# for Children

Campaign for Greater Access to Pediatric HIV and TB testing and treatment

Caritas Internationalis

Caritas Internationalis is a confederation of 164 Catholic relief, development and social service organizations working to build a better world, especially for the poor and oppressed, in over 200 countries and territories. Since 1987, Caritas has contributed significantly to the global response to HIV/AIDS. One such activity in response to HIV/AIDS involves advocacy on the global, national, and local levels, for more comprehensive laws and policies to assure full access to care, treatment, support and education among those living with and/or affected by HIV.

In its advocacy with the Specialized Agencies of the United Nations, Caritas enjoys an excellent partnership with the Joint United Nations Programme to fight HIV and AIDS (UNAIDS) and the World Health Organization (WHO). UNAIDS and Caritas first established a Memorandum of Understanding in 1999 to guide their collaboration in this field; the agreement was renewed in 2003 and continues in effect to the present time. Caritas and UNAIDS have pledged to work together, from their different perspectives, to promote awareness, especially among young people, to prevent new infections, to advocate for the rights of those infected, to promote access to care and treatment, and to eliminate discrimination at all levels of society. Caritas also collaborates closely with the WHO Stop TB Department to promote better integration of TB initiatives in HIV programmes; with the WHO Pandemic Flu Unit to raise awareness on the measures to take in case of such a pandemic also at Church level. In 2008, Caritas endorsed the WHO "Make Medicines Child Size" Campaign which aims to raise awareness and to accelerate action in order to address the need for improved availability and access to safe child-specific medicines for all children under 15.

In its attempts to build solidarity with persons living with or affected by HIV, in particular those who are the most poor and marginalized in society, Caritas has joined other Catholic Church-related organizations to form the Catholic HIV and AIDS Network (CHAN). This Network includes partnership agencies engaged in support of HIV programming in the areas of education, health, social services, defence of human rights, social and economic development, and pastoral care.

For more information about the activities of Caritas Internationalis and its member organizations in response to HIV/AIDS please see
**www.caritas.org**

For information about Caritas Internationalis' special relationship with UNAIDS, please see
**www.caritas.org/activities/hiv_aids/sinethemba_a_caritas_response_to_aids.html?cnt=374**

*The data on the number of children living with HIV and in need of treatment are taken from the UNAIDS 2008 Report on the global AIDS epidemic (July 2008) www.unaids.org/en/KnowledgeCentre/HIVData/GlobalReport/2008/2008_Global_report.asp and from the UNICEF, WHO and UNAIDS "Third Stocktaking Report" www.unicef.org/publications/files/CATSR_EN_11202008.pdf*

*Photos do not imply the HIV status of the person depicted.*

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## What is HAART?

**HAART stands for Highly Active Anti-retroviral Therapy. It is the combination of at least three anti-retroviral (ARV) medications that work on blocking the entry of the Human Immune-Deficiency Virus (HIV) into human blood cells and on slowing down the process by which this virus takes over and destroys such cells. The treatment is not capable of eliminating HIV from the body of an infected person but it can slow down the destruction of his/her immune system and thus assure that s/he will live longer and will enjoy a better quality of life.**

# Rationale

Anti-retroviral medications (ARVs) can make the difference between life and death for more than 800,000 HIV-positive children under 15 years of age. If children living with HIV do not gain access to treatment that is appropriate to their needs, their physical development and the conditions of the setting in which they live, they are subjected to unnecessary suffering and die faster than do HIV-positive adults. HIV is extremely aggressive in the small bodies of children. Regrettably, despite evidence that treatment is very successful in children living with HIV, even in resource-limited settings, there remain significant obstacles to pediatric ARV scale-up. For children living with both HIV and Tuberculosis (TB) the situation is even worse.

Only 15 percent of children in need of anti-retrovirals are afforded access to them. On a daily basis, this causes the deaths of more than 800 children under the age of 15. Despite the fact that TB remains the main cause of death among children with AIDS, pediatric drug formulations are not available to treat TB/HIV co-infection in children.

