

# WHO-Facts Sheet

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## 1. CHILD-SPECIFIC MEDICINES, A GLOBAL PRIORITY

Reducing child mortality and treating children affected by major diseases are global priorities expressed in the Millennium Development Goals (Goals Four and Six <http://www.un.org/millenniumgoals>). A pre-condition to achieve these goals is increased production and availability of essential medicines for children. At present, many medicines for priority diseases are not developed for children; and when they are, they are not reaching the children who need them most.

Children metabolize medicines differently from adults. They therefore need different dosage forms. Differences also exist between children of different ages, body weight and physical conditions. Child-specific medicines are those manufactured to suit the age, physical condition and body weight of the child taking them.

Apart from dosage, child specific medicines need to be in a format that is palatable to children. Small children have trouble swallowing big tablets but can tolerate oral solution or syrups. For children with chronic conditions such as HIV/AIDS, where several medicines must be taken daily, the fixed-dose combination approach - several medicines in one pill - is best. However, the few existing paediatric fixed dose combinations developed for children are generally three times more expensive than the adult dosage form.

### Research and development gaps

There is little knowledge about the effects certain medicines can have on children. This is partly due to the fact that fewer clinical trials are conducted in children than in adults. The ethical approach

to conducting clinical trials is to obtain signed informed consent from volunteers before they take part in a trial. Obtaining informed consent from a child - particularly in the younger age bracket - is clearly difficult. Insufficient clinical trials for paediatric medicines in turn lead to information gaps related to quality and safety. Those gaps deter pharmaceutical companies from researching and developing child-friendly medicines and generics companies from producing them at lower cost.

In addition, children are generally a silent sector of the population, relying on others to speak for them - they do not vote, they do not buy and generally do not have a public voice in society. Although they would benefit from more pharmaceutical research and development, they do not have the means to demand it.

### Distribution problems

Child specific medicines already developed and available, often do not reach the children who need them most. For instance, diarrhoea, which can easily be treated with oral rehydration salts plus zinc, still kills 1.9 million under-fives every year. Oral rehydration salts are easy to use, easy to manufacture and relatively inexpensive. Due to years of advocacy campaigns, they are widely available in developing countries. Zinc, on the other hand, is not easily found in areas with a high incidence of diarrhoeal disease. Oral rehydration solution with zinc is more effective than without it. There may be numerous, poverty-related causes for the fact that children are still dying of diarrhoeal diseases, but one obvious reason is that the full remedy - rehydration salts plus zinc - is not made available to them.

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### The target diseases

WHO estimates that of all the child killers, five conditions in particular demand immediate action:

- **Pneumonia and other acute lower respiratory infections**

An estimated 20% of all deaths in children under-five are due to acute lower respiratory infections, representing the single most important cause of infant mortality worldwide. Pneumonia alone causes approximately 2 million deaths every year which could be prevented with proper access to child-specific medicines.

- **HIV/AIDS**

Although contributing to only about 3% of all annual deaths in children under-five, paediatric HIV is a growing public health challenge. Every day, an estimated 1150 children become infected.

- **Malaria**

An estimated 1 million children die every year due to malaria infection and 40% of the world's children live in malaria-endemic countries. In Africa, a child dies of malaria every 30 seconds. Although malaria is a priority illness and has been the subject of numerous global conferences and calls to action, the issues of access to and development of child specific treatment need to be further addressed.

- **Diarrhoeal diseases**

An estimated 1.9 million children under five die each year from diarrhoea and related complications. This amounts to 18% of all under-five deaths and means that more than 5000 children die every day as a result of diarrhoeal diseases, which can be treated easily and effectively.

- **Tuberculosis**

About 1.1 million (12%) of the 8.8 million new tuberculosis cases in 2005 occurred in children under 14 years of age.

### Lymphatic filariasis and schistosomiasis

Although not major killers of children, the neglected tropical diseases filariasis and schistosomiasis are also prioritized by WHO because of gaps in either the development or accessibility of medicines. WHO estimates that 330 million children under 15 years of age currently require chemotherapy to prevent Lymphatic Filariasis in endemic areas (Asia, Pacific, Africa and South America). Another 125 million children in the same age category require preventive treatment for

schistosomiasis. The necessary medicines exist in paediatric form but are hardly available or accessible to the targeted populations.

### WHO action

Recognizing the lack of child specific medicines, the Member States of WHO passed a resolution on "Better Medicines for Children" during the 2007 World Health Assembly, the Organization's annual meeting.

In order to explore ways to promote more research and development into paediatric medicines and to improve knowledge on the quality, effectiveness and safety of these medicines, WHO created an Expert Sub-Committee to develop an essential medicines list for children. The list, finalized and published in December 2007, consists of 206 medicines, including anti-AIDS treatment, vaccines, anaesthetics, hormones, vitamins and minerals.

