Global Movement for Children

Saving Lives

Children’s right to HIV and AIDS treatment
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EXECUTIVE SUMMARY

A child dies from AIDS related illnesses every minute. Approximately 2,000 children are infected with HIV every day.

Children are silent witnesses to AIDS. Millions of children around the world are affected by the crisis unfolding around them. They watch their families, teachers and community members suffering and dying from this highly stigmatized disease. Ultimately, many children miss out on their own childhoods because of the extra responsibilities they bear and the economic and social insecurity that results from the sickness or death of their parents or caregivers.

HIV-positive children are particularly invisible. Some 2.3 million children under the age of 15 are living with HIV worldwide, the majority of them with no access to any form of care or treatment. Currently, less than 5 per cent of HIV-positive children have access to the paediatric AIDS treatment they desperately need. Without treatment, most children with HIV will die before their fifth birthday. Children account for only 14 per cent of overall HIV infections, but they represent 18 per cent of all AIDS deaths. Over 90 per cent of children living with HIV live in sub-Saharan Africa. These children also have the least access to any treatment – either to prevent infection or to combat the disease, an inequity with disastrous consequences, as AIDS has already caused infant mortality in Africa to increase by more than 19 per cent, and contributes strongly to increases in under-five mortality in this region as well. Unless the world takes urgent account of the specific impact of AIDS on children there will be no chance of meeting Millennium Development Goals (MDG) 6 – to halt and begin to reverse the spread of the disease by 2015. Failure to meet the goal on HIV and AIDS will adversely affect the world’s chances of progress on the other MDGs.

The deaths of these children are not inevitable. HIV-positive children can and do respond to antiretroviral treatment. They must be given their chance at life.

All around the world, communities are providing the front line response to AIDS. However, they cannot respond alone; more direct support from governments and the international community is urgently needed. Currently, very few children orphaned or made vulnerable by HIV and AIDS outside of Eastern Europe receive any kind of public support. Responding to the crisis among children is clearly not seen as a global priority yet.

International and national commitments to fight HIV and AIDS have gained momentum over the last two decades - between 2002 and 2004 alone, AIDS funding nearly tripled. However, the commitments still fall far short of needs, and children in particular do not explicitly appear in AIDS funding commitments. Coordinated action must be taken now to PROTECT the rights of children infected with HIV and to INVEST in their future.
Protect children

- **Treatment for all by 2010.** The international community must uphold the commitment to universal treatment by 2010 and recognize that children have specific treatment needs. This includes providing HIV-positive women with appropriate interventions to prevent mother-to-child transmission; ensuring access to cotrimoxazole preventive treatment for infants born to HIV-infected mothers, and ensuring access of all children to antiretroviral treatment. This last item may require using the flexibilities provided in the World Trade Organization’s Doha Ministerial Conference on trade-related aspects of intellectual property rights (TRIPS) for the acquisition of antiretroviral medicines.

- **Child specific treatment targets.** National governments and international bodies must be held responsible for immediately increasing the numbers of children on antiretroviral treatment. This includes recognizing children’s right to antiretroviral treatment as a fundamental human right, explicitly including children in national and international treatment targets, committing donor funds to meeting these targets; and ensuring children are included when monitoring progress.

Invest in the future

- **Child-focused research and development.** Governments, donors and pharmaceutical companies must, respectively, support and produce antiretroviral treatment appropriate for young children. There is a pressing need to develop simple and affordable diagnostic tests for young children to ensure early identification of infection, increase child-focused research and development, and produce affordable, fixed-dose combination antiretroviral drugs for young children.

- **Improve health care systems of poor countries.** National governments and international donors must work together to improve the health-care systems of poor countries in order to support drug treatment for all. National governments must make the health-care sector a top priority in budgets, international donors must increase investment in the development of health care systems, and health professionals must be trained to meet children’s treatment needs.