# What are the challenges?

- **Difficulty of diagnosing HIV in infants;**
- **The need to increase access to measures that prevent the transmission of HIV from an HIV-positive mother to her child, during pregnancy, birth or breastfeeding;**
- **The lack of fixed dose combinations (FDCs), 3 pills in one, adapted for easy administration to children, even by non-medical personnel in resource poor settings;**
- **The lack of FDCs to treat HIV/TB co-infection in children;**
- **The high cost of HIV and TB therapy in children;**
- **The weak health systems and the low number of pediatricians trained to treat babies and children living with HIV or both HIV and TB.**

### Difficulty of diagnosing HIV among infants

One major barrier related to pediatric treatment of HIV is the difficulty with detecting HIV in babies younger than 18 months. This is mainly due to two reasons: limited availability of diagnostic tests capable of identifying HIV among infants and adaptable for use in resource-limited settings; and low coverage of prevention of mother-to-child transmission programmes (PMTCT).

The most common test for diagnosing HIV is one that identifies HIV-antibodies. Infants acquire antibodies from their mothers in order to fight off potential infections during their earliest months of life. Thus a positive HIV-antibody test result in a baby might simply be indicating that the mother has HIV but not necessarily that the virus itself has been passed to the child. Virological tests, such as polymerase chain reaction (PCR) technique, are employed to detect the virus among children younger than 18 months old. However, such tests require expensive and sophisticated laboratory equipment and trained staff. As a result, in high-income countries, children can be tested within 48 hours and an accurate result can be available in 6 weeks. However, in low- and many middle-income countries, HIV is detected in children only after they already manifest AIDS-related symptoms or once they are two years old. In both cases, it might be too late for anti-retroviral therapy to be effective. In 2007, only 8 percent of children born to HIV-positive women were tested before they were 2 months old.

[1] www.unicef.org/publications/index_42124.html

A recent report of the UN Secretary General, Ban Ki-moon, on *Children and the Millennium Development Goals*[1], states, "In one of the worst-affected areas of Namibia, 43 percent of pregnant women are HIV-positive. In the absence of any intervention, between 20 and 45 percent of infants born to HIV-infected women will contract the virus". In Europe and North America pregnant women living with HIV are given ARVs in order to prevent the transmission of the virus to their children.

### Need to increase access to Prevention of Mother-to-Child Transmission (PMTCT) of HIV

In relation to PMTCT, even though treatment is available to prevent the transmission of HIV from mother to child, approximately 420,000 children were newly infected with HIV during 2007, mainly through mother-to-child transmission. This was the case, as well, for the 90 percent of the 2.1 million children under 15 years of age who today are living with HIV. If coverage of PMTCT could be increased, not only would there be a great reduction in the number of HIV-positive children, but also it would be easier and more effective to start treating the child of an HIV-positive woman immediately after birth, even if diagnostic tools for detecting HIV in children are not available. Indeed, mother-to-child transmission of HIV can be reduced to less than 2 percent by a package of interventions comprising ARV prophylaxis and treatment, elective caesarean section and avoidance of breastfeeding, when appropriate. Since

the 90 percent of HIV-positive children live in developing countries and PMTCT coverage is very limited there, we might say that pediatric AIDS is not an issue of great concern to people living in high-income nations.

### Lack of pediatric fixed dose combinations

For children, the course of HIV is particularly aggressive. The virus multiplies rapidly, destroying their defenses against infection and facilitating the development of pneumonia, TB and other opportunistic infections. Without adequate care and treatment, as many as one third of children born with HIV will die before their first birthday, and half of them will die before they are two years old. Children being treated with Highly Active Anti-retroviral Therapy (HAART) must take three or more different anti-retroviral drugs several times a day in order to avoid the development of resistance to a single drug and to prevent the virus from progressing into AIDS.

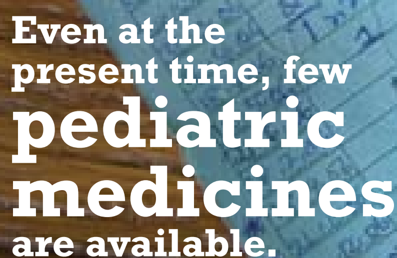
It is estimated that approximately 800,000 children urgently need HIV treatment. These medicines must be formulated differently than those for adults and in a way that takes into consideration the climactic conditions in the areas in which they will be distributed and used. It also should be noted that, in many low-income settings, clean drinking water and supply of electricity are not always available on a continuous basis.

