Making paediatric HIV a priority
Annual report 2013

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The Collaborative Initiative for Paediatric Education and Research (CIPHER)

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Despite significant progress in preventing new paediatric HIV infections, there are still 3.2 million children living with HIV worldwide. The paediatric population remains significantly disadvantaged with respect to treatment, with only 34% of eligible children receiving antiretroviral therapy (ART) compared with 65% of eligible adults. As the HIV epidemic matures, there is an increasing population of adolescents living with HIV; in recent years, this particularly vulnerable group has seen a 50% increase in AIDS-related mortality, compared with a decrease of 30% in the global population. These young people face unique challenges, which the Collaborative Initiative for Paediatric HIV Education and Research (CIPHER) is committed to placing firmly on the global public health agenda.

CIPHER was launched in 2012 with the support of a generous two-year unrestricted educational grant from ViiV Healthcare. Positioned as the flagship paediatric HIV research initiative of the International AIDS Society (IAS), in 2012/13, CIPHER focused on two main goals:

- Promoting and investing in targeted research to optimize service delivery and clinical management of infants, children and adolescents in resource-limited settings (RLS)
- Convening stakeholders and establishing collaboration mechanisms to strengthen communication, knowledge transfer and exchange among paediatric HIV cohorts.

As a first step, a comprehensive research agenda in paediatric HIV was developed in collaboration with key stakeholders and experts. CIPHER started promoting this agenda through a core programme of activities, including a competitive grant programme, a global cohort collaboration and online cohort database. These activities were well received and highly successful, and by the end of 2013, paediatrics was adopted as one of the three priorities of the IAS.

The CIPHER Grant Programme was designed specifically to attract early-stage investigators to paediatric HIV research in order to cultivate a new generation of scientists dedicated to the field and to foster innovative ideas and evidence-based approaches and interventions. All projects funded must address one of the 12 clinical and operational priority research questions identified by the needs assessment, and they must take place in RLS. The call for letters of intent for this grant resulted in 143 applications, underlining the need for funding in this gap area. To maximize the impact of CIPHER in 2013, a total of US$1 million was granted to seven young investigators.

The cohort collaboration initiative is the first to bring together the main cohorts worldwide, and represents about 280,000 children and adolescents affected by HIV. The collaboration commenced with a CIPHER-convened paediatric HIV cohort investigator meeting attended by cohort researchers and HIV experts. This provided the platform for two global cohort collaboration projects: (1) the durability of first-line ART in children in RLS; and (2) the global epidemiology of adolescents living with HIV since birth.

The online interactive database of paediatric HIV cohorts was formally launched on 4 December 2013 in the wake of World AIDS Day. An online centralized database of paediatric HIV cohorts has hitherto not existed. The CIPHER database is an invaluable tool for researchers, industry, donors and other interested parties to search and find out more about paediatric HIV cohorts worldwide. As a platform for knowledge sharing, it has the potential to foster increased collaboration between cohort studies and mainstreaming of data collection.

A special issue of the open-access *Journal of the International AIDS Society* (JIAS), “Perinatally HIV-infected adolescents”, was also produced, disseminating the latest research and highlighting the emerging needs and challenges of this special population.

At the 7th IAS Conference on HIV Pathogenesis, Treatment and Prevention (IAS 2013), CIPHER hosted and contributed to several events, notably the announcement of the CIPHER grantees at the official awards ceremony and a press conference. At the CIPHER Executive Committee meeting and the Scientific and Technical Advisory Committee meeting, the grantees presented their research projects and CIPHER received much applause for how much had been achieved within one year.

