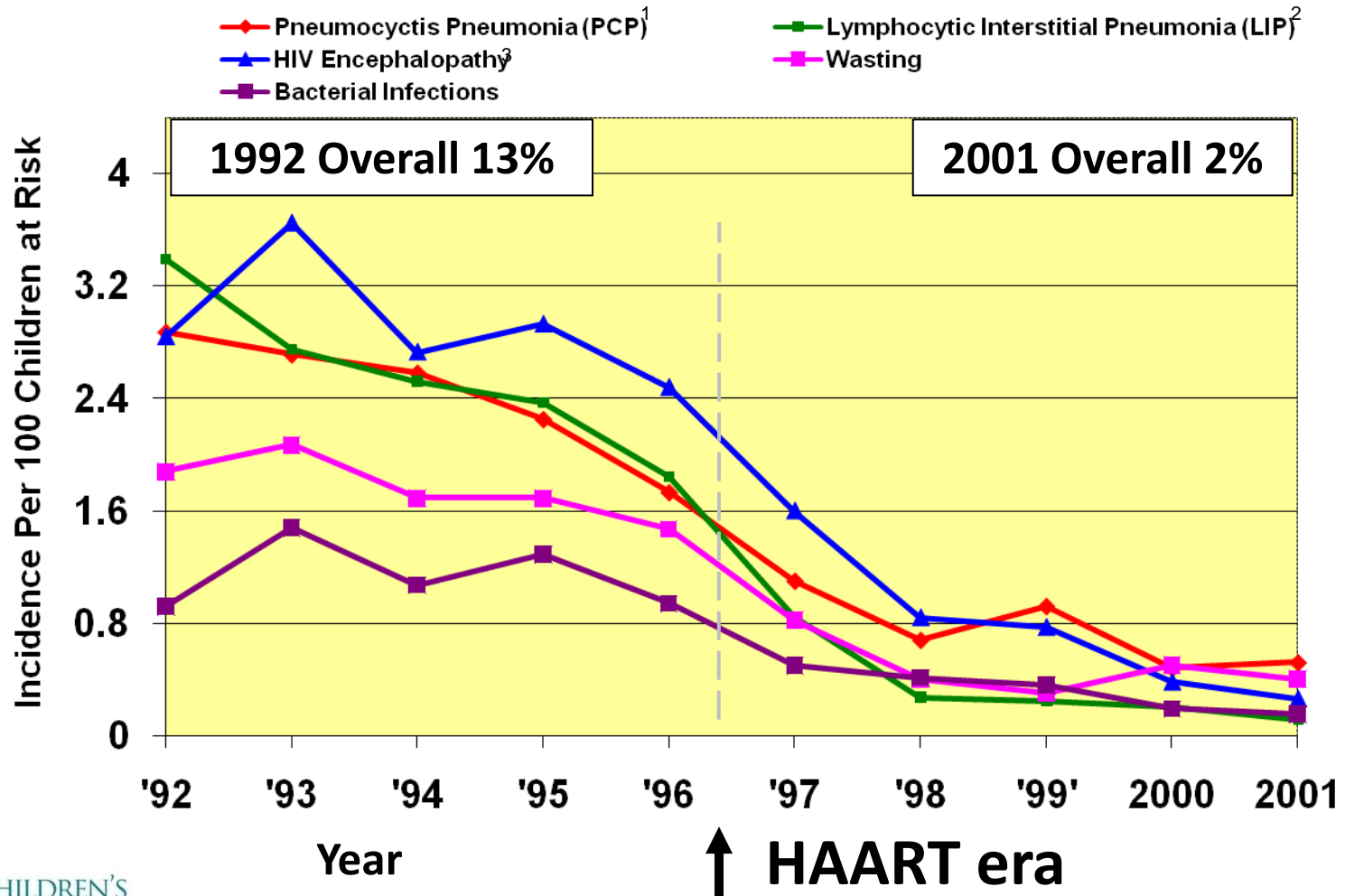
75% LIVING IN 12 COUNTRIES

High transmission risk in the absence of any intervention



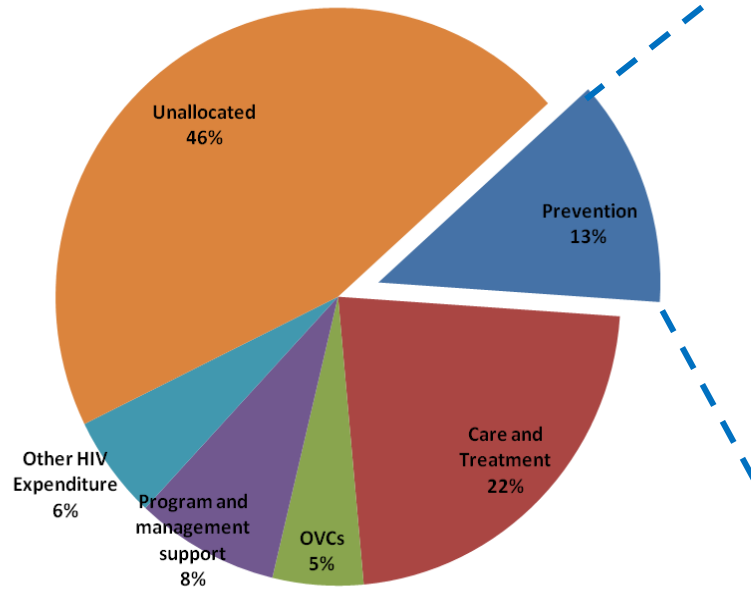
Dramatic reduction of MTCT possible by introducing HAART

Incidence of Selected AIDS-Defining Conditions Per 100 HIV-Infected Children at Risk, U.S.

