Dear Friends and Colleagues - Partners in the Caritas Internationalis HAART for Children Campaign

Access to treatment for children living with HIV is the major theme covered in this issue. Two recent events also focused on this and related issues: the International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention held in Vancouver this July 2015; and the release of the UNAIDS report “How AIDS changed everything, MDG 6: 15 years, 15 lessons of hope from the AIDS response”. In the latter publication, UNAIDS announces that the goal of 15 million people on life-saving anti-retroviral treatment (ART) by 2015 had been met nine months ahead of schedule.

As one of the most remarkable successes in the AIDS response, UNAIDS highlighted the significant decrease in new HIV infections among children. In the year 2000, approximately 520,000 children were newly infected with HIV; most of these children died before their second birthday because they lacked access to “child-friendly” anti-retroviral treatment (ART). In response to this tragic situation, top priority was given to early diagnosis of women living with HIV and to their treatment with anti-retroviral medications (ARVs) in order to prevent the transmission of the virus to their children. UNAIDS estimates that between 2000 and 2014, the percentage of pregnant women living with HIV with access to antiretroviral therapy rose to 73% and new HIV infections among children dropped by 58%. That is very good news!

The “bad news”, however, is that diagnosis and treatment for children who have been infected with HIV remains a major challenge. As of 2014, only 32% of the 2.6 million children estimated to be living with HIV had been diagnosed and only 32% of these children had access to ART. It is true that at least 32% of HIV-positive children were treated in 2014 vs. 14% in 2010. However paediatric treatment coverage remains notably lower than it is for adults (41%).

Why is there such a gap in making treatment available for children?

We have failed in achieving timely and prompt diagnosis and treatment of babies and children. The focus on prevention of mother-to-child transmission (PMTCT) has been quite necessary, but such programmes often miss the children who already are infected. Another major challenge is the retention of mothers and children in HIV treatment. Moreover, TB and HIV programmes need to be integrated, given the fact that tuberculosis remains a major cause of death for both adults and children living with HIV. Finally, while HIV-positive children recently have attracted more attention by governments and the international community, much more expertise and funding must be dedicated to saving their lives.

In this issue we have the pleasure to share with you an interview with Dr Julio Montaner, a pioneer in the field of combination of anti-retroviral (or “triple”) therapy and a promoter of “treatment as prevention”. Dr. Montaner talks about the International AIDS Society.
Conference on HIV Pathogenesis, Treatment and Prevention held in Vancouver during July 2015. He also pays tribute to the role of Faith based organizations (FBOs) in reaching out to the most vulnerable populations and providing them with competent, compassionate, and respectful treatment, care and support. He talks about paediatric AIDS as a global priority and identifies the urgent need for developing additional pediatric formulations of ARVs to address the needs of the millions of children that are today living with HIV.

Janice Lee from the Drugs for Neglected Diseases Initiative (DNDI) shares her insights on the major obstacles to scale up treatment for children living with HIV and the limitations of the currently available paediatric treatment. She also discusses current DNDI efforts address unmet ARV needs experienced by children.

Tabitha Wangari, Clinical Officer from the Lea Toto programme in Kariobangi, one of the many slums in Nairobi (Kenya), talks about screening and treatment for TB among HIV-positive clients. She also describes the challenges being faced with implementation of preventive therapy with Isoniazid, since an adequate supply of this medicine is not readily available. Finally, she shares the success story of a young, HIV-positive client who, thanks to successful TB treatment, has been able to return to school.

With this issue, Caritas aims to call for more attention to treatment of children living with HIV and HIV/TB co-infection. We must give children living with HIV the life they deserve so that they can live it to the fullest. The global community has accomplished this for adults. How can we allow the children to be left behind?

Pope Francis joined his own thoughts and prayers to these very same hopes and goals when he sent a message, through his Secretary of State, Cardinal Pietro Parolin, to the participants in the International HIV/AIDS Conference in Vancouver and expressed his “esteem for their work and the dedication it requires.” He gave thanks for the lives saved by Highly Active Anti-Retroviral Treatment (HAART) and for the use of “Treatment as Prevention” and noted that such efforts “give witness to the possibilities for beneficial outcome when all sectors of society unite in common purpose. Finally, he assured the participants of his prayers “that all advances in pharmacology, treatment, and research will be matched by a firm commitment to promote the integral development of each person as a beloved child of God.”