Drug treatment needs for children are well known. By mid-2005, nearly 700,000 children needed antiretroviral therapy and 4 million needed cotrimoxazole prophylaxis, a life-prolonging antibiotic. Treatment is not just drug therapies. Meeting the treatment needs of children requires a comprehensive package of care and support. While this paper will focus on the drug treatment needs of children, we recognize that drug treatment is only one part of the solution. But as long as drug treatment for HIV-positive children remains inadequate, their overall treatment needs cannot be met.
PROTECT CHILDREN

CALL TO ACTION: TREATMENT FOR ALL BY 2010

- Provide services to all women to prevent mother to child transmission.
- Ensure children access to cotrimoxazole.
- Accelerate the availability of antiretroviral treatment, applying as necessary the safeguards included in the WTO Doha Ministerial Declaration to ensure the acquisition of antiretroviral medicines.

During the 2005 G8 Summit and UN World Summit, leaders worldwide committed to come as close as possible to providing lifesaving anti-retroviral treatment to all adults and children who need it by 2010. For this commitment to be upheld, national and international leaders must recognize the unique treatment needs of children.

Provide services to all women to prevent mother to child transmission

The rapidly increasing number of HIV positive children is driven by a failure to prevent mother to child transmission (MTCT). Without services to prevent MTCT, about 35 per cent of infants born to HIV positive mothers will acquire the virus during pregnancy, labour, delivery or breastfeeding. Globally, 90 percent of all
HIV positive children are infected through MTCT\textsuperscript{16}.

We do not lack preventative measures or knowledge of how to prevent transmission. Evidence from North America and Europe shows that providing a mother with a full range of preventive mother-to-child transmission services can reduce the risk of transmission to less than 2 per cent\textsuperscript{17}.

Currently, less than 10 per cent of HIV positive pregnant women received drug therapies to prevent passing on infection to their infants\textsuperscript{18}. This is a gross violation of the rights of both these women and their children.

**Ensure children access to cotrimoxazole**

Cotrimoxazole is highly effective in preventing life-threatening opportunistic infections in HIV infected children\textsuperscript{19}. For example, a study in Zambia found up to a 43 per cent drop in mortality when HIV infected children had access to cotrimoxazole alone\textsuperscript{20}. Because HIV is more aggressive in children, they are highly prone to opportunistic infections, particularly during the first few months of life when HIV diagnosis in children is extremely difficult. Given these realities, cotrimoxazole is recommended for all children born to HIV infected mothers until the HIV status of the child is confirmed negative. As of June 2005, an estimated 4 million children needed this life saving treatment\textsuperscript{21}, costing less than three cents of a dollar a day per child\textsuperscript{22}. This is a small price for saving many lives.

**Accelerate the availability of antiretroviral treatment, applying as necessary the safeguards included in the WTO Doha Ministerial Declaration to ensure the acquisition of antiretroviral medicines**

To ensure treatment for all, governments must be able to purchase and distribute antiretroviral medicines to children, including appropriate paediatric formulations for children less than 3 years old. The special requirements of young children must be met.

Patents must not be allowed to create a barrier to antiretroviral treatment for children. Patents were intended to encourage invention and creativity. Patent protection is provided by the 1994 World Trade Organization (WTO) agreement on trade-related aspects of intellectual property rights (TRIPS)\textsuperscript{23}. However, due to public health concerns and sustained campaigning by civil society, some flexibility to TRIPS is contained in the 2001 Doha Ministerial Declaration. Least developed country members of WTO have the option of postponing compliance to TRIPS until 2016. More generally, under compulsory licensing, a government can cite ‘public interest’ to allow generic drugs to be produced without the agreement of the patent holder. Alarmingly, trade pressures have made governments reluctant to postpone compliance or cite ‘public interest’ to override patent laws. Furthermore, bilateral trade agreements pushing for increased levels of patent protection can undermine the ability of developing country governments to exercise the flexibilities of the Doha Declaration.

Governments must be supported in applying the flexibilities allowed under the Doha Declaration on the TRIPS agreement for the sake of public health,
promote widespread availability of adult formulations of antiretroviral drugs for older children and the development and production of generic paediatric formulations for younger children.

Patent holders have increasingly been willing to provide voluntary licenses to allow for generic production of antiretroviral drugs, and this development should be encouraged to ensure that royalties are kept low, so prices are not unduly elevated.