The list should serve as a reference for countries to develop national lists according to their specific public health priorities, and is the beginning of a longer process to ensure that child specific medicines are developed and delivered to the intended patient group.

The initial objective of WHO's work in this area is to tackle HIV/AIDS, malaria, tuberculosis, pneumonia and diarrhoeal diseases, which account for over 50% of under-five mortality.

More specifically, WHO will work towards the following objectives:

- Increase additional and independent studies on the development of paediatric medicines and their efficacy and safety;
- Provide better information on child specific medicines to prescribers, pharmacists and health workers;
- Explore ways of fast-tracking the regulation of quality paediatric formulations;
- Establish systems for ensuring that health facilities have adequate stocks of essential medicines and clinical consumables for children;
- In the absence of clinical trials, identify safety and efficacy indications for which essential medicines may be used in paediatric formulations;
- Improve infrastructure and equipment to store liquid paediatric formulations which are less stable than solid dosages;
- Monitor the use of unlicensed, off-label and unsafe medicines for children.

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## 2. GLOBAL HIV PREVALENCE HAS LEVELLED OFF

### Improvements in surveillance increase understanding of the epidemic, resulting in substantial revisions to estimates

New data show global HIV prevalence—the percentage of people living with HIV—has levelled off and that the number of new infections has fallen, in part as a result of the impact of HIV programmes. However, in 2007 33.2 million [30.6 – 36.1 million] people were estimated to be living with HIV, 2.5 million [1.8 – 4.1 million] people became newly infected and 2.1 million [1.9 – 2.4 million] people died of AIDS.

There were an estimated 1.7 million [1.4 – 2.4 million] new HIV infections in sub-Saharan Africa in 2007 - a significant reduction since 2001. However, the region remains most severely affected. An estimated 22.5 million [20.9 – 24.3 million] people living with HIV, or 68% of the global total, are in sub-Saharan Africa. Eight countries in this region now account for almost one-third of all new HIV infections and AIDS deaths globally.

Since 2001, when the United Nations Declaration of Commitment on HIV/AIDS was signed, the number of people living with HIV in Eastern Europe and Central Asia has increased by more than 150% from 630 000 [490 000 – 1.1 million] to 1.6 million [1.2 – 2.1 million] in 2007. In Asia, the estimated number of people living with HIV in Viet Nam has more than doubled between 2000 and 2005 and Indonesia has the fastest growing epidemic.

These findings were released today by the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the World Health Organization (WHO) in the report '2007 AIDS Epidemic Update'.

### Continuing improvements to latest estimates

The new report reflects improved and expanded epidemiological data and analyses that present a better understanding of the global epidemic. These new data and advances in methodology have resulted in substantial revisions from previous estimates.

While the global prevalence of HIV infection—the percentage of people infected with HIV - has levelled off, the total number of people living with HIV is increasing because of ongoing acquisition of HIV infection, combined with longer survival times, in a continuously growing general population.

Global HIV incidence - the number of new HIV infections per year - is now estimated to have peaked in the late 1990s at over 3 million [2.4 – 5.1 million] new infections per year, and is estimated in 2007 to be 2.5 million [1.8 – 4.1 million] new infections, an average of more than 6 800 new infections each day.

This reflects natural trends in the epidemic, as well as the result of HIV prevention efforts.

The number of people dying from AIDS-related illnesses has declined in the last two years, due in part to the life prolonging effects of antiretroviral therapy. AIDS is among the leading causes of death globally and remains the primary cause of death in Africa.

"These improved data present us with a clearer picture of the AIDS epidemic, one that reveals both challenges and opportunities," said UNAIDS Executive Director Dr Peter Piot. "Unquestionably, we are beginning to see a return on investment—new HIV infections and mortality are declining and the prevalence of HIV levelling. But with more than 6 800 new infections and over 5 700 deaths each day due to AIDS we must expand our efforts in order to significantly reduce the impact of AIDS worldwide."

### Revision of estimates

UNAIDS, WHO and the Reference Group on Estimates, Modelling and Projections have recently undertaken the most comprehensive review of their methodologies and monitoring systems since 2001. The epidemic estimates presented in this year's report reflect improvements in country data collection and analysis, as well as a better understanding of the natural history and distribution of HIV infection. This information is vital in helping countries understand their epidemics and respond to them more effectively.

UNAIDS and WHO are now working with better information from many more countries. In the past few years a number of countries, most notably in sub-Saharan Africa and Asia, have expanded and improved their HIV surveillance systems, conducting new, more accurate studies that provide more precise information about HIV prevalence than earlier studies. In addition, 30 countries mostly in Africa have conducted national representative population-based household surveys. These have also informed adjustments for other countries with similar epidemics that have not conducted these surveys. New assumptions have also been made as a result of a better understanding of the natural history of untreated HIV infection.