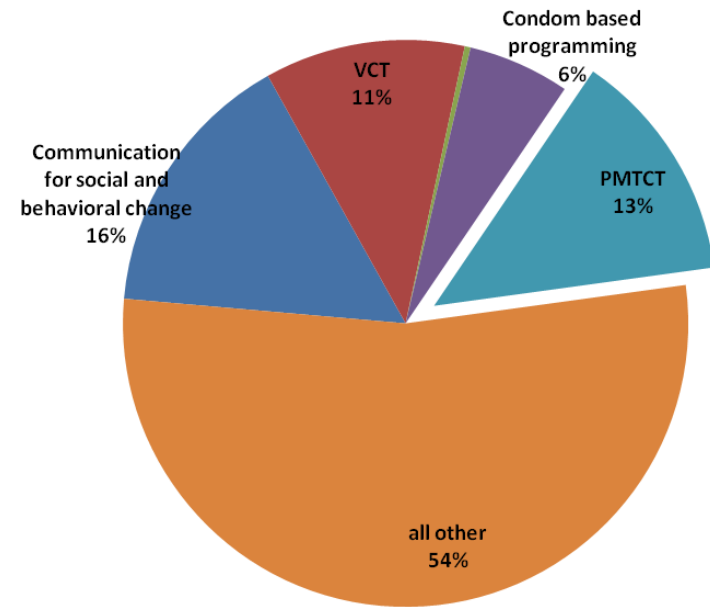


PMTCT neglected by global funding for HIV/AIDS- 1.7% of total over 2006-2007

HIV expenditure by service type, US \$3.8 billion



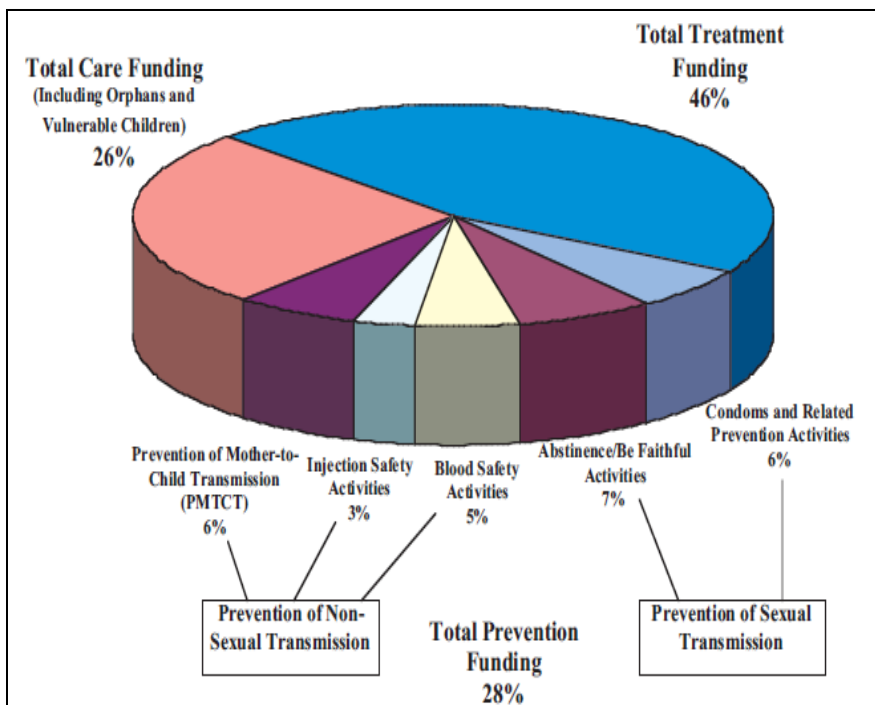
Break-down for Prevention expenditure= US \$492 million



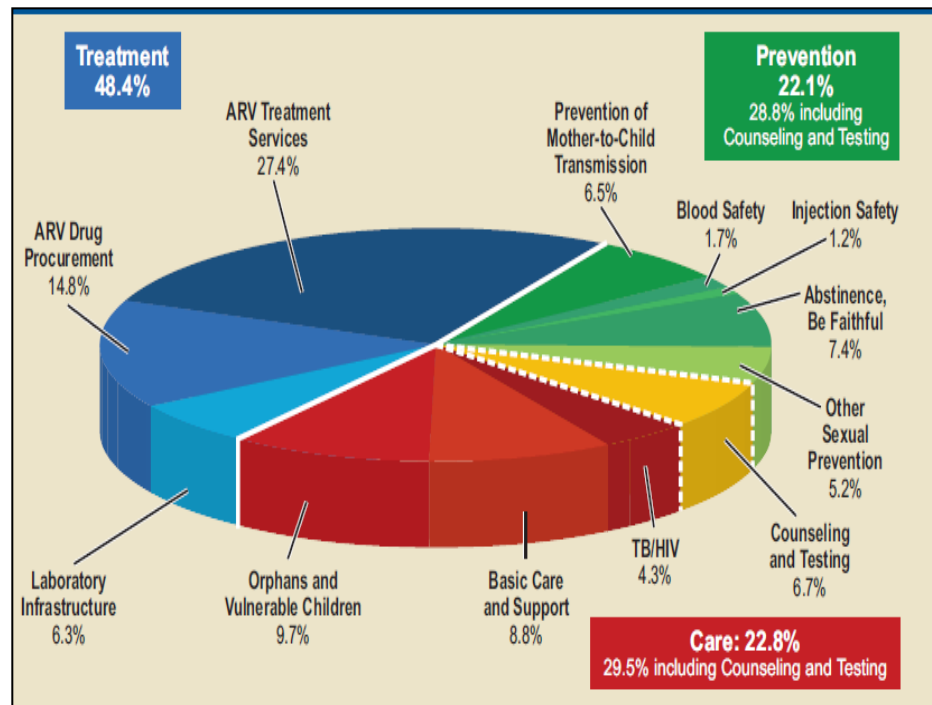
An illustration of funding allocation by PEPFAR

PEPFAR's overall funding has gone up from \$2.7 billion in FY 2005 to \$6 billion in FY2008. However, treatment related activities continue to dominate the funding allocation

FY 2005- \$2.7 Billion



FY 2008- \$6 Billion



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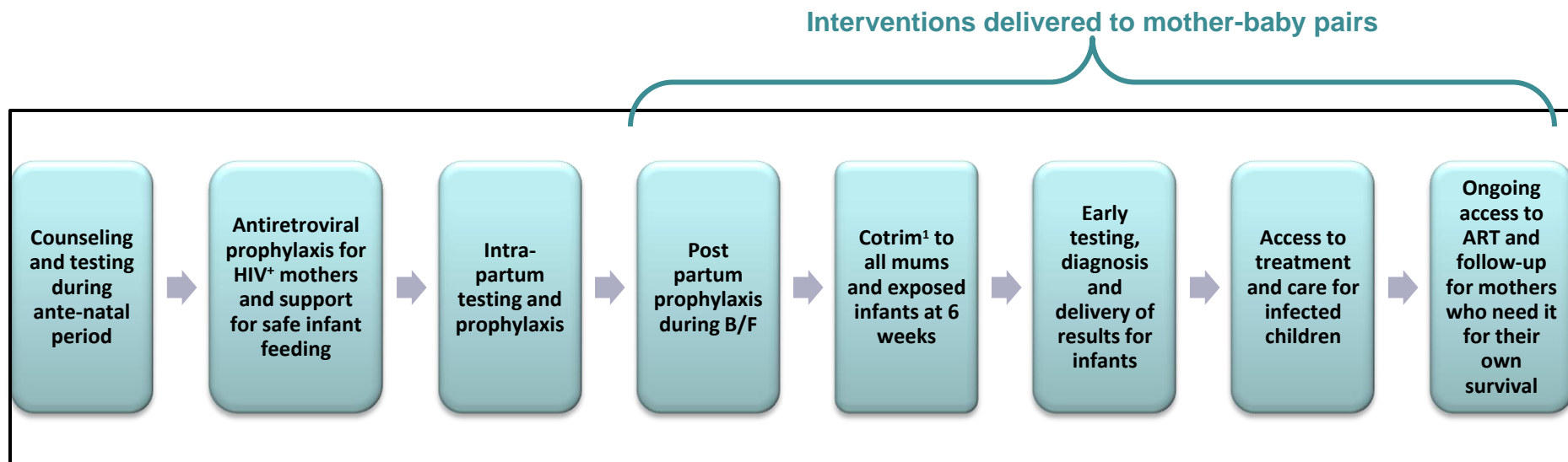
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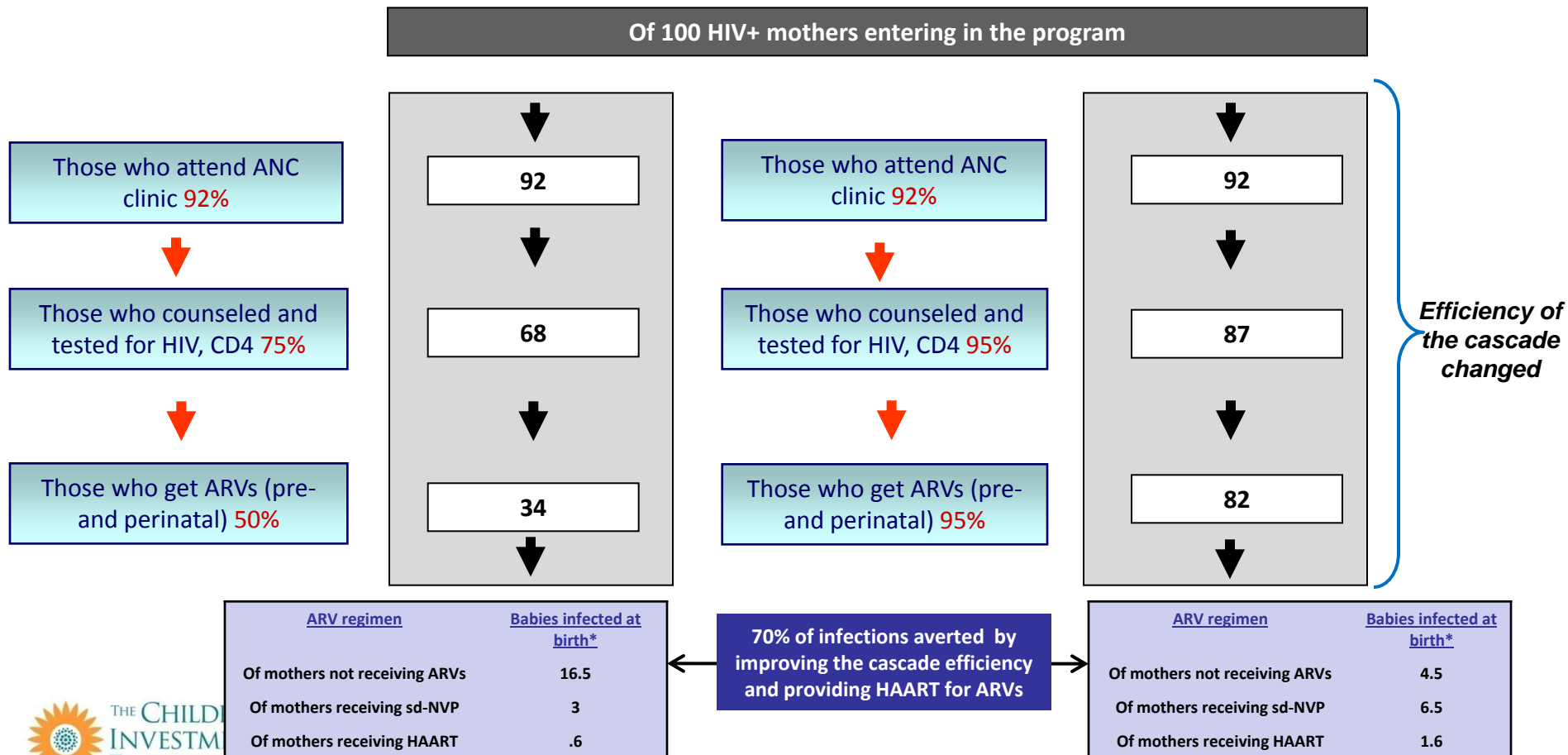
Integrated approach to PMTCT and Pediatric interventions