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1 Letter of Cardinal Pietro Parolin, Secretary of State, on behalf of His Holiness Pope Francis, Vatican City, to Dr. Julio Montaner, St. Paul’s Hospital, Vancouver British Columbia, Canada, 5 June 2015.

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**Interview with Dr. Julio Montaner: Treatment As Prevention Can Stop AIDS**

Ms. Francesca Merico

There are people who really changed, and continue to change, the world for the better. Without a doubt, Dr. Julio Montaner is one of them. He is an Argentinean/Canadian physician, professor and researcher, who, through his medical discoveries, has helped to save millions of lives.

For more than 30 years, Dr. Montaner has been on the front lines of the global response to AIDS. He initiated the concept and use of triple therapy, or combination anti-retroviral treatment, which dramatically slowed the spread of HIV and the rate AIDS-related deaths.

He also is the promoter of “treatment as prevention” which promotes early diagnosis and treatment of people living with HIV in order to decrease the development of AIDS-related illnesses and to reduce the possibility of transmitting HIV to others.

This year, Monsignor Robert J Vitillo, Head of the Caritas Internationalis Delegation to the UN in Geneva and Special Advisor on HIV and AIDS and Health, was invited by Dr. Montaner to present the work of Faith Based Organizations (FBOs) in providing treatment to people living with HIV at the

The Conference represented a unique opportunity for all those involved in the global response to HIV to examine and exchange the latest scientific developments in HIV-related research, and to explore how such developments can be realistically applied in implementation programmes.

We took this opportunity to interview Dr. Montaner on his expectations from the Conference and on treatment for children.

What are your expectations from this Conference? Can you anticipate some of the findings that will be presented at the Conference?

We were very proud to host the International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention here in Vancouver this July 2015. The Conference brought together 5000 scientists, policy makers, advocates, and community representatives to discuss the latest scientific discoveries to fight the HIV/AIDS epidemic. We came together at a very interesting time because, over the last 20 something years, we have seen a great evolution regarding various evidence-based strategies that are now shown, proven and demonstrated.

![Image of Dr. Montaner and colleagues]

Left to right: Dr. Zunyou Wu, Director of National Center for AIDS/STD Control, China; Dr. Nina Volkow, Director, National Institute on Drug Abuse, USA; Mr. Michel Sidibe, Executive Director, UNAIDS; Dr. Fabio Mesquita, Director, National AIDS Programme, Brazil; Msgr. Robert J. Villito, Special Advisor on Health and HIV/AIDS, Caritas Internationalis; Dr. Julio Montaner, Director, BC Centre for Excellence in HIV/AIDS, St. Paul’s Hospital, Vancouver, Canada; Dr. Robert Sindelar, Vice President for Research, St. Paul’s Hospital, Vancouver, Canada; Mr. Dick Vollet, President, St. Paul’s Hospital Foundation, Vancouver, Canada.

Now we can be highly effective in stopping morbidity, mortality, and HIV transmission all together at once. I am referring to the fact that treatment of HIV with antiretroviral therapy, by shutting down replication, not only stops the progression of this disease virtually completely, therefore people do not progress to AIDS or death, but, in addition to that, because biological fluids are virtually sterilized, therefore free of the Human Immunodeficiency Virus, transmission from all routes is interfered with to nearly a complete degree.

This is an interesting time because, in 1996, we had the privilege to host the international AIDS Conference here in Vancouver and that was when, for the first time, the word Highly Active Antiretroviral Therapy (HAART) was articulated based on research that we and others had done throughout the world. The standard of care immediately changed to adopt triple therapy, or HAART, for the benefit of those infected. Within a decade we had sufficient data to claim, for the first time, that treatment as prevention could not only stop HIV from progressing to AIDS and death, but also to stop the epidemic as a whole.