By end 2013, paediatrics was named as one of three IAS priorities, largely due to increased awareness and the overall success of CIPHER. For 2014, CIPHER will continue to promote the paediatric HIV research agenda by building on the solid core programme developed in this initial phase and extend its activities in paediatric HIV to such areas as advocacy and implementation of programmes for scale-up of care and services. Widening the scope of CIPHER stakeholders to include additional partners and sponsors is part of this strategy.
Introduction

Much progress has been made in scaling up prevention of mother-to-child transmission (PMTCT), with a record number of 900,000 pregnant women receiving antiretroviral therapy (ART) for PMTCT in 2012. Overall, an estimated 800,000 new paediatric infections were prevented between 2005 and 2012. This represents a major part of recent progress made in reversing the course of the epidemic: in the past two years, half of all reductions in new HIV infections have been among newborn children.

Despite this progress, 3.2 million children were living with HIV in 2012 and 230,000 died from AIDS-related causes in 2011. UNAIDS reported 260,000 new infections in children in 2012. The paediatric population remains significantly disadvantaged with respect to access to treatment, with only 34% of eligible children receiving ART compared with 65% of eligible adults. And while the number of children exposed to antiretrovirals (ARVs) for prophylaxis and maternal treatment is increasing, there is insufficient data on the long-term impact of early and extended ARV exposure on growth and development.

Access to timely and reliable early infant diagnosis remains only one of many key challenges that paediatric populations face in resource-limited settings. Retention in care, adolescent adherence and transition to adult ART programmes, as well as disclosure, psychosocial support and HIV/STI prevention, are additional challenges. With increasing implementation of PMTCT and ART coverage, studies examining the long-term impact of early and extended ARV exposure on the growth and development of HIV-infected and uninfected children are needed. Data are also lacking on optimal ART initiation and management, paediatric formulations (first-line, second-line and salvage therapy) and interactions between ARVs and drugs to treat co-morbidities. Increased efforts in bridging these identified research gaps are needed to support evidence-based policies and improve the treatment and care of infants, children and adolescents living with HIV.

The International AIDS Society (IAS) has undertaken significant work to identify priority clinical and operational research questions for women and children and to advocate for increased investments in this research agenda as a priority in the work of the IAS-Industry Liaison Forum (IAS-ILF). An environmental scan, Mapping HIV Research Priorities for Women and Children, and the consensus statement, Asking the Right Questions: Advancing an HIV Research Agenda for Women and Children, released in 2010, provided the foundation for the IAS’s ongoing role in promoting and accelerating HIV research relevant to women and children in low- and middle-income countries.

The generous support of the ViiV Healthcare UK Paediatric Innovation Seed Fund made it possible for the IAS to build on its previous efforts in promoting paediatric HIV research – leveraging its convening power to bring together leading international scientists, clinicians and policy makers to address the needs of infants and children living with HIV – by establishing the Collaborative Initiative on Paediatric HIV Education and Research (CIPHER).

1 UNAIDS Global Fact Sheet, WORLD AIDS DAY 2012.
About CIPHER

The IAS launched CIPHER in 2012 with support from ViV Healthcare to begin to address outstanding research gaps related to clinical management and delivery of services to infants, children, and adolescents affected by HIV in resource-limited settings. CIPHER is guided by a world-class Scientific and Technical Advisory Committee (STAC) of experts in paediatric HIV convened by the IAS.

The key objectives of CIPHER are:

- Promoting priority paediatric research by providing investigator-driven research grants and capacity building, with promotion and dissemination of research findings
- Strengthening paediatric cohort collaboration by convening paediatric cohort stakeholders and identifying opportunities for collaboration, and serving as a clearing house for technical support to paediatric cohort investigators.

The first step was to develop a comprehensive research agenda in paediatric HIV in collaboration with key stakeholders and experts; this was titled Evidence for Action: A Needs Assessment of HIV Research Priorities for Paediatric Populations. CIPHER started promoting this agenda through a competitive grant programme, convening a paediatric HIV cohort investigator meeting and providing the platform for two global cohort collaboration projects. A special issue in the Journal of the International AIDS Society (JIAS), “Perinatally HIV-infected adolescents”, was produced and an online paediatric HIV database was developed.

As the paediatric priority of the IAS, in 2014, CIPHER will continue to promote this research agenda by building on the solid core programme developed in this initial phase and extend its activities to advocacy and implementation science. Widening the scope of CIPHER stakeholders to include additional partners and sponsors is part of this strategy.