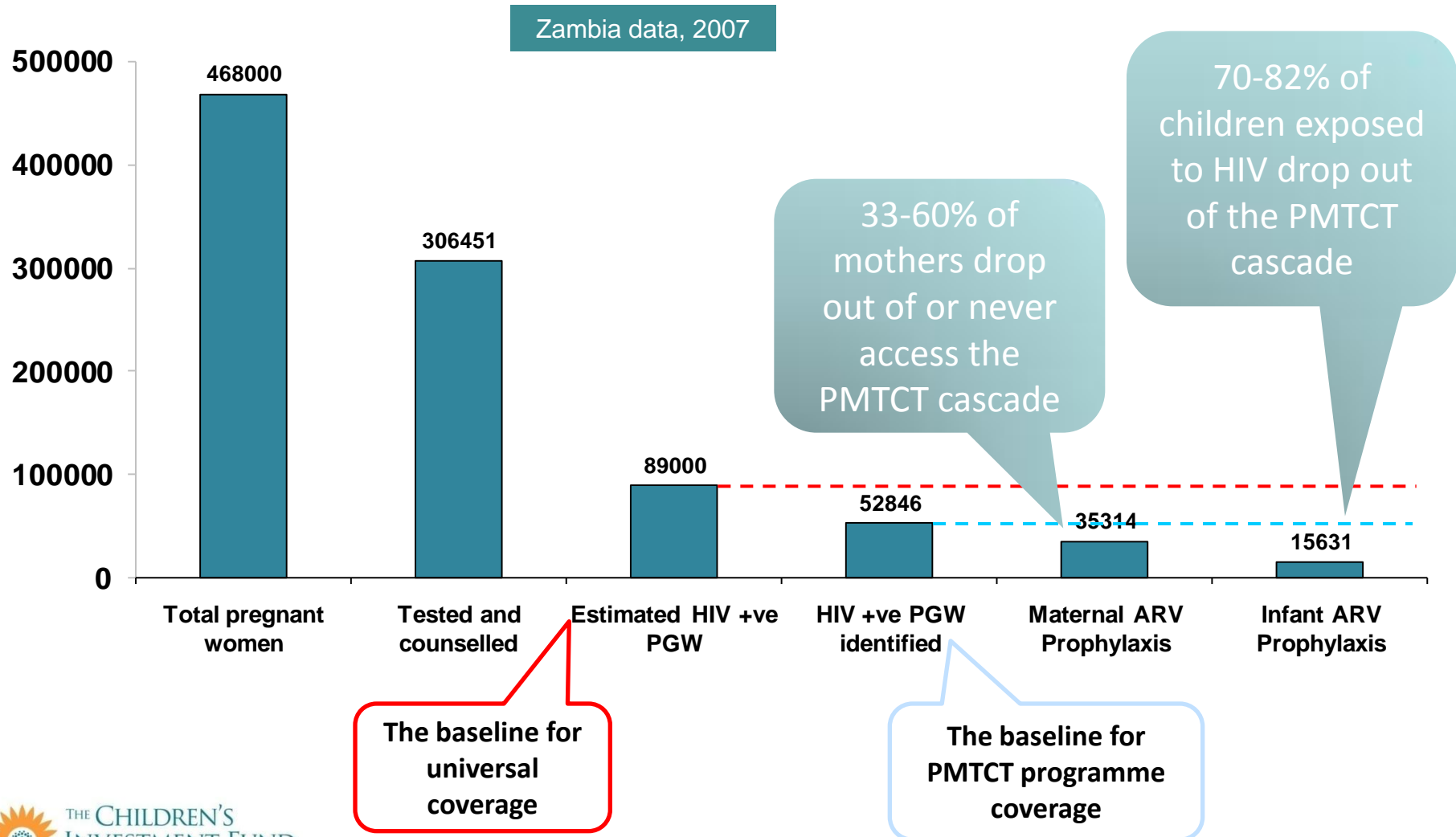
1. Given these linkages between PMTCT and pediatric interventions, it is important to identify and track all infected mother-baby pairs to ensure their completion of services along the cascade shown above.
2. Given the strong linkages between mother's and child's survival², it is possible to maximise the HIV free survival of the infants by keeping mums alive through PMTCT interventions.