Today the scientific community gathered in Vancouver to actually recommit their support for this strategy and, in that context, we saw an enthusiastic endorsement of the United Nations 90-90-90 target, which calls for at least 90 percent of the people infected with HIV to be diagnosed, 90 percent of them to be treated with sustainable ART of the highest quality, and at least 90 percent of them to be virologically suppressed on a sustainable basis. So, by the year 2030, as a result of this strategy, we could see the virtual elimination of the AIDS pandemic: meaning that we would see approximately a 90 percent decrease of the disease burden in terms of HIV morbidity, mortality, and remission as a result of achieving this very ambitious new target.

You did an incredible work with vulnerable groups in Canada, promoting treatment for all, first and foremost for injecting drug users, demonstrating that HAART saves lives and reduces the chances of HIV transmission. You say that it is imperative to create “paths of treatment” for all, not excluding vulnerable groups. What should be done to increase treatment access for children living with HIV? What kind of treatment is needed for the children? What kind of research is still needed for children living with HIV? What should be done to eliminate the treatment gap between adults and children living with HIV?

The only way we can begin to conceive an end to this
pandemic is if we ensure that there is global, universal access to antiretroviral therapy and related services. We need access to testing. We need to facilitate access to care, and, by care, I mean a comprehensive package of care. We need free access to antiretroviral therapy and related support strategies. In other words, we need a comprehensive strategy that addresses the needs of people living with HIV and that recognizes the needs of those at risk globally, without leaving anyone behind. This means that every group in our society, which is affected by HIV, needs to be approached with an open mind so that we understand where they are at. We need an open mind so that we can better understand where we can meet them. If we are with them, we can ensure optimal access to the services that are essential to protect them against disease progression and to protect their peers, their partners, their families, from the ravages of HIV. We have done a lot of work at trying to identify strategies to access the most vulnerable populations. Whether that may be with injecting drug users or with other minorities particularly affected by HIV, the lesson we have learned is that there is no “one size fits all.” We have to be very creative to build up the strategies, depending on the priorities and needs, the perceived needs, and the real needs of the communities we are trying to help.

There should be no doubt in our mind that pediatric HIV should be a top priority. Today we have the tools to truly stop vertical transmission of HIV. It really is a sin to see children born with HIV today in our world when we have the knowledge on how to stop 100 percent of such events. The appropriate, timely, and effective treatment of a woman with HIV, and of her partner as well, because at the end of the day we want to protect the family, will lead us to 100 percent protection of the child being born to that mother. So, it is critical that we make every effort to ensure that every mother, every father, and their family have priority access to ART so we can stop 100 percent of pediatric cases.

Having said that, there is an urgent need for pediatric formulations of ARVs to be developed in order to address the needs of the millions of children that today are living with HIV. We need strategies to address the nature of the kids wherever they may be, paying particular attention to the plea of orphans because of AIDS, who unfortunately are still highly prevalent, particularly in the poorest places in the world. We need resources, we need the support, we need the outreach so we can engage children, and more specifically orphans, in appropriate care and treatment so they can lead the normal life that they deserve.

In your view how have faith-based organizations contributed to Treatment as Prevention, in the past and at the present time? What do you feel these organizations can do to engage even more effectively in this life-saving initiative? What “comparative advantage” is brought by faith-based organizations to this field of HIV response?

Faith-based organizations (FBOs) have played a critical role in helping us to reach the most vulnerable populations. The mere fact that FBOs have the vocation for serving the most vulnerable in our society everywhere, including in my own city of Vancouver, where St. Paul's Hospital led the charge to facilitate access by men who had sex with men, by injection drug users, by minorities affected by HIV, during a time when many others did not want to get involved, is a reminder of the critical role that FBOs have in facilitating the work that we are engaged with. In addition, FBOs have arms that reach very far into the most resource-limited areas of the world. Coming from Argentina, I have seen the work of the FBOs in the slums of Buenos Aires or in the rural areas of my country, and I have always been impressed by the willingness of them to go where no one else wants to go, and, in doing so, to approach the individual in a holistic way, in ways that individuals feel themselves valued, respected, and supported. This is critical if we are going to engage people in remote situations, those not being looked after properly by their own peer members of society. If we are going to engage those that are most vulnerable in treatment and prevention, this is an investment for life. And if we can bring it to them through the hands of the faith-based organizations that they trust, with which they are engaged for a variety of other social supports, the chances for us to be successful will be much, much better.
Dear Dr Montaner,

His Holiness Pope Francis thanks you for informing him of the forthcoming International Conference on HIV/AIDS in Vancouver. He sends prayerful greetings to all taking part, and expresses his esteem for their work and the dedication it requires.