Until recently, no formulations of anti-retroviral medicines were available for specific use among children. As a consequence, caregivers had to break in half or crush adult tablets, with the risk of under- or over- dosing. Today, the majority of medicines for pediatric AIDS are in the form of syrups, or single tablets. The lack of child-friendly fixed dose combinations (FDCs), 3 pills in one, adapted to the climate and conditions of resource-limited settings is another major challenge to pediatric AIDS treatment. This situation might be considered a consequence of the relatively small number of children born with HIV in high-income countries and consequent lack of interest in developing such formulations for use in developing countries, where the margin of profit might be quite low.

> In March 2008, Bristol Myers Squibb announced that the company would stop the distribution of the 100mg pediatric capsule formulation of efavirenz in France. The official reason given was that "the volume of prescription does not allow adequate quality levels"[2]. However, many pediatricians and NGOs point out that few children living with HIV can be found in France and other European countries.



[2] PRESS RELEASE BY TRT-5, EATG (EUROPEAN AIDS TREATMENT GROUP) & SIDACTION, Medical care for children living with HIV infection: the US pharmaceutical company BMS must start producing Sustiva® 100mg again!, 1 August 2008




Korogocho is one of Nairobi's 199 slums. It is built on the city rubbish dump. HIV and TB are endemic here, as well as extreme poverty, criminality and substance abuse. In Korogocho, people find their food in the rubbish-dump. In this slum, there is no water. Yet approximately 350,000 people live here. Most of the people with AIDS cannot afford nutritious food, so the ARV treatment is less effective. If we give ARVs to children when their immune system is already too weak or when they have no food, we simply accelerate their deaths.

### ARVs in liquid form

Pediatricians often have only liquid formulations available. Syrups are difficult to dose properly and to administer; they are costly to transport and difficult to store without refrigeration. Since syrups are so difficult to handle, some pediatricians are forced to suspend HIV therapy for some children. Moreover, for grandparents, who are the primary caregivers for orphans due to AIDS, and for older siblings, in child-headed households, it is too complicated to administer the correct dose of ARV using a syringe or a spoon several times per day. If drugs are not administered in the right dosage, they cause more damage than benefit.

### ARVs in tablet form

Ordinarily, ARVs in tablet form need to be taken with food and water. Let us not forget how difficult it is to find safe drinking water and regular food supplies in remote settings or urban slums.

### Three pills in one

In 2006, six years after the first adult fixed dose combination was used in developing countries, some generic manufacturers started producing FDCs for children living with HIV. Since three different drugs are combined into one pill, the treatment regimen is simplified, and it is easier to administer by caregivers and better tolerated by children. Regrettably, even at the present time, few pediatric FDCs are available and only two of them have been listed in the World Health Organization (WHO) essential medicines list for children[3].

### HIV/TB co-infection in children

HIV and TB are commonly called the deadly duo. TB is the most common opportunistic infection among people living with HIV and it is the leading cause of death among them. In Africa, a person with HIV and TB dies every three minutes[4]. TB is curable, even in persons with HIV, and yet such deaths continue to occur. Sadly, a large number of children infected with TB remain undiagnosed and worldwide



[3] www.who.int/childmedicines/publications/EMLc%20(2).pdf
[4] *TB in children*, TB Alert, www.tbalert.org.

two children die of TB each minute of every day. Such deaths usually occur among children who are co-infected with TB and HIV.

Indeed, both diagnosis and treatment of TB in people living with HIV are complex tasks. In particular, the drugs to treat TB interact with and lessen the efficacy of ARVs. According to Médecins Sans Frontières (MSF), the most neglected of all those suffering from TB/HIV co-infection are children: "Children with TB and HIV develop disease more quickly and die more quickly. The drugs needed to treat both TB and HIV are not available in child-friendly palatable liquid forms, nor are tablets small enough for young children to swallow. When drugs are available, they often are very expensive"[5].

### ● The high cost of HIV therapy

When child-friendly ARVs have been developed, they often are not registered or marketed in the countries where they are most needed, and usually they are very expensive.

### ● Weak health systems and few pediatricians

Also affecting the access of children to ARV treatment is the unacceptable state of health systems in most of the countries hardest hit by the pandemic and the shortage of skilled healthcare workers, in particular, of pediatricians and nurses familiar with treating children. Unlike adults, children taking ARVs demand constant check-ups and advice from trained personnel in order to receive maximum benefit from and adhere to their respective treatment programs.