PMTCT cascade: potential to avert 70% of child infections by driving both access and effective treatment

- By improving mothers' access to testing and basic ARV regimens, 44% of child infections can be averted
- It is possible to avert an additional 25% of child infections by providing mothers with more efficacious regimens such as HAART

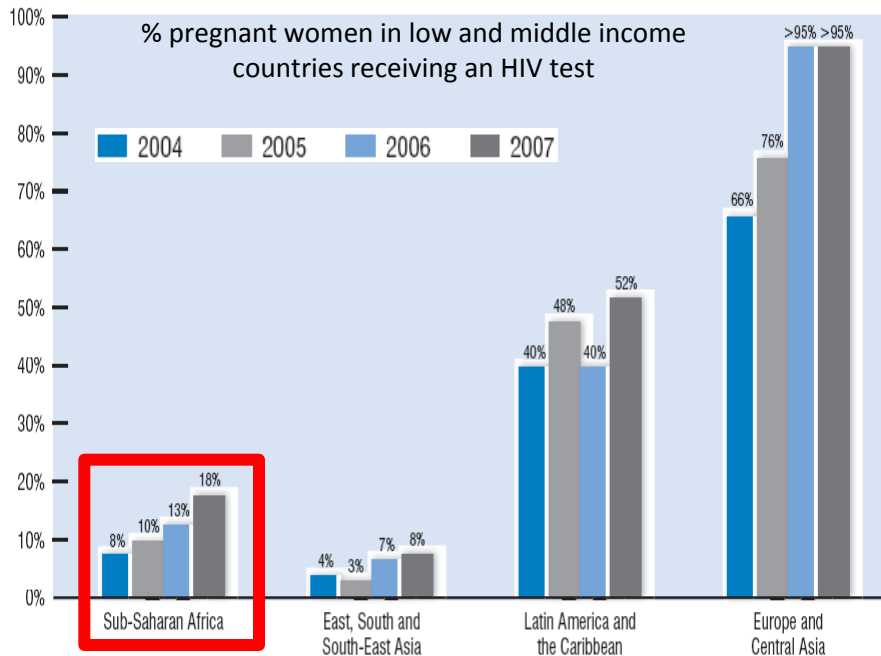


At present, there is a dramatic drop off for mothers throughout the cascade

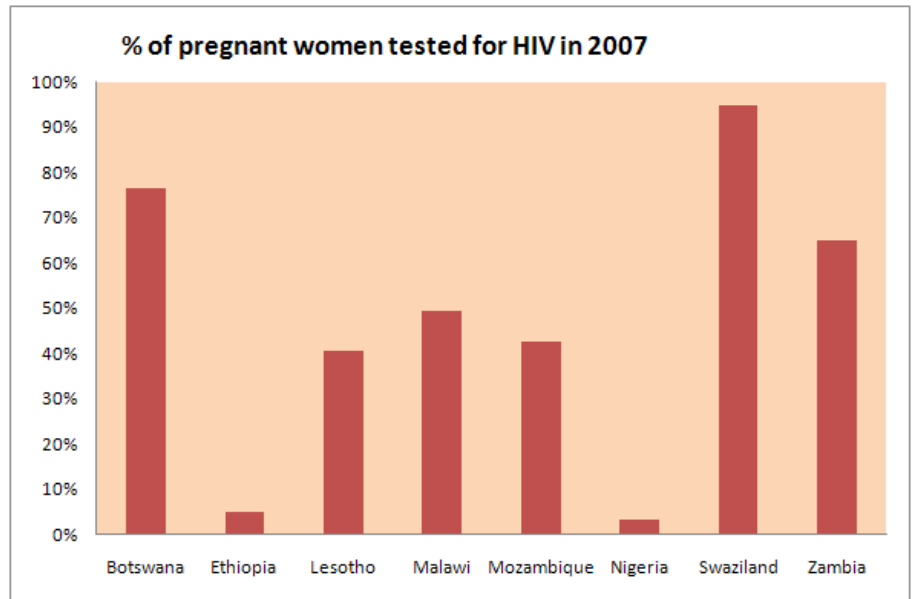


HIV testing of pregnant women slowly increasing with significant variations by country

Inter regional variations in % of pregnant women receiving an HIV test in 2007

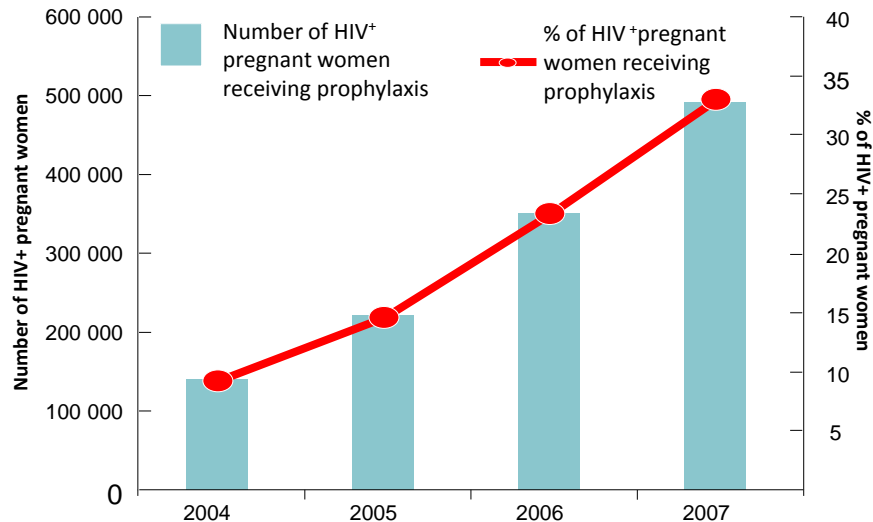


Intra regional variations in Sub Saharan Africa for women receiving an HIV test in 2007

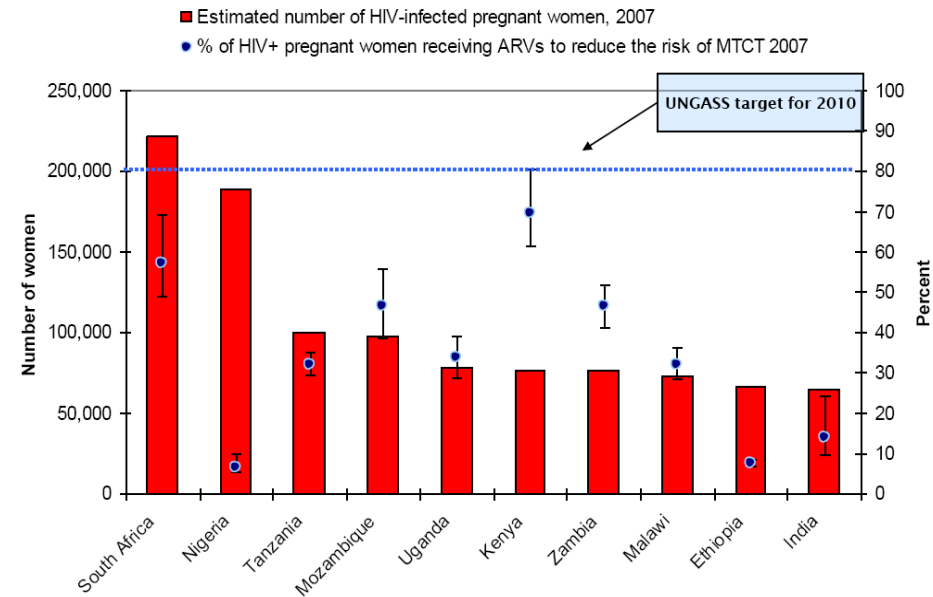


Low but increasing rate of pregnant HIV+ women are receiving prophylaxis for MTCT

Increase in the percentage of pregnant women with HIV receiving prophylaxis for PMTCT in low- and middle-income countries¹