His Holiness is grateful for the many advances made in the prevention and treatment of HIV/AIDS, particularly through Highly Active Antiretroviral Therapy, and the promotion of “Treatment through Prevention”. The lives that have been saved, both through the reduction in the number of new infections and the better health and longer lifespan of those already diagnosed, gives witness to the possibilities for beneficial outcomes when all sectors of society unite in common purpose. He hopes that further efforts may be made to make the fruits of research and medicine available to the world’s poorest people, especially orphaned children, upon whom this scourge often places the heaviest burden. He likewise prays that all advances in pharmacology, treatment and research will be matched by a firm commitment to promote the integral development of each person as a beloved child of God. Upon all of you, the Holy Father invokes abundant divine blessings of wisdom and peace.

With every good wish, I am

Yours sincerely,

[Signature]

Secretary of State
Early Treatment of Babies with HIV: An Urgent Public Health Priority - Interview with Janice Lee from Drugs for Neglected Diseases Initiative (DNDi)

Ms. Francesca Merico

During the past number of years, the international community has made significant progress to scale-up antiretroviral therapy in low- and middle-income countries. However, while there have been huge increases in treatment of adults living with HIV, children have not benefited from the same level of treatment coverage. It is estimated that, of the 3.2 million children living with HIV and AIDS, only 647 000 receive ART. Without treatment, half of these children will die before their second birthday and 80% will die before the age of five.

The World Health Organization projects that, in 2020, approximately 1.9 million children will be living with HIV, with an estimated 1.6 million in need of antiretroviral treatment.

Why are children still left behind? What is the current paediatric treatment situation? Why is access to ART so limited for children? What additional advocacy is needed?

These were some of the questions we raised with Janice Lee, Project Manager at the Drugs for Neglected Diseases Initiative (DNDi) in Geneva. Janice is a very dynamic and competent pharmacist whom I had the pleasure to meet when she was working for the Campaign for Access to Essential Medicines for Doctors Without Borders (MSF).

Janice, what are the major obstacles for scaling up treatment for children living with HIV?

The lack of appropriate medicines for children is a major barrier for maximizing access to treatment for children. Currently, available anti-retroviral (ARV) formulations for babies and small children contain alcohol, are difficult to store and transport, have a horrible taste, require refrigeration, have a short shelf life when exposed to heat. Some of these medicines are expensive and are not available in dosages that are recommended by WHO in accord with the respective weight of the children. In addition, there is a significant level of negative interactions between HIV medicines and TB medicines.

Another major obstacle is encountered with regard to early diagnosis of HIV among babies. We still lack appropriate tools to diagnose HIV in infants and young children, especially in low-income and remote settings. Then there is the accompanying stigma when HIV testing is requested for a baby, and the lack of information on how to deal with the situation once a baby or a child receives such a diagnosis. If we want to eliminate the treatment gap between adults and children, communities and families must be sensitized about the importance of early diagnosis and treatment in children.

Also, programmes to prevent the transmission of HIV from mothers to children, and treatment literacy efforts should pay more attention to children.

What are the limitations of the current treatment?

Current paediatric anti-retroviral (ARV) formulations do not meet the 2013 WHO Guidelines recommending the use of protease inhibitor-based first-line regimens for all children under 3 years of age. WHO recommends early diagnosis and immediate treatment of HIV-positive infants and children under the age of five, regardless of CD4 count (NOTE: These cells play an important role in the human body’s immune response to infections). Children under the age of 3 years should be treated with a combination of protease inhibitors (PIs). However, the only available PI for young children, Lopinavir/Ritonavir combination (LPV/r), is not available in a child friendly formulation: it has high alcohol content; it is unpalatable; its
action is adversely affected by heat and thus requires refrigeration; and it is not adapted to low-income settings.

Some experts say there is enough treatment for children living with HIV, what is your opinion in this regard?