Clinical Research

- Pharmacokinetic and pharmacodynamic studies of paediatric antiretroviral drugs and co-morbid conditions (particularly for TB, malaria, other common childhood illnesses and nutritional interventions for malnutrition).
- Studies evaluating optimal ART initiation, long-term management and complications in children (especially children over two years of age) and adolescents.
- Studies evaluating the short-term and long-term impact of in utero exposure to maternal antiretroviral therapy and the short-term and long-term impact of paediatric antiretroviral therapy on physical and cognitive development of HIV-infected infants, children and adolescents (key areas include neonatal outcomes, metabolism, bone mineral density, and other clinically-relevant laboratory and biological markers).
- Studies evaluating the short-term and long-term impact of in utero exposure to maternal antiretroviral therapy on physical and cognitive development of HIV-exposed uninfected children and adolescents.
- Studies evaluating and/or validating diagnostic assays to assess neurocognitive and physical development in HIV-exposed infected or uninfected infants, children and adolescents in resource-limited settings.
- Evaluations and/or validation of simplified, standardized diagnostic tools to assess neurocognitive and physical development in HIV-exposed infected or uninfected infants, children and adolescents in resource-limited settings.

Operational Research

- Evaluations of interventions to improve access to reliable early infant diagnostics, including rapid test protocols.
- Studies evaluating interventions and optimal models for integrating paediatric HIV services with maternal, newborn and child health and other health services.
- Studies evaluating interventions and optimal models for promoting early post-natal and long-term programme retention and reducing loss to follow up.
- Studies evaluating optimal approaches to support childhood and adolescent adherence and transition to adult ART programmes.
- Studies evaluating the most effective interventions to support disclosure, access to psychosocial and sexual and reproductive health services, and delivery of biomedical HIV and sexually transmitted infection prevention interventions for adolescents.
The CIPHER Grant Programme was specifically designed to attract early-stage investigators to paediatric HIV research in order to cultivate a new generation of scientists dedicated to the field, and to foster innovative ideas and evidence-based approaches and interventions. All projects funded must address one of the 12 clinical and operational priority research questions identified by the needs assessment. The grants are for up to US$75,000 each for up to two years; 80% of direct costs of the grant must be spent in resource limited settings (RLS).

In 2012, the call for letters of intent (LOIs) for this grant resulted in 143 applications, underlining the great need for funding in this gap area. Twenty-four applicants were asked to submit a full proposal. Following a rigorous peer review, seven projects were selected, addressing five clinical and two operational research gaps.

To maximize the impact of CIPHER in 2013, a total of US$1 million was granted to seven young investigators. Grantees were awarded at the 7th IAS Conference on HIV Pathogenesis, Treatment and Prevention (IAS 2013), where they also participated in grantee networking sessions. In addition, they were announced at the ViiV Healthcare paediatric press conference and the 5th International Workshop on HIV Paediatrics.

- Paul Bangirana from Uganda, Makerere University, for the project entitled Does HIV subtype moderate ART effect neurocognitive functioning in children?
- Degu Dare from Ethiopia, Addis Ababa University, for the project entitled Antiretroviral treatment outcomes among adolescents living with HIV in Ethiopia.
- Rebecca Hodes from South Africa, University of Cape Town, for the project entitled Promoting adolescent antiretroviral adherence and sexual and reproductive health uptake in South Africa: How can health and social protection services collaborate programmatically with HIV-positive adolescents?
- Steven Innes from South Africa, Stellenbosch University, for the project entitled Novel methods for detecting and minimizing chronic cardiovascular, metabolic, respiratory, renal and bone disease in HIV-infected children treated with antiretroviral therapy in southern Africa.
- Atupele Kapito-Tembo from Malawi, University of Malawi College of Medicine, for the project entitled Pharmacovigilance of infants exposed to antiretroviral drugs given to HIV-infected mothers during breastfeeding.
- Matthew Kelly from the United States, Children’s Hospital of Philadelphia, for the project entitled The Effect of in utero exposure to HIV and antiretroviral therapy on the microbiology and outcomes of severe pneumonia.
- Nelleke Langerak from the Netherlands, University of Cape Town, for the project entitled HIV encephalopathy: definition of the natural history, physical characteristics and imaging findings in a group of children with gait abnormalities.
Evaluation of the application and review process