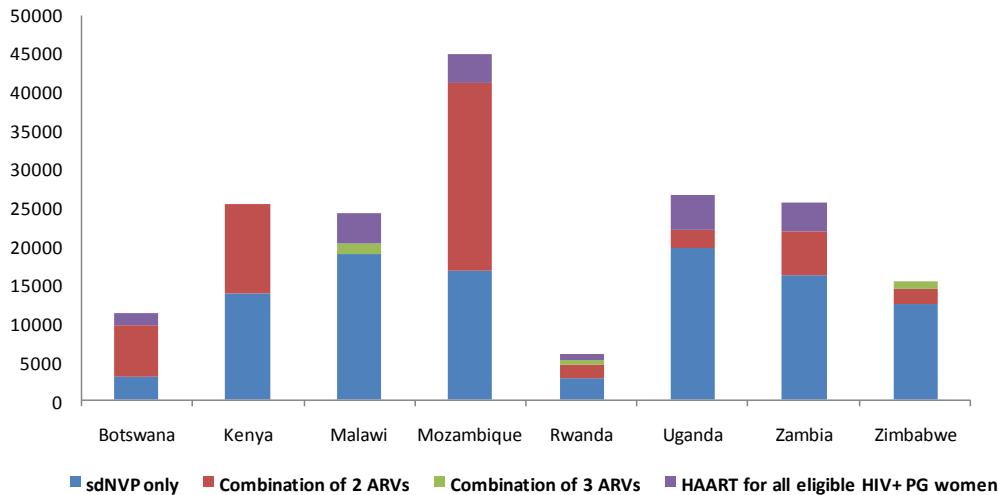


Variations in the coverage of antiretrovirals for HIV infected women in 2007²

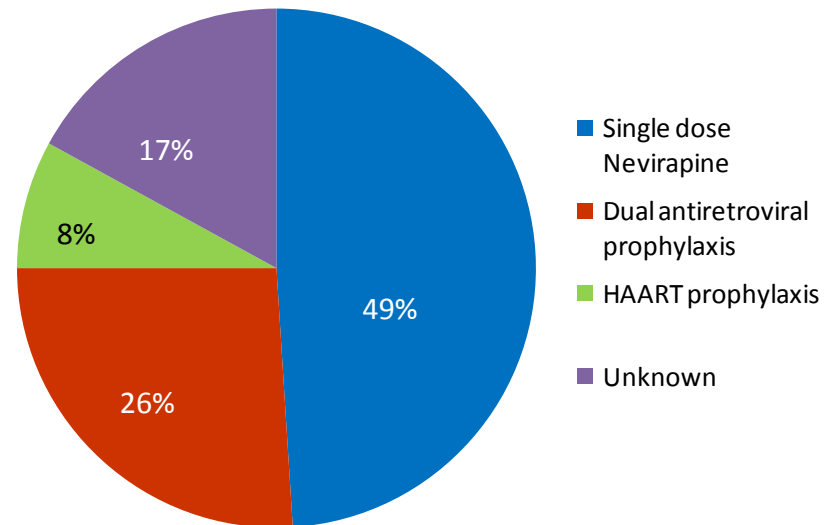


Suboptimal antiretroviral regimens are the norm for mothers in low and middle income countries

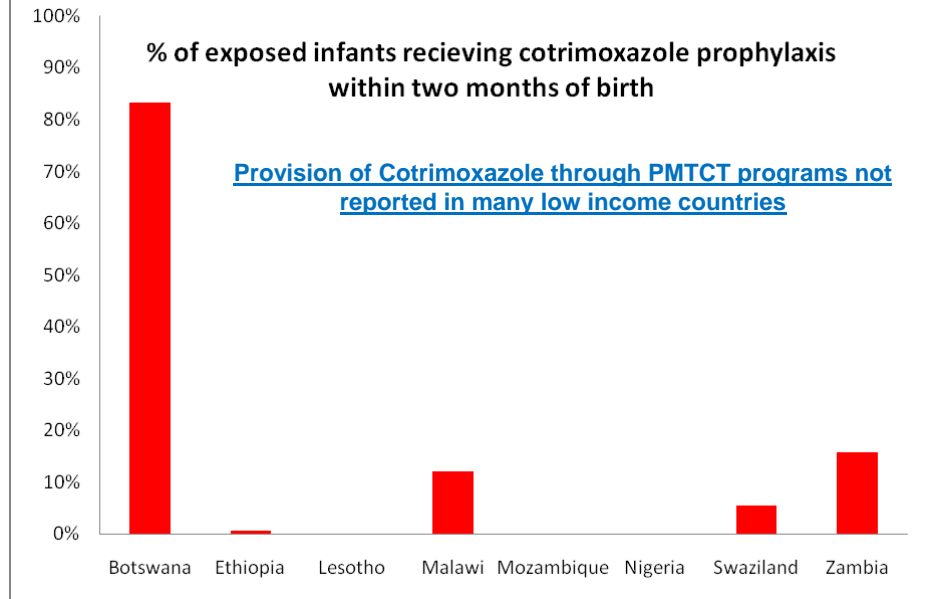
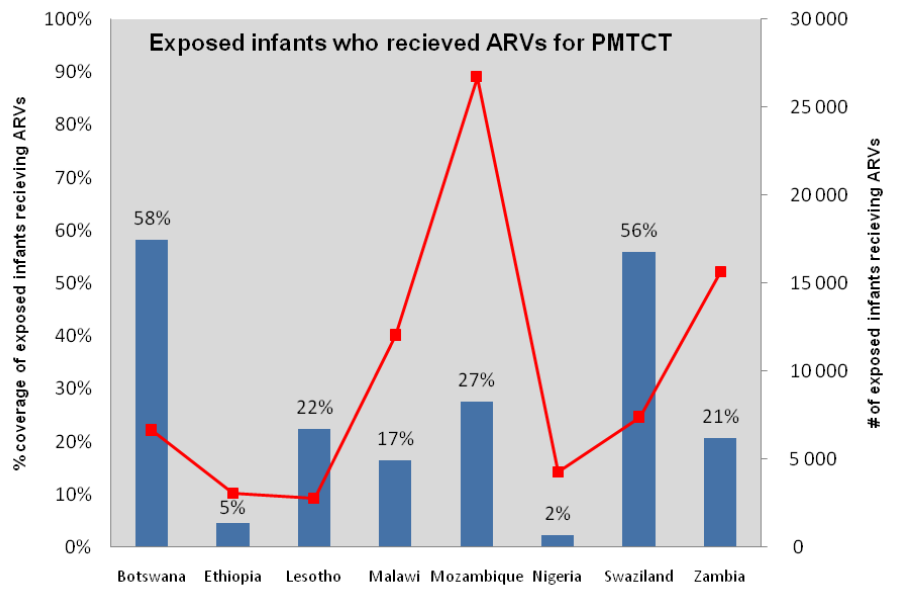
Number of HIV+ Pregnant Women Receiving Different ARV Regimens¹



Distribution of antiretroviral regimens received by pregnant women living with HIV, 2007²