Advocacy has truly changed the situation from the past. Now there are several medicines for treating HIV in children; however they are not adapted to local settings. For instance, there are a lot of syrup formulations, which are difficult to transport and store. Syrups might be the preferred option in developed countries, but they are not ideal in poor settings. Also, new drugs are not always in line with the WHO weight band dosing chart, which would make paediatric treatment easier to administer and to take in poor and remote areas.

What is DNDi doing to address unmet treatment needs?

DNDi is working to develop a combination for very young children: a solid formulation, heat stable and taste masking. We tested about 30 formulations of LPV/r. It is a very difficult molecule to work with and it loses bioavailability (ability to be absorbed in the human body) when we try to change the taste of such a combination. We have tested them in animals. We are optimistic that two such medicines showed positive results, and we will test them in humans during July/August 2015. The outcomes of such testing are expected within a month. We believe we could submit a dosage for pre-qualification to the Food and Drug Administration of the USA (FDA) within one year. Also, within this timeframe, we are hoping to study the effects of this formulation in children.

We also have in place a living (human subject) study of the effectiveness of Lopinavir/ritonavir among children living with HIV. We are conducting this study in Kenya where we already have regulatory approval. This study is meant to provide early access to “child friendly” fixed dose combinations (FDCs) in poor and remote settings. The major issues being studied are: how to administer such treatment without food and how to give it to children below 5 kg and younger than 6 months.

What are the pharmaceutical companies you are working with?

We are working with Cipla (a generic pharmaceutical company based in India) for the development of two 4 in 1 child friendly formulations of LPV/r. Lopinavir/ritonavir presently is the major focus in terms of FDCs for children. We are not closing the doors to other pharmaceutical companies. However, medicines for paediatric HIV treatment do not represent a big and profitable market; therefore, they do not attract a lot of interest.

What about children living with HIV/TB co-infection?

Even though TB is the major cause of death in children living with HIV, this disease is hard to diagnose and still under-diagnosed. We have an ongoing study in South Africa on the interaction of Lopinavir/ritonavir and TB drugs. We are collecting data related to the interaction between these medicines when administered to young children, and we believe DNDi will provide more accurate and up-to-date information by 2016. The objective of DNDi is to develop and register a stand-alone drug that will serve as a “booster” for the standard anti-retroviral medicines presently being used for children living with HIV.

What additional advocacy is needed?

On the ground, DNDi is working in Kenya on how to do advocacy on paediatric AIDS by involving people living with HIV and AIDS, and committees of health workers, such as the National Empowerment Network of People Living with HIV/AIDS, the International Community of Women living with HIV Kenya Chapter and the Kenya National AIDS & STI Control Programme. They are helping DNDi to identify children living with HIV and promoting early treatment for such children. Also, we produced and are using a brochure that offers information about the importance of early testing and treatment for babies and children.
At international level, it is necessary to advocate in order to fill two gaps: diagnosis and treatment of babies and of children. With regard to medicines, new treatment must be developed for babies and children living with HIV in poor settings, in particular focusing on Africa where the 90% of HIV-positive children live. Also, new formulations must follow the WHO dosing chart to make treatment easier to administer to and be taken by children.

**Children with HIV can have a bright future**

**Could my child have HIV?**

HIV prevention has done a lot of good, but some children are still infected at birth or become infected later through breastfeeding. Others become infected from mothers that do not know their HIV status, or who become HIV positive after giving birth.

Children that are infected with HIV can appear healthy or ill early in life.

Children can grow up healthy especially when they are tested and treated early.

**What kind of treatment is out there and how much does it cost?**

There are many kinds of treatment today that are made especially for kids. They are safe and easy to give. They help kids to do well. Treatment is lifelong and is free. You will get treatment at the healthcare centre.

**My child seems fine, so why would I test him or her for HIV?**

Children with HIV get sick easily because their bodies cannot fight off other diseases that attack them. Some children with HIV can appear healthy, but when they start to appear sick, it may already be too late. Without treatment they will die.

While it may seem stressful, it is important to test your child, according to the doctor’s advice. It is important to test children right away and start treatment with no delay. So don’t wait until it’s too late, a lot can be done to help!