The current estimate of 33.2 million [30.6 – 36.1 million] people living with HIV replaces the 2006 estimate of 39.5 million [24.5–47.1 million]. Applying the improved methodology retrospectively to the 2006 data, the 2007 report revises that figure, now estimating that in 2006 there were 32.7 million [30.2 – 35.3 million] people living with HIV. The single biggest reason for the reduction in global HIV prevalence figures in the past year was the recent revision of estimates in India after an intensive

reassessment of the epidemic in that country. The revised estimates for India, combined with important revisions of estimates in five sub-Saharan African countries (Angola, Kenya, Mozambique, Nigeria, and Zimbabwe) account for 70% of the reduction in HIV prevalence as compared to 2006 estimates.

“Reliable public health data are the essential foundation for an effective response to HIV/AIDS”, said WHO’s HIV/AIDS Director Dr Kevin De Cock. “While these new estimates are of better quality than those of the past, we need to continue investing more in all countries and all aspects of strategic information relating to health.”

“The data for measuring the HIV epidemic used by UNAIDS/WHO has considerably expanded and improved in recent years,” said Ron Brookmeyer, Professor of Biostatistics and Chair of the Master of Public Health Program, The Johns Hopkins Bloomberg School of Public Health. “Nevertheless, there is a need to further improve the representativeness of the underlying data. There is a need to expand disease surveillance systems to better track the sub-epidemics in risk populations within each country.”

“More accurate estimates and trends will ultimately lead to improvements in the design and evaluation of prevention programmes,” added Professor Brookmeyer, who was also the Chair of the Independent Review Panel at the recent International Consultation on epidemiological estimates convened by UNAIDS and WHO. UNAIDS and WHO will continue to update their methodology as new data becomes available from research studies and surveillance data from countries.

#### **Progress seen but more needs to be done**

HIV prevalence among young pregnant women (15 – 24), attending antenatal clinics, has declined since 2000/2001 in 11 of the 15 most-affected countries. Preliminary data also show favorable changes in risk behavior among young people in a number of countries (Botswana, Cameroon, Chad, Haiti, Kenya, Malawi, Togo, Zambia, and Zimbabwe). These trends suggest that prevention efforts are having an impact in several of the most affected countries.

In sub-Saharan Africa, continued treatment scale-up and HIV prevention efforts are also bringing results in some countries, but mortality from AIDS remains high in Africa due to the extensive unmet treatment need. Cote d’Ivoire, Kenya and Zimbabwe, among others, have all seen downward trends in their national prevalence. Beyond sub-Saharan Africa, declines in new HIV infections have also occurred in South and South-East Asia, notably in Cambodia, Myanmar and Thailand.

There is a need to adapt and revive HIV prevention efforts as some countries are seeing a reversal of declining trends. Burundi’s declining trend from the late 1990’s did not continue beyond 2005 and HIV prevalence started to increase again at most surveillance sites. Despite achievements in reversing the epidemic in Thailand, HIV prevalence is rising among men who have sex with men and has remained high among injecting drug users over the past 15 years, ranging between 30% to 50%.

UNAIDS and WHO officials point out that the new estimates do not change the need for immediate action and increased funding to scale up towards universal access to HIV prevention, treatment, care and support services.

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### **3. STATUS OF GLOBAL EFFORTS AGAINST TOBACCO AND WHO’S POLICY PACKAGE**

The World Health Organization (WHO) released new data showing that while progress has been made, not a single country fully implements all key tobacco control measures, and outlined an approach that governments can adopt to prevent tens of millions of premature deaths by the middle of this century.

In a new report presenting the first comprehensive analysis of global tobacco use and control efforts, WHO expressed that only 5% of the world’s population live in countries that fully protect their population with any one of the key measures that reduce smoking rates. The report also revealed that governments around the world collect 500 times more money in tobacco taxes each year than they spend on anti-tobacco efforts. It finds that tobacco taxes, the single most effective strategy, could be significantly increased in nearly all countries, providing a source of sustainable funding to implement and enforce the recommended approach, a package of six policies called MPOWER as below:

- Monitor tobacco use and prevention policies
- Protect people from tobacco smoke
- Offer help to quit tobacco use
- Warn about the dangers of tobacco
- Enforce bans on tobacco advertising, promotion and sponsorship
- Raise taxes on tobacco

“While efforts to combat tobacco are gaining momentum, virtually every country needs to do more. These six strategies are within the reach of

every country, rich or poor and, when combined as a package, they offer us the best chance of reversing this growing epidemic," said Dr Margaret Chan, Director-General of WHO. Dr Chan launched the WHO Report of the Global Tobacco Epidemic at a news conference with New York Mayor Michael Bloomberg who remarked that "No country fully implements all of the MPOWER policies and 80% of countries don't fully implement even one policy. While tobacco control measures are sometimes controversial, they save lives and governments need to step up and do the right thing."