Anti-retrovirals for children are currently three times more expensive than the adult formulations[6]. A person with AIDS in Europe spends about 8,000 Euro a year for medicines and medical examinations. The final data is that the cost of the therapy is between 8,000 to 12,000 Euro, whereas the annual expenditure in Sub-Saharan countries is only 10 Euro. Pharmaceutical companies claim that costly medicines are due to costly research, although research often is supported by public funds, and profit in the pharmaceutical sector is second only to that in the massive computer industry[7].

[5] TB Co-Infection, MSF, www.msfaccess.org/main/hiv-aids/introduction-to-hivaids/tb-co-infection
[6] Essential medicines for children, WHO, 16 April 2007, www.news-medical.net
[7] *Multinational Pharmaceutical Companies and Third World Poverty*, Agenzia Fides, 28 August 2008.

# The child's right to health:

## it is more than simply keeping a promise

**In 2009, the Convention on the Rights of the Child will be 20 years old. On this special occasion we want political leaders to tell the children of the world how they have promoted and respected the child's right to health. We also need to keep the pressure up so that all children living with HIV can access the life-saving treatment they deserve.**

These are all barriers that mitigate against the child's right to the highest attainable standard of physical and mental health recognized in the Convention on the Rights of the Child (CRC)[8], which this year celebrates its 20th anniversary. The child's right to health also is expressed in many other international human rights instruments[9].

### The Convention on the Rights of the Child

The Convention on the Rights of the Child, to which 193 States (99 percent of all nations) are bound, requires States to recognize the right of children to enjoy, without discrimination, the highest attainable standard of health and access to facilities for the treatment of illness and rehabilitation of health. Moreover, States Parties must strive to ensure that no child is deprived of his or her right of access to such health care services.

Access to medicines is a fundamental element of the child's right to health under article 24 of the CRC, as interpreted by the Committee on the Rights of the Child in its General Comment on HIV and AIDS. Indeed, the Committee declared "States must ensure that children have sustained and non-discriminatory access to comprehensive treatment and care, including necessary HIV-related drugs, goods and services". In particular, "States should negotiate with the pharmaceutical industry to make the necessary medicines locally available at the lowest costs possible".

Article 24 of the CRC builds on article 6, which recognizes that every child has the inherent right to life and that States Parties shall ensure, to the maximum extent possible, the survival and development of the child.

### The role of pharmaceutical companies

States have the primary responsibility to enhance access to medicines. Moreover, the Millennium Development Goals (MDGs) recognize that other stakeholders, including pharmaceutical companies, should share this responsibility. The Committee on Economic Social and Cultural Rights also confirmed that the private business sector has responsibilities regarding the realization of the right to the highest attainable standard of health. Thus, while governments have the primary responsibility for implementing the right to health, pharmaceutical companies can exert a profound impact on the realization of this right. It also must be recognized that pharmaceutical companies set the prices of diagnostic equipments for detecting HIV in children or of pediatric ARVs at an unaffordable level. When they do so; when they do not invest in research and development of much needed medications to treat HIV in children; or when they lobby for legal standards that limit access to medicines for HIV-positive people, these companies are obstructing the State's ability to respect, protect and fulfill the right to health.

[8] www.unhchr.ch/html/menu3/b/k2crc.htm

[9] The Universal Declaration on Human Rights: the Universal Declaration on Human Rights says that "motherhood and childhood are entitled to special care and assistance", which is of particular relevance for the scaling up of programmes to prevent the transmission of HIV from mother-to-child, and for the care of children during and after birth. The Declaration adds in article 25 "All children […] shall enjoy the same social protection".

The International Covenant on Economic, Social and Cultural Rights: the International Covenant on Economic, Social and Cultural Rights, in article 12 paragraph 2, clearly states that access to medicines is an indispensable part of the right to health. This means that under International Law, States have a duty to ensure that existing medicines are available within their borders. They also have a responsibility to take measures in order to ensure that much-needed new medicines are developed, become available and are accessible.

In the General Comment, on HIV and AIDS the Committee also examined the issue of mother-to-child transmission: "Infants and young children can be infected with HIV during pregnancy, labour and delivery, and through breastfeeding. States are requested to implement strategies recommended by the United Nations Agencies, including the provisions of essential drugs, e.g, anti-retroviral drugs, appropriate antenatal, delivery and post-partum care, and making voluntary counseling and testing available to pregnant women and their partners. Counseling of HIV-positive mothers should include information about the risks and benefits of different infants feeding options".