There were 33 respondents to the evaluation survey of the application and review process who had submitted a LOI but were not selected for a full application. The vast majority of these respondents found the application process satisfactory, including instructions (91%), the scope and length of the LOI form (82%), as well as the support received from the CIPHER team (94%). Most of the 33 survey respondents worked in sub-Saharan Africa (76%), followed by Asia and south east Asia (12%). A minority of the respondents indicated that improvements could be made regarding technical aspects of filling out the online form and the length of the LOI (four respondents), and would like to have had more support from the secretariat, as well as clarity on how and what kind of support could be received (two respondents).

Of the 24 applicants invited to submit a full proposal, 14 responded to the evaluation survey. The majority were likewise satisfied with the full application process. One applicant indicated that he/she had technical issues with the online form, whereas another applicant would have liked to have had more space provided in the full application. Other suggestions included more detailed feedback from reviewers, as well as a quicker response with a decision on whether an application had been accepted or not. Such feedback will be taken into account in future rounds of the CIPHER Grant Programme.

Full proposals underwent a rigorous, independent peer review, in which they were reviewed by three experts in the field. Most responding reviewers found the system satisfactory, including the instructions (94%), the number of applications reviewed (81%), the scoring scale (94%), the timeline (75%), the conflict of interest policy (94%) and the support received from the CIPHER team (75%). Three respondents mentioned that they would have liked to be given more time to review applications (at least two months for an in-depth review). Comments were also made regarding the importance of reviewing a minimum number of applications in order to be able to rank fairly. Some respondents would also be interested in accessing the other reviewers’ comments and being informed of the final grading and results of the funded proposals.
Paediatric HIV Cohort Investigator Consultation

On 13-15 May 2013, CIPHER convened a Paediatric HIV Cohort Investigator Consultation with investigators from the major paediatric HIV cohorts worldwide. The objectives of the meeting were to establish a baseline description of the cohorts and their activities, and to identify priority gaps needed to inform policy that could be addressed by cohort collaboration and a mechanism for addressing those gaps.

Co-chaired by Lynne Mofenson (National Institutes of Health, USA) and Linda-Gail Bekker (IAS Governing Council/Desmond Tutu AIDS Foundation, South Africa), the meeting included a series of cohort presentations, breakout groups and plenary report backs, which resulted in discussion and consensus recommendations. The agenda was structured and chaired to best leverage the expertise of participants not only in developing recommendations for strengthening paediatric cohort collaboration, but also to encourage innovative ideas for research projects that are important and could even be pursued through other funding channels.

The objectives of the meeting were achieved beyond expectations. Notably, the meeting defined a research agenda of knowledge gaps that can be addressed by cohort collaboration and resulted in agreement by the investigators present to collaborate on data-sharing projects. The projects will look at two critical research gaps in paediatric HIV: (1) the durability of first-line ART in children in resource-limited settings; and (2) the global epidemiology of adolescents living with HIV since birth.

These two projects aim to fill research gaps and support evidence-based policy decisions to optimize care and treatment of children and adolescents. For example, data on the durability of ART regimens is critical to inform clinicians, public health policy and programme planning. This is particularly important in HIV-infected children under five years old who, according to the new 2013 WHO Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection, have been recommended to initiate immediate therapy and are likely to need life-long treatment. However, data on the probability of switch to second-line in children are limited, and definitions of what constitutes “second-line” treatment vary. Also, with increasing access to ART, HIV-infected children now live longer, making perinatally HIV-infected adolescents an emerging and growing population. In