The report also documents the epidemic's shift to the developing world, where 80% of the more than eight million annual tobacco-related deaths projected by 2030 are expected to occur.

This shift, the report says, results from a global tobacco industry strategy to target young people and adults in the developing world, ensuring that millions of people become fatally addicted every year. The targeting of young women in particular is highlighted as one of the "most ominous potential developments of the epidemic's growth."

WHO is also working with global partners to scale-up the help that can be offered to countries to implement the strategies. Dr Douglas Bettcher, Director of WHO's Tobacco Free Initiative, said the six MPOWER strategies would create a powerful response to the tobacco epidemic. "This package will create an enabling environment to help current tobacco users quit, protect people from second-hand smoke and prevent young people from taking up the habit," he said.

Other key findings in the report include:

- Only 5% of the global population is protected by comprehensive national smoke-free legislation and 40% of countries still allow smoking in hospitals and schools;
- Only 5% of the world's population lives in countries with comprehensive national bans on tobacco advertising and promotion;
- Just 15 countries, representing 6% of the global population, mandate pictorial warnings on tobacco packaging;
- Services to treat tobacco dependence are fully available in only nine countries, covering 5% of the world's people;
- Tobacco tax revenues are more than 4000 times greater than spending on tobacco control in middle-income countries and more than 9000 times greater in lower-income countries. High-income countries collect about 340 times more money in tobacco taxes than they spend on tobacco control.

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#### **4. HOME TREATMENT FOR CHILDREN WITH SEVERE PNEUMONIA JUST AS EFFECTIVE AS HOSPITAL**

Pneumonia is the largest single killer of children under five years old around the world. Almost four children die from pneumonia every minute. About 60% of pneumonia cases in the developing world are caused by bacteria and can be treated with antibiotics, whereas most cases of pneumonia in developed countries are viral.

A new study which shows that treating children with severe pneumonia at home is just as effective as treating them in hospitals could significantly change the way the illness is managed in developing countries, saving a significant number of lives every year and taking pressure off health systems.

Researchers from Boston University School of Public Health, supported by the World Health Organization (WHO) and U.S. Agency for International Development (USAID) conducted a study in Pakistan involving 2037 children with severe pneumonia who were randomly assigned to get either injectable antibiotics in a hospital or antibiotic pills at home. The trial was the first to compare the outcomes of hospital treatment of severe pneumonia with home-based treatment, and the results demonstrated the safety and efficacy of treating it with oral antibiotics outside of a hospital setting.

In the study, there were 87 (8.6%) treatment failures in the hospitalized group, and 77 (7.5%) in the group treated at home. Of the five children (0.2%) who died during the study, four were in the hospitalized group and one was at home.

This study confirmed the findings of three other trials at sites in Africa, Asia, Europe and Latin America, which showed that oral antibiotics were just as effective as injectable antibiotics in treating hospitalized children with severe pneumonia.

"The potential impact of these results is enormous," said the article's co-author Dr Shamim Qazi, Medical Officer with the WHO's Department of Child and Adolescent Health and Development. "Effective management of pneumonia is critical to improving child survival. Being able to treat children with severe pneumonia safely and effectively in their own homes would be of huge benefit to both families and health systems, by reducing the need for admission to hospital".

Similar research studies, if implemented into programs around the globe, is expected to increase access to critical care in disadvantaged communities and could support the potential to diagnose and treat severe pneumonia by community health workers.

The current guidelines advise health workers to provide oral antibiotics for cases of non-severe pneumonia and to refer severe and very severe cases to hospitals for treatment with antibiotics by injection. However, many children with severe pneumonia who are currently referred for admission to a hospital either die before they reach there or are so sick by the time they arrive that nothing more can be done to save them.

A small number of cases of very severe pneumonia (around 2-3% of all pneumonia cases) will still require treatment with injectable antibiotics in a hospital.

Families in the poorest countries, where the

majority of children are affected by pneumonia, may not have easy access to hospitals. In-patient treatment may not be an option for parents who cannot leave their homes to accompany the sick child. In addition, children with severe pneumonia are vulnerable to infections as a result of weak immunity and could be at increased risk in crowded hospital wards. A community-based approach would bring treatment to people's homes, so that children with pneumonia can be identified and begin treatment before the onset of life-threatening complications.

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