Thus, the measures that should be taken by States to prevent the transmission of HIV from a mother to her children include the following: medical protocols for HIV testing during pregnancy; information campaigns among women concerning mother-to-child transmission; the provision of affordable drugs, and of care and treatment to HIV-positive women, their infants and families, including counseling and infant feeding options.

# Children seem to remain **forgotten** in efforts to address HIV and AIDS.

### Why are children left behind?

Governments and pharmaceutical companies play a major role in children's access to medicine. Yet children seem to remain forgotten in global and national efforts to address HIV and AIDS. Many countries have no data on the number of children living with HIV or with TB, or on the number of children in need of treatment and on those who receive it. Sadly, pediatric ARVs for treating HIV and HIV/TB co-infection in children are not considered to be profitable. This is due to the fact that the market for pediatric anti-retrovirals exists mainly in low-income countries: thanks to PMTCT, relatively few children are born with HIV in higher-income nations.

How can we allow profits to be given priority over people? How can we allow a child to contract HIV from his or her mother, when presently there are cost-effective measures to avoid such transmission? How can we tolerate the fact that an HIV-positive child will die of AIDS-related illnesses just because governments and pharmaceutical companies do not want to invest in the research on and development of much needed child-friendly formulations to treat HIV and HIV/TB in children?

We must recognize our responsibility for these children: "The law of profit alone cannot be applied to that which is essential for the fight against hunger, disease and poverty"[10].

In 2008, the UN General Assembly adopted the last report of the former Rapporteur on the Right to Health, Mr Paul Hunt, in which he presents the *Human Rights Guidelines for Pharmaceutical Companies*. These Guidelines are meant to identify what pharmaceutical companies should do to help realize the human right to obtain access to medicines. The Guidelines set forth a human rights regimen designed to pressure pharmaceutical companies to embrace a "right to health"[11].

[10] Intervention by His Excellency Msgr. Diarmuid Martin to the Plenary Council of the World Trade Organization on trade-related aspects of intellectual property rights, 20 June 2001.

[11] The Guidelines call for: the adoption of corporate mission statements that expressly recognize and implement the "right to health"; the use by corporations of "human rights impact assessments" when formulating and implementing their corporate strategies, policies, programmes, projects and activities; the adoption of a governance system that makes Board members directly responsible and accountable for the corporation's access to medicines strategy; and the dilution of corporate intellectual property rights relating to medicines. Unfortunately the majority of pharmaceutical companies are opposed to these Guidelines, and the adoption of the report by the UN General Assembly went almost unnoticed. Thus, much more needs to be done to disseminate the Guidelines and to promote their use.

# Caritas Internationalis and pediatric AIDS

During this year which marks the 20th anniversary of the Convention on the Rights of the Child, Caritas will collaborate with United Nations (UN) Specialized Agencies, with UN Human Rights mechanisms, and with other interested organizations in a campaign to prevent further loss of these children and to scale up efforts to prevent the transmission of HIV from a HIV-infected mother to her child. Caritas will undertake its promotion of the child's right to health together with CHAN (the Catholic HIV and AIDS Network)[12], and with the Ecumenical Advocacy Alliance (EAA)[13].

Since pharmaceutical companies have a key role to play in improving access to medicines for women and children living with HIV, Caritas also will maintain its cooperation with IFPMA, the International Federation of Pharmaceutical Manufactures & Associations[14].