While young children in developing countries have the greatest need for treatment, they also give the least financial incentive to pharmaceutical companies. There is increasing recognition in the pharmaceutical industry, however, that paediatric formulations of antiretroviral drugs will not necessarily be profitable over the long term. The greater the success in preventing mother-to-child transmission, the lower the demand will be for paediatric formulations. Nevertheless, industry must ensure that they invest in paediatric formulations so young children are not simply left to die.

Several companies have begun to develop and produce paediatric formulations of fixed-dose combinations (FDCs) of antiretroviral drugs. The international community must encourage the pharmaceutical industry to accelerate this development and production and ensure accurate forecasting of demand and long-term sustainable financing to allow universal access to treatment.

**ACT NOW to ensure treatment for all by 2010:**

Governments must:

- Ensure equitable access to a comprehensive package of services to prevent mother-to-child transmission designed to meet the context-specific needs of mothers and their children;

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**Treatment in action: One child’s story**

Kirabo, aged 6, lost both her parents to AIDS and was herself infected through mother to child transmission.

Before free antiretroviral treatment became available in Kampala, she suffered from a virus that causes facial disfigurement. Kirabo was discriminated against in her community because of her appearance and frequent illness. Despite this, she still desperately wanted to go to school.

When antiretroviral drugs became available, Kirabo was put onto treatment at the Mildmay Centre in Uganda, 12 kilometres outside of Kampala on the Kampala-Entebbe road. She responded very well, and within six months she was like any other child, in good health and going to school without fear of facing stigma and discrimination.

Unfortunately, Kirabo’s only caregiver was her grandmother. When her grandmother died, Kirabo was taken in by her extended family outside of Kampala. She is no longer able to access her treatment and has dropped out of care. Treatment must be available to all who need it regardless of location.
Provide cotrimoxazole to all children known to be HIV-positive and to all those born to HIV-positive mothers until their HIV status is determined;

Exercise the TRIPS flexibilities in order to ensure treatment for all.

Donors must:

Provide resources, technical assistance and new medicines to scale-up prevention of mother to child programmes;

Invest resources in providing cotrimoxazole for all children in need;

Encourage developing countries to make use of TRIPS flexibilities, including providing technical assistance on the use of existing flexibilities, and, where feasible, helping develop domestic generic manufacturing capacity.

Industry must:

Invest in the development and production of paediatric formulations of antiretroviral drugs;

Engage in the granting of voluntary licenses to allow generic production of antiretroviral drugs.

CALL TO ACTION: CHILD SPECIFIC TREATMENT TARGETS

- Recognise that children's right to treatment is a fundamental human right;
- Explicitly include children in national and international initiatives.

In 2005, approximately 1 million people in low- and middle-income countries received antiretroviral treatment, living longer and better lives. While this shows important progress, treatment needs are far from met. Globally, less than 5 per cent of children in need are receiving any kind of treatment.

**Recognize that children's right to treatment is a fundamental human right**

In 2001, United Nation Member States pledged to increase the world's response to AIDS using a human rights framework. Recognizing children's right to treatment is essential to upholding this commitment.

Children's right to treatment is specifically outlined in the 2003 General Comment 3 on HIV and AIDS and the rights of the child issued by of the Committee on the Rights of the Child (see box). Ultimately, it is the responsibility of signatory governments to uphold a child's right to prevention, care and treatment.

Children can and do respond to treatment. Where treatment is available, more than 80 per cent of children live to see their sixth birthday. Some children are surviving until their twenties. Denying children the right to treatment denies them the right to survival, growth and development.
Explicitly include children in national and international initiatives

In order to ensure universal access to treatment and uphold the human rights of children, children must be explicitly included in treatment targets.

Governments are failing to prioritise children in national antiretroviral targets. Globally, less than 5 per cent of children in need receive anti-retroviral therapy (ART). Proportionally, more positive children than positive adults require treatment. For equitable access based on treatment need children should make up at least 13 per cent of the total number receiving ART.

Some progress is being made. Children are beginning to receive some attention. In Malawi, children make up 5 per cent of those on ART, while in Mozambique the number is 6 per cent. Swaziland has developed guidelines for providing antiretroviral therapy that include treatment for children. The explicit consideration of children is crucial - treatment targets will result in treated children.