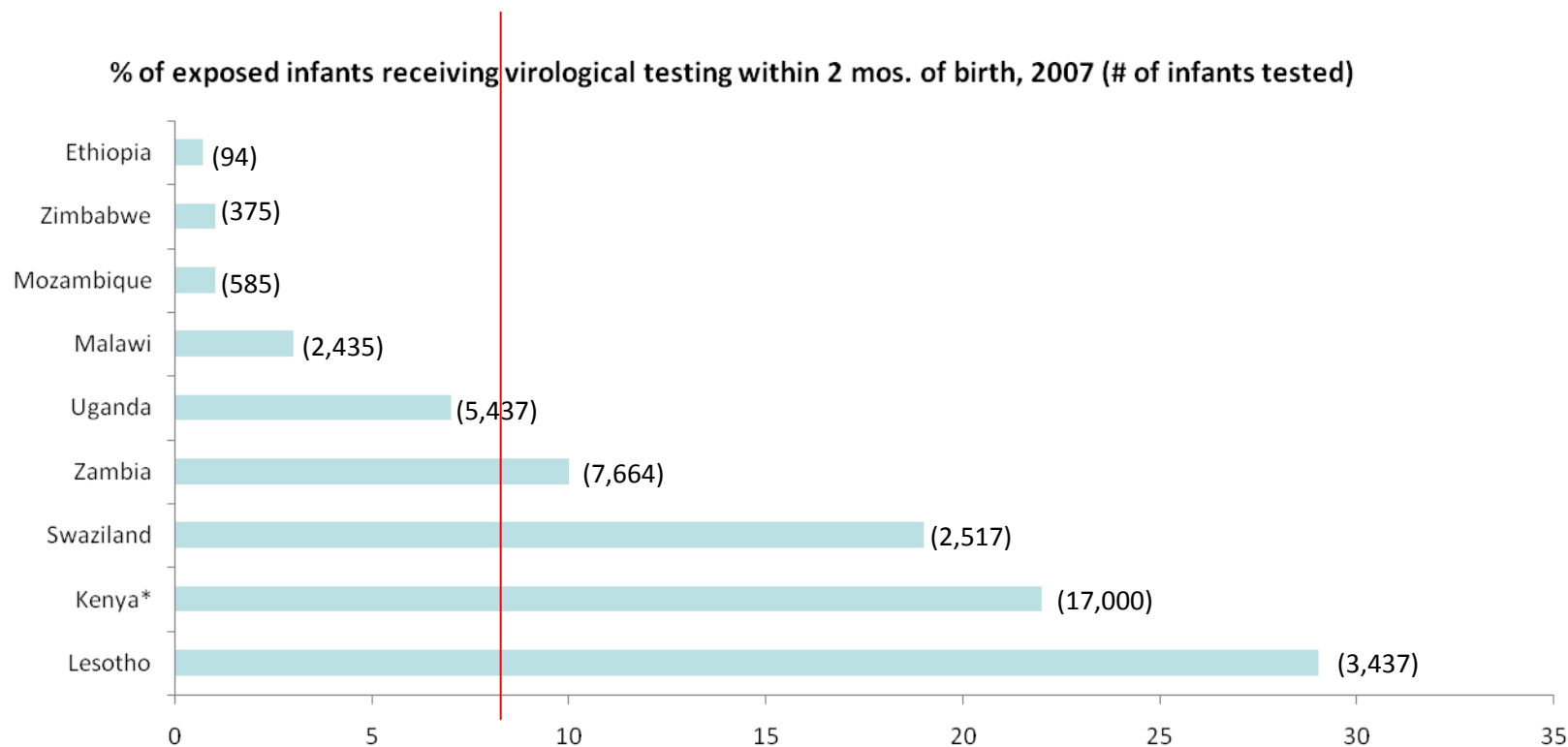


Majority of HIV exposed infants not receiving Cotrimoxazole prophylaxis and ARVs for PMTCT



50% of infected infants die by 2 years of age in the absence of early treatment

On average in high-prevalence countries, only about 8% of HIV-exposed infants were tested for HIV within two months of birth



Data was unavailable for other high-burden countries: India, Nigeria, South Africa and Tanzania.

* UNAIDS data for Kenya is published only as a range; calculations based on 150,000 children estimated to be living with HIV in 2007.

On average, more than half of positive children are lost to follow up after testing

- As much as 20-50% lost to follow up across post-testing, care and treatment stages, and as high as 80% loss from PMTCT services¹
 - In Cameroon, nearly one-quarter of HIV-infected antenatal attendees were lost between HIV testing and time of delivery; in Kenya, 30% of live infants in the cohort were not available for HIV testing during the two-year follow-up period²
- Estimates from a CHAI retention study across Cameroon, Swaziland, Zambia, Ethiopia and Kenya reflect an average LTFU of 53% between testing positive and treatment. The range of estimates vary significantly from 82% in Swaziland to 35% in Zambia³.
- While LTFU continues to be an issue for adult patients on ART, the proportion of children dropping out of care and treatment is disproportionately higher

Table 2. Median Follow-Up and Rates of Patient Attrition, as Reported, from Antiretroviral Treatment Programs

Study Code	Median Follow-Up (Months)	Died (A)	Lost to Follow-Up (B)	Stopped ARVs (C)	Total Attrition from ART (D) ^a	Total Retained (E) ^a	Transferred Care (F)	Total Retained at Original Site (G) ^a
Botswana 1	22.2	15.7%	8.4% ^b	—	24.1%	75.9%	5.2% ^c	70.7%
Botswana 2	10.2	16.8%	5.4%	—	22.2%	77.8%	—	77.8%
Botswana 3	12	5.2%	12.4% ^d	—	17.6%	82.4%	12.1%	70.3%
Cameroon 1	13	6.6%	25.1% ^e	—	31.7%	68.3%	—	68.3%
Cameroon 2	11.1	7.7%	38.5%	—	46.2%	53.8%	—	53.8%
Cameroon 3	6.2	—	—	—	—	—	—	—
Cameroon 4	18	1.9%	25.5%	—	27.5%	72.5%	—	72.5%
Cote d'Ivoire 1	—	—	—	—	—	—	—	—
Kenya 1	—	11.3%	19.0%	7.7%	38.0%	62.0%	9.0%	53.0%
Kenya 2	9.2	5.4%	24.5% ^e	—	29.9%	70.1%	—	70.1%
Kenya 3	11	9.9%	7.0%	—	16.9%	83.1%	—	83.1%
Kenya 4	7.1	4.2%	8.8%	1.8%	14.8%	85.2%	0.7%	84.5%
Kenya 5	9	12.1%	15.3% ^f	—	27.4%	72.6%	—	72.6%
Kenya 6	11.7	1.1%	34.8% ^g	—	35.9%	64.1%	4.9%	59.2%
Malawi 1	8.3	18.6%	7.0% ^h	0.5%	26.1%	73.9%	—	73.9%
Malawi 2	6	7.8%	7.9%	0.8%	16.5%	83.5%	1.9%	81.6%
Malawi 3	6	27.7%	7.8%	2.8%	38.3%	61.7%	—	61.7%
Malawi 4	6.2	7.0% ^h	33.6%	4.0%	44.6%	55.4%	—	55.4%
Malawi 5	6.3	8.9%	2.4% ^a	2.0%	13.3%	86.7%	—	86.7%
Mozambique 1	9.5	12.5%	9.3%	—	21.8%	78.2%	—	78.2%
Senegal 1	46.0	23.0%	4.0% ⁱ	—	27.0%	73.0%	—	73.0%
South Africa 1	12.3	6.8%	2.9%	—	9.7%	90.3%	10.5%	79.7%
South Africa 2	18.7	5.0%	25.1%	—	30.1%	69.9%	—	69.9%
South Africa 3	13.9	13.2%	0.3% ^a	3.0%	16.5%	83.5%	1.0%	82.5%
South Africa 4	19.5	5.4%	25.4%	—	30.8%	69.2%	—	69.2%
South Africa 5	12.0	13.5%	19.3%	—	32.8%	67.2%	4.0%	63.2%
South Africa 6	12.0	16.8%	2.2%	—	19.0%	81.0%	4.9%	76.1%
Uganda 1	16.8	21.5%	39.3%	—	60.8%	39.2%	—	39.2%
Uganda 2	3.3	16.0%	24.0%	3.0%	43.0%	57.0%	9.0%	48.0%
Uganda 3	6.0	14.3%	4.8%	—	19.0%	81.0%	—	81.0%
Zambia 1	6.8	7.1%	21.0% ^k	0.4%	28.5%	71.5%	—	71.5%
Multi 1	22.2	7.8%	6.3% ^o	—	18.0%	82.0%	—	82.0%
Multi 2	7.0	8.0%	7.0%	—	19.7%	80.3%	0.3%	80.0%
Weighted averages	9.9 ^f	—	—	—	—	77.5% ^m	—	—

Sources: 1. Documented in South Africa by Patten J et al, Clinical and Vaccine Immunology, Feb. 2007

2. Bulletin of the WHO, Volume 86, Number 1, January 2008, 1-80

3. Clinton Foundation report to CIFF, March, 2009

4. Rosen S, Fox MP, Gill CJ. Patient retention in antiretroviral therapy programs in sub-Saharan Africa: a systematic review. PLoS Med 2007 Oct 16;4(10):e298

Key barriers and best practices in PMTCT and Pediatric care and treatment interventions

Common barriers

Best practices

Counseling and testing during pregnancy

- Poor quality of ANC infrastructure
- Stigma and fear of rejection by family
- **Reliance on “opt-in” testing model, resulting in sub-optimal uptake**
- **HIV testing technology slow, highly laboratory-dependent**

- Community based approaches
- **“Opt-out” testing**
- **Rapid HIV test kits to allow same-day results**
- Task shifting among staff

Antiretroviral prophylaxis for HIV+ mothers and support for safe infant feeding

- Logistical difficulties in delivering the most efficacious ARV regimens
- ARV stock outs
- **Introducing new regimens requires revising guidelines, issuing policies, ensuring supply systems, retraining staff, etc.**
- Insufficiently rigorous counseling about feeding options

- Repeat drug dispensation and recurrent counseling
- **Referral mechanisms between laboratory, ANC and ART clinics**
- Improve training on infant feeding for health workers
- **use infant immunization services for postnatal infant feeding assessment, counselling and follow-up nutrition support**

Intra partum testing and prophylaxis

- Unaffordability of facility based delivery
- **No access to testing in labour for untested women delivering at home**
- HIV+ women in delivery wards not offered ARV prophylaxis

- **Incentives for women to deliver in facilities including subsidized delivery fees, transport subsidies, nutrition supplements**
- Links with safe motherhood programmes
- Traditional birth attendants trained and linked to health facilities and trained midwives

Prophylaxis to reduce exposure during B/F?

- Missing linkages between PMTCT and ART such that exposed infants are missed once their mothers drop out
- Limited number of PCR machines at a country level
- **Delays in communicating results to the parent/caregiver**
- **Missing referral networks with other services including nutrition, neonatal health, IMCI, immunization, malaria and TB**
- Limited lab and clinic human resources, as well as training in paediatric-specific skills
- Restricted expansion of paediatric ART access points from urban/tertiary to rural/primary
- Paediatric-friendly drug formulations are needed sooner and at lower prices to address major dosing and supply-chain constraints

- **Leveraging 6-week immunization visit to follow up for other HIV services**
- **Child health cards in Malawi and Rwanda revised to track HIV related information**
- Child health days which integrate HIV testing with delivering other health and nutrition services to children on a large scale
- Provider initiated testing and counselling
- **Establish family-centered services that treat adults and children together, to better assure follow-up**
- **Provide RUTF through ART sites to increase retention and improve outcomes, while integrating HIV-testing at CMAM (community-managed acute malnutrition) service sites to identify older children**

Access to treatment and care for infected children

- ART largely unavailable to women accessing PMTCT
- **ANC, delivery, and postpartum health services are vertical and uncoordinated**

- Institute measures to follow-up HIV+ pregnant women after delivery are essential -- mobilize community leaders for follow-up
- **Adopt a family-centered approach to HIV care and treatment**

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'Big win' achieved by CIFF

The Starting Point

- 2 million children under 15 believed to be living with HIV/AIDS; 270,000 dying annually; 370,000 new infections in 2007
- In 2004/5, only 10,000 children accessing treatment outside Thailand and Brazil largely because of exorbitant drug prices (>\$1,500/child/year)
- Children on treatment mostly using crushed adult tablets
- Practitioners anxious about providing paediatric treatment

CIFF's Investment for Children

- Created a consortium of funders to jointly commit \$4.5M to bulk purchase antiretrovirals (ARVs) for 10,000 children from generics and persuade producers to supply at lower price (\$180/child/year); CIFF assumed risk for on-going treatment until Global Fund or others picked up treatment costs
- Supported Clinton Foundation to expand children accessing ARVs by 75,000 annually by identifying children needing treatment, training and mentoring practitioners, and working with producers to develop fixed dose formulations
- CHAI leveraged initial price decrease to secure additional funds for next wave of commodities purchase via consortia of governments led by France while CIFF and others continued to fund training, identification of children and capacity to treat

Transformation Achieved

By end of 2007, drug costs had fallen by more than 96% under \$50/child/year, making treatment at scale "affordable" and therefore sustainable; 200,000¹ children initiated on treatment

A Snapshot of CIFF's investments in PMTCT to date

Organisation	Country	CIFF Funding Duration	Total committed funding (In US \$ millions)	HIV Prevalence Among Pregnant Women (in the program catchment areas)	Mother-Infant Pairs Targeted	Estimated Baseline MTCT Rate	Target MTCT Rate
CHAI	Lesotho	2008-2010 ¹	14.7	27% ^{1.1}	24 975	15-22% ^{1.1}	10-18% ^{1.1}
	Malawi		6	16.8% ^{1.1}	8 613	19-25% ^{1.1}	11-19% ^{1.1}
	Ethiopia		5.4	3.5%	1 980	27-40%	14-23%
	Tanzania		11.5	9.4%	N/A	20-28%	10-18%
	Cambodia		1.1	1.1%	333	27-41%	11-19%
	Vietnam ²		0.9	0.37% ²	6 000 ²	29-43% ²	10-17% ²
	China ²		2.3	0.4% ²	2 400 ²	12-19% ²	5-9% ²
AMPATH	Kenya	2006-2007	0.3	7%	2 400 ³	22-30%	<5%
MSF	Malawi	2006-2008	1.5	19.8% ⁵	-	19-25%	<15%
PREFA	Uganda	2008-2011	6.1	7.5%	10 524	30%	6.5% ⁴

1. This doesn't take into account CIFF's funding for M&E of these programs that will extend till mid-2013.

1.1 The MTCT estimates are the results of CHAI's modeling based on women who go through ANC and enter PMTCT services today and how the MTCT rates will change once PMTCT interventions are improved upon.

2. Program details are still in negotiations with governments and are subject to change.

3. Reduced down to a cohort of 157 m/b pairs

4. Revised down from 8% as a result of change in PMTCT ART policy in Uganda

5. Based on HIV Sentinel Surveillance Report 2003. Malawi Ministry of Health & Population and National AIDS Commission. November 2003.

'Big win' going forward

The Starting Point

- Of 33 million people living with AIDS today, more than 50% are women and 2 million children
- A majority of infected mothers do not know their infection status due to limited access to testing and diagnosis
- 66% of HIV+ pregnant women are not accessing any prevention and treatment. In the absence of any interventions, 25-40% of pregnant women transmit the infection to their children
- In low and middle income countries, infected mothers are administered sub-optimal drugs for preventing transmission
- Early diagnosis and treatment of infants can avert up to 80% of HIV related deaths before the age of 2 years. However, in 2007, 8% of 1.5 million HIV exposed infants received early testing.
- Currently, 28% of children in need of treatment are receiving it.
- More than half of positive, identified children drop out from the recommended care and treatment, risking their survival

CIFF's Investment for Children

- Assure routine diagnosis of all pregnant women and for those who are HIV-infected with CD4>350, provide the most effective regimens to preserve their own health and to prevent transmission
- Assure early testing and aggressive follow-up of all exposed infants and treatment for those who are found to be infected
- Integrate PMTCT and pediatric care and treatment services with other maternal and child health services to have maximum impact on **HIV free survival**
- Maximize **retention** of children under care and treatment by assuring follow-up and seamless linkages from PMTCT/other entry points to ART centres
- Support efforts to build the evidence base to guide the improvement of national PMTCT and pediatric policies and practices.

Transformative Goal

Maximize the access to, and completion of effective PMTCT and pediatric treatment services to accelerate the reduction in estimated 270,000 annual child deaths due to HIV /AIDS

Guiding assumptions for investments in CIFF's HIV/AIDS portfolio

■ Support programs that:

- i. keep both the mother and baby alive and HIV-free; provide quality care and treatment to both mothers and infants with linkages to other MCH services
- ii. strengthen access, utilization and quality of comprehensive PMTCT services along the entire cascade
- iii. provide mothers with the most effective and safest choices for infant feeding and treatment
- iv. strengthen community support in every phase of the cascade where it has been proven to impact mother and child survival
- v. **measure the impact of PMTCT interventions on HIV free survival**
- vi. build clinical and operational evidence to effect global and national policy and practice change
- vii. build national capacity to scale up and sustain programs

Vision & goals

To avert paediatric HIV infections and ensure HIV free survival for children while keeping mums alive

CIFF aspirations

Maximize pregnant women's access to and uptake of testing, counselling and results

- 80% of pregnant women in the area get tested and receive timely results
- 100% of HIV+ pregnant women are screened for treatment eligibility

Illustrative indicators of success

Provide the most effective ARVs for prophylaxis and treatment

- 100% of infected women with CD4<350 put on Highly active antiretroviral therapy (HAART)
- 80% of women receiving HAART are on care and treatment at 36 months
- 100% of infected women with CD4>350 get WHO prescribed standard ARVs for prophylaxis during ante-natal, intra-partum and post partum to minimise the risk of transmission

Maximize availability and uptake of infant testing, diagnosis and prophylaxis

- 100% of exposed infants get cotrim for prophylaxis at 6 weeks
- 80% of exposed infants get tested and diagnosed at 6 weeks
- 80% of exposed infants get confirmatory testing, post weaning

Provide high quality care and treatment to all infected mothers and children

- 100% of infants identified positive are enrolled in treatment and care
- 100% of all HIV+ women continue to be enrolled in care and treatment
- 100% of older children who test positive are screened for eligibility and initiated on treatment if appropriate
- 100% of exposed infants are alive and HIV free at 24 months of age

Geographical focus on Sub Saharan Africa which bears 90% of global burden of the disease for children

CIFF criteria for investment selection

Demonstrable impact

- Demonstrable, peer reviewed evidence of program's impact
- Potential to measure the impact through rigorous monitoring and evaluation
- Generates evidence on best practices for global advocacy

Scalable intervention

- Reaches significant proportion of potential direct beneficiaries (i.e. coverage)
- Proven capacity to deliver large impact on children- direct, indirect or both combined
- Potential for leverage beyond direct coverage; game changing at least in the regional context, eventually global

Sustainable

- Attractive to co-investors such as ELMA, Norway, Elton John, Global fund, PEPFAR, national governments
- Built upon the gaps in existing infrastructure for creating sustainable, long term solutions
- Potential to get others in the field to adopt best practices
- Realistic exit planning integrated within program strategy from the start

Value for money

- Potential to reduce costs over time as the program achieves scale efficiencies
- Focuses on providing treatment and care to both mothers and children

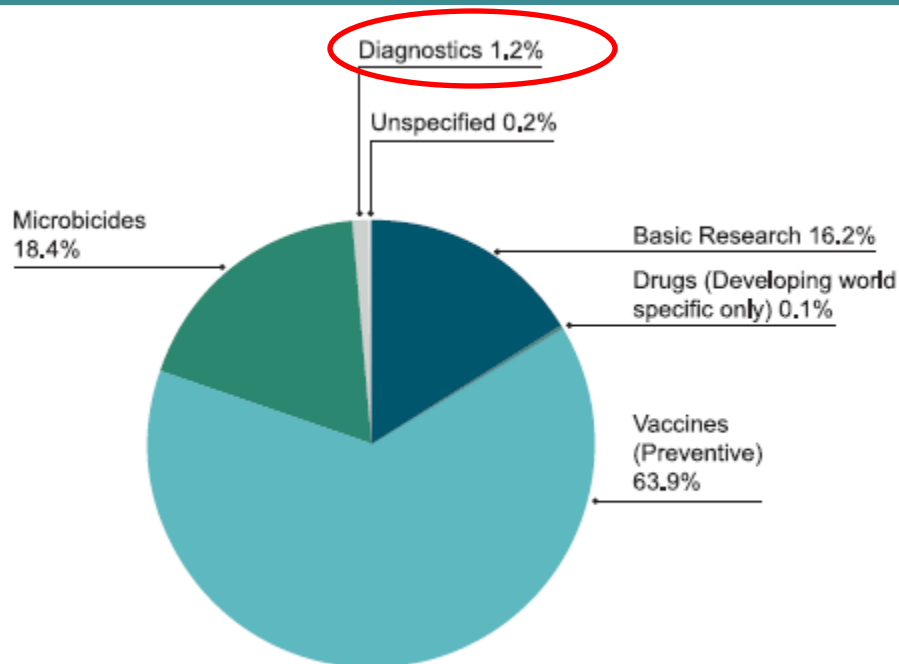
Innovative approach

- Seeks to build evidence for new, promising techniques to achieve success in any or all parts of the cascade
- Innovation may focus on any aspect of the intervention, from the science (e.g., ARV regimens) to service delivery, community support, policy development, etc.

Additional 'big-win' opportunities

1. Accelerate development and implementation of new point of care diagnostics for children and mothers that can be effectively delivered in low-income settings

HIV/AIDS R&D funding by product type in 2007



- New point of care diagnostics, are increasingly being identified as a major barrier in identifying HIV positive children and providing them with timely treatment
- However, only a modest \$12.4 million was spent on R&D for diagnostics in 2007

Source: Health policy division, The George Institute for International Health, 'Neglected disease research and development: How much are we really spending?', 2008

Additional 'big-win' opportunities

2. Universal testing and access to HAART for a population level impact on prevalence and incidence rates with a complete elimination of vertical transmission

■ Potential Approach:

- Universal testing and counselling across a limited geography (1-2 districts) followed by immediate HAART to all those who are found infected
- Use PMTCT to reach out to all HIV positive women and children in the area
- Ensure high adherence

■ Potential impact:

- Population level reduction in new HIV infections over time
- Reduction in MTCT, maternal mortality and infant mortality rates in areas with high prevalence
- Policy change to make universal HAART a recommended standard for prevention and treatment programs