# What is Caritas asking for?

| GOALS | TARGETS | ACTIONS REQUIRED |
|---|---|---|
| Scaling up PMTCT | Governments | to provide HIV counseling and testing as part of the routine package of screening tests during pregnancy and delivery care |
| | | to integrate PMTCT programmes into existing public health systems |
| | | to make clinics accessible, for instance, by providing travel services and changing opening hours |
| | | to use rapid testing with same-day results |
| | | to increase efforts to reach women who deliver at home |
| | | to treat babies of HIV-positive women immediately after birth |
| | | to provide counseling and support on infant feeding options to women living with HIV |
| Pediatric Diagnostic Tools | Governments | to identify early HIV diagnosis as a priority activity in child health programming |
| | | to offer early infant diagnosis at vaccination sites |
| | | to test infants at 4/6 weeks using PCR testing for HIV DNA in infants, including dried blood spot specimen collection |
| | | to build national and local laboratory capacities to facilitate HIV diagnosis in infants, including skilled staff |
| | | to revise child health cards to include HIV-related information in order to treat children in a timely and effective manner |
| Pediatric treatment | Pharmaceutical Companies | to develop more and cheaper anti-retroviral treatment suitable for babies and children, in particular pediatric fixed dose combinations suitable for poor settings |
| | | to address the research and development gaps in medicines for TB/ HIV co-infection in children, in particular with respect to dosage forms and clinical trials |
| | Governments | to develop national HIV and AIDS strategic plans with a strong focus on PMTCT, diagnosis of HIV and TB in babies and children, and treatment for babies and children living with HIV and HIV/TB co-infection |
| | | to take measures to increase food security in children as lack of food is a major barrier to children's access to medicines |



[12] CHAN is a large group of Catholic agencies, which support a wide range of programmes in response to HIV/AIDS.

[13] The Ecumenical Advocacy Alliance is an international network of over 100 churches and church-related organizations committed to campaigning together on common concerns on HIV and AIDS and food security.

[14] www.ifmpa.org

# What can I do?

- Promote the Caritas HAART for Children campaign. We are advocating with governmental officials, with pharmaceutical companies, and with universities and research institutes to promote greater access to PMTCT and pediatric HIV and TB testing and treatment worldwide. Visit **www.caritas.org/activities/hiv_aids** to know more about this campaign!

- Promote the HAART for Children logo on your website.

- Become familiar with the work of the following organizations on PMTCT and pediatric AIDS:

UNAIDS - Pediatric Treatment
www.unaids.org/en/PolicyAndPractice/HIVTreatment/PediatricTreat/

UNAIDS - PMTCT
www.unaids.org/en/PolicyAndPractice/Prevention/PMTCT/

WHO - Make Medicines Child Size Campaign
www.who.int/childmedicines/en

WHO - PMTCT
www.who.int/hiv/pub/mtct/pmtct/en/

WHO - Diagnostics
www.who.int/hiv/amds/diagnostics/en

UNICEF - Unite for Children Unite against AIDS
www.uniteforchildren.org

- Become informed on how to prevent the transmission of HIV from a mother to her child and on pediatric AIDS.

- Add information on PMTCT and pediatric AIDS and TB in your own language on your website.

- Organize meetings with governmental health officials and pharmaceutical companies based in your country to find out what they are doing to promote the child's right to health. Share this information with us by writing to **fmerico@caritas-internationalis.com**

- Take action to help children living with HIV by joining the "Children Letter Writing Action". Children are encouraged to write letters to governments and pharmaceutical companies asking them to improve diagnostic tools and treatment for children living with HIV. Visit **www.caritas.org/activities/hiv_aids/prescrition_for_life.html**

- Set up a local PMTCT and pediatric AIDS campaign in your church, school, college or university and share with us what you are doing by writing to **fmerico@caritas-internationalis.com**

- Meet with decision-makers at universities and research centers to encourage additional research and development of HIV and TB testing and treatment for children.

- Work with the media to highlight the problems and solutions.

- Visit **www.caritas.org** regularly where you will find information, updates, stories and additional actions to promote PMTCT and pediatric AIDS.

> Pope Benedict XVI, in his message for the celebration of the 2009 World Day of Peace, says: "Then, too, the necessary medicines and treatment must be made available to poorer peoples as well. This presupposes a determined effort to promote medical research and innovative forms of treatment, as well as flexible application, when required, of the international rules protecting intellectual property, so as to guarantee necessary basic healthcare to all people"[15].



[15] Message of Pope Benedict XVI for the celebration of the World Day of Peace, 1 January 2009, Fighting Poverty to Build Peace, www.vatican.va

“I like the sea because it is very large and clean. However, my life is limited because of being HIV-positive. I ask everyone to understand that I would not choose to be like this. They should be open-minded and have a big heart, like the sea, to accept other infected children and me. I cannot protect myself, so I ask other people to help me, to treat me with kindness and to give me a chance to develop and be happy in society. Thank you”

– 12-year-old boy, Camillian Social Center of Rayong, Thailand[16]

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[16] The Bridge of Hope, Camillian Social Center Rayong, Thailand www.camillian-rayong.org