The treatment needs of children cannot be met without substantial donor funding. By mid 2005, 700,000 children were in urgent need of ART. Another 4 million needed cotrimoxazole. To ensure children’s needs are met, stakeholders must be held accountable to providing treatment for children. Donors must support treatment targets that are equitably disaggregated by gender and age. However, the fight against AIDS will not be won if the needs of children are ignored.

ACT NOW to hold stakeholders accountable for treating children.

Governments must:
- Include children in national treatment targets;
- Track treatment distribution by gender and age.

Donors must:
- Hold governments responsible for formulating and meeting child-specific treatment targets;
- Commit funds to supporting governments in the realisation of national treatment targets.

International organisations and UN Agencies must:
- Explicitly include children in international treatment initiatives;
- Hold national partners responsible for meeting treatment targets.

Article 25 of General Comment 3 on HIV and AIDS and the Rights of the Child

The obligations of States parties under the Convention extend to ensuring that children have sustained and equal access to comprehensive treatment and care, including necessary HIV-related drugs, goods and services on a basis of non-discrimination... States parties should negotiate with the pharmaceutical industry in order to make the necessary medicines available at the lowest costs possible at local level.

Committee on the Rights of the Child (January, 2003)
INVEST IN THE FUTURE

CALL TO ACTION: CHILD-FOCUSED RESEARCH AND DEVELOPMENT

- Develop simple and affordable diagnostic tests;
- Increase research and development for child specific treatment needs;
- Produce fixed dose combinations for young children.

Currently, market pressures and financial incentives are given priority over children’s needs, and the ‘lack of a market’ masks the violation of children’s basic human right to child-appropriate treatment.

Develop and make available simple and affordable diagnostic tests

Treatment cannot start without clear diagnosis. The most commonly available and easy to use diagnostic test is inaccurate in children under 18 months of age\(^3\),\(^2\). Infant diagnosis requires a complicated test measuring the presence of the HIV virus\(^3\),\(^3\). Unfortunately, these tests require technical expertise as well as costly equipment, placing them out of reach of poor countries\(^3\),\(^4\).

According to Médecins Sans Frontières, up until 2005, multinational companies that produce diagnostic tests had shown little interest in developing accurate, simple, fast and affordable tests for diagnosing HIV infection in children\(^3\),\(^5\) or in supporting
national owned initiatives. Without treatment, up to 60 per cent of HIV infected children will die before their second birthday\textsuperscript{36} - delayed diagnosis and treatment is simply not an option.

**Increase research and development for child specific treatment needs**

Despite an urgent need for paediatric formulations, child-appropriate treatment is sorely lacking. Alarmingly few drugs in the current World Health Organization’s ART guidelines are available in formulations that are affordable, feasible or acceptable for use in young children\textsuperscript{37}.

The limitations of current formulations are substantial:

- Most paediatric formulations are available either in liquid form - raising issues of volume measurement, palatability and refrigeration - or in a powder form - which must be mixed with clean water;
- Some tablet and capsule formulations are available only for adult consumption, forcing practitioners to chop or crush them;
- Many drugs have adverse side effects that make administration to children much more difficult;
- As children grow and develop, their treatment needs rapidly change. However, there is a lack of information on dosing and efficacy of ARTs in young children\textsuperscript{38};
- Even with access to first line-regimes, expensive second-line drugs must be available to address issues of resistance and intolerability.

The lack of research and development means that treatment of children is often imprecise. Health care workers and caregivers are forced to make do with what is available, often crushing adult tablets and estimating doses. This is complex for the caregiver and imprecise for the child, reducing lifesaving treatment to a guessing game.

Second-line therapies are far more expensive for children than for adults. In the least developed countries and in sub-Saharan Africa, where antiretrovirals are most needed, when second-line drugs are available, they are 6 to 12 times more expensive than first-lines\textsuperscript{39}. This reality fundamentally limits treatment options for children.

**Produce fixed dose combinations for young children**

The development of new drugs has focused mainly on adults. To date, there has been little investment in drugs specifically for children. This is seen clearly in fixed-dose combination (FDC) drugs.

FDCs simplify treatment and increase adherence. Some FDC pills available for adult use combine three drugs, enabling patients to take one pill twice a day. This simple treatment regime would be of great benefit to children and their caregivers.

Despite the advantages of FDCs and positive clinical trials (see box), these combinations are largely unavailable for children and none of the FDCs currently on the market has been tested or formulated for use in children\textsuperscript{40}.

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**A study from Uganda** has looked at the feasibility and effectiveness of generic FDC tablet (Triomune) in HIV positive children. 81 children were given Triomune as a first line regime. The preliminary data clearly illustrates that the use of fixed dose combination pills in HIV infected children is feasible and effective. CD4 count significantly increased and viral load significantly decreased during the first 48 weeks of treatment.

The study highlighted the cost of drugs as well as lack of suitable formulations, HIV diagnostic tests, and knowledge of ART in children as barriers to treatment.

Barlow-Mosha 2005
ACT NOW to invest in child focused research and development

Pharmaceutical and diagnostic companies must
- Give children's rights priority over market interests;
- Develop and make available simple and affordable diagnostic tests for infants;
- Increase research and development for child-specific needs;
- Produce fixed-dose combination antiretroviral therapy for young children.

Donors must
- Invest resources in research and development for child-specific treatment needs, including simple and affordable diagnostic tests and fixed-dose combination antiretroviral therapy for children.

CALL TO ACTION: IMPROVE HEALTH CARE SYSTEMS OF POOR COUNTRIES TO DELIVER DRUG TREATMENT

- Make the health-care sector a top priority in national budgets.
- Increase donor investment in the development of health care systems.
- Train health-care professionals to meet children’s treatment needs.

Drug therapy will not work in isolation. All care and treatment must be supported by a strong health-care system providing essential health services, including care and support.

Make the health-care sector a top priority in national budgets

Governments must make health care a top priority in national budgets. Across Africa, this means upholding the Abuja Declaration on HIV and AIDS, in which African states set a target of allocating at least 15 per cent of their annual national budgets for the improvement of health care to help address the HIV and AIDS epidemic, a commitment that has thus far been largely unmet. Currently, a third of countries in Africa have allocated 10 per cent or more of their national budgets to health care, while 38 per cent have allocated 5–10 per cent and 29 per cent have allocated below 5 per cent.

Until health services are made a top priority, health-care systems will continue to struggle to support treatment needs, and treatment goals will be missed. Health care must be made a priority in national budgets if we are to save lives.

Increase donor investment in the development of health care systems

International donors and multilateral agencies (e.g., the World Health Organization, the World Bank, the United Nations Development Programme) must work with national governments to strengthen health-care systems. A strong health-care system will meet both the diagnostic and treatment needs of children:
Technical investment is essential for initial diagnosis, treatment at the primary health-care level and ongoing monitoring of therapies.

Adequate numbers of staff trained to meet children’s needs are crucial for ensuring quality of care for children;

Access to drug therapies cannot be assured without a robust health-care system, including effective procurement, adequate supply chain and comprehensive monitoring and evaluation.

Weak health-care systems are unable to respond to opportunistic infections that plague children with underdeveloped immune systems. Yet, appropriately caring for childhood illnesses can delay the need for antiretroviral treatment. Furthermore, the health-care system must be able to respond to the management of pain and to side effects that arise with therapy.

The lack of effective health-care systems raises serious concerns about sustaining adherence to drug therapies because of inadequate follow-up support. Resistance to ART develops quickly if drug regimes are not carefully followed. When resistance develops, second-line drugs must be given. Currently, in countries with large numbers of HIV-infected children, there are very few, and only very expensive, second-line treatments available for children43.

Already weak health-care systems are buckling under the strain of the pandemic. It is the responsibility of the international community to provide crucial support to national governments to strengthen these failing systems and to protect the rights of all children.

Train health professionals to meet children’s treatment needs

Treating children is different from treating adults. Given the lack of research and development into children’s diagnostics and treatment, health-care workers often find themselves uninformed and unsupported, making do with what is available.

While international guidelines are essential for streamlining the treatment of children, these need to be adapted locally. Also, health professionals must be trained to respond adequately to the care needs of children.

Trained health-care professionals also provide essential support to communities engaged in fighting the pandemic, including working with caregivers to meet the daily needs of their children.

ACT NOW to strengthen health care systems

Governments must

- Make the health-care sector a top priority in national budgets;
- Provide health-care professionals with comprehensive treatment guidelines and training packages on treating HIV-positive children as an integral part of the treatment response.

Donors must

- Increase investment in the development of health care systems;
- Provide financial support for national health professional training packages.
Treating a child is more than tablets and syrups. Carers of HIV positive children must address difficult issues, including:

- Who decides a child should be tested?
- When and how should the child be told that they are living with HIV?
- How do carers address the different emotional needs of children?

Emotional support is essential for all children. Some children may feel angry when they learn they are HIV-positive. At the same time, they may be living with a mother who is ill and feel anxious for her as well as for themselves. Some children have contracted HIV through abuse, and there is little support or counselling for these children. Older children who contract HIV sexually need to discuss their feelings towards sex and their own sexuality. There are also many issues of stigma and discrimination, access to education and the ability to interact safely with other children.

In South Africa, Save the Children is developing a training module to sensitize home-based caregivers to the needs of children. Home-based caregivers will be encouraged to be open with children, listen to them, and offer a treatment package that includes nutrition, opportunities to interact with other children and strong psychosocial support.
CONCLUSION

The human rights of children are severely threatened in a world with HIV and AIDS. Stigma and discrimination, economic insecurity and growing burdens of care on families and communities all increase the vulnerability of children. Children also find themselves taking on caregiver roles, losing their childhood under the burden of HIV and AIDS.

The invisibility of HIV-positive children dramatically increases their vulnerability. Every minute, a child dies of AIDS-related illnesses. Without treatment, most HIV-positive children will die before they are five. The time for action is now.

We are failing children.

The international community has committed to fighting HIV and AIDS. We have committed to treatment and believe children and adults have a right to this treatment and support. We have increased the available resources. But, to date, we have ignored the needs of children.

Governments alone cannot respond to the myriad problems created by the pandemic. However, with common objectives, governments and donors can generate resources and expand partnerships crucial to protecting the rights of all children.

Protect children

- Treatment for all by 2010 must recognize children’s unique needs. The international community must prevent mother-to-child transmission, provide cotrimoxazole, and ensure access of all children to antiretroviral treatment, using as needed the flexibilities provided in the WTO Doha Ministerial Conference on trade-related aspects of intellectual property rights (TRIPS) for the acquisition of antiretroviral medicines.

- Child-specific treatment targets will ensure equitable access for children. It is essential to recognize treatment as a human right, explicitly include children in all treatment targets and commit donor funding to meeting these targets.

Invest in the future

- Research and development is urgently needed for children. Governments and donors must support pharmaceutical companies in developing simple and affordable diagnostic tests, increasing research and development for child-specific needs and producing paediatric fixed-dose combinations.

- Treatment for all by 2010 requires strong health-care systems. National governments and international donors must work together to make the health-care sector a top priority in national budgets, invest in the development of health-care systems and train health-care professionals to meet children’s treatment needs.

Only by acting now can we save the most vulnerable victims of HIV and AIDS. We can protect these children, and we owe it to them to invest in their future.
ABOUT THE REPORT

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REFERENCES


3. In this paper, children are defined as between the ages of 0 and 18.


5. UNICEF and UNAIDS, A Call to Action: Children, the Missing Face of AIDS, op. cit.

6. Ibid.


8. Ibid.


14. The focus of this paper is on drug treatment. As such, treatment will from now on refer to drug treatment.


17. UNICEF and UNAIDS, A Call to Action: Children, the Missing Face of AIDS, op. cit.


20. Ibid.

21. Ibid. Estimate of all children who are known to be HIV positive or who are born to positive mothers but whose own status is unknown.

22. UNICEF and UNAIDS, A Call to Action: Children, the Missing Face of AIDS, op. cit.


28. Ibid.

29. Ibid.


32. The Elisa test is an HIV anti-body test that measures the body's immune system response following infection. It is not accurate in children under 18 months because maternal antibodies can still be in the child's body until this time.

33. HIV DNA Polymerase Chain Reaction tests (PCR) – for more information see www.aidsmap.com.


35. Ibid.


38. Ibid.