**Where should I go to get my child tested?**

Go to your nearest health facility with no delay! Someone will explain to you what to expect results, and help you to understand the results.

**What will happen if my child tests positive for HIV?**

Your child will be given treatment for free and will be followed by doctors and nurses to ensure he or she is doing well, grows well, and stays well.

**What will the treatment actually do to my child?**

Treatment will quickly help the body to become stronger by fighting the virus. Some children can have some side effects, depending on the medicines, such as a rash or diarrhoea. The side effects are generally mild and go away with time. The important thing is to speak to a nurse or doctor about anything you notice. They are there to help, and make sure your child is safe and gets the right treatment as he or she grows.

**DNDi**

Therapy for neglected tropical diseases.
Kariobangi is one of the health facility centers under Lea Toto programme. Lea Toto is a community programme that covers Nairobi’s informal settlements, providing comprehensive care and treatment for HIV clients and their families. Kariobangi has the highest number of beneficiaries (496) in the Lea Toto programme, which covers the following informal settlements: Kariobangi, Korogoco, Huruma and Mathare.

TB screening and treatment is key in our health care provision for all clients enrolled, not only in Kariobangi but in all the Lea Toto programme. TB screening of clients is done during every visit except for those already on TB treatment. Those diagnosed with TB are put on treatment immediately, and they are treated for a period of 6 months, or for 8 months if the situation involves “re-treatment”. After the 6 -or 8-month period, 99% have been cured of TB and, during the last year, we have not lost any clients due to TB.

The main challenge we have been facing in Kariobangi, and in Lea Toto, is implementation of IPT (preventive therapy with Isoniazid) to prevent TB. Since we cannot access an adequate supply of this medicine, as per the IPT treatment guidelines, we have suspended implementation of IPT prophylaxis. However, we continue to fully implement intensive case finding to ensure screening, early diagnosis and initiation of treatment with people identified as living with TB.

Currently, we have 7 clients on TB treatment as well as on Highly Active Anti-Retroviral Treatment (HAART). They are all doing exceptionally well after starting treatment for TB.

**Case story**

A client, Mary Raha (not her real name), was enrolled in Lea Toto Kariobangi on 31 July 2014, as a transfer from a nearby health center. She had been in care for HIV since 2007, when she was diagnosed as co-infected with both HIV and TB. She did not progress very well over the years, and her highest CD4 count was 443, despite good adherence to the anti-retroviral medicines, as reported by the mother. The mother requested a transfer upon noting her daughter’s poor and deteriorating state.

Upon enrolment at Kariobangi, she weighed 17.85 kilos and was severely malnourished. She was very sickly, had diarrhea and vomiting, and refused to eat properly. She was stabilized with rehydration salts and medicines. Baseline tests were carried out to have a clear picture of her CD4 count, viral load, liver function, and kidney function, and a thorough TB screening was carried out. At the time, her sputum samples were negative for TB but the rest of the tests were worrying, with CD4 count being 5 and viral load of more than 1million.

After in-depth team consultations on the various interventions to support and treat Mary, a medical decision was made to start treatment for extra-pulmonary TB and to change her ARV drug regimen. The treatment course was 8 months, and nutritional support was initiated in order to deal with the malnutrition. The mother, who sold art pieces at the Masai market, quit her job in order to accompany the child to clinic appointments and monitor her feeding at home.

The journey has been tough, with several referrals to Kiambu, Mbagathi and St. Mary’s Hospitals due to acute malnutrition and severe bouts with opportunistic infections. Each time, the child was discharged in stabilized condition but still required much attention and rehabilitation. The team
recommended and supplied locally available energy-dense foods to complement what the mother could afford and to make sure that the child had a balanced diet and thus was ensured quality care. The team also made home visits to improve home-based care. Despite all the challenges, Maria Raha continued to improve medically and to satisfactorily gain weight.

She went on to sit for her KCP Examination despite being away from school for a long time; she showed average performance, and the school, which has a secondary section, agreed to admit her since she appeared to be a promising student.

This month, Maria Raha completed her TB treatment and has been declared cured of this disease, and the team is greatly impressed by her progress and by the successful interventions they were able to facilitate for this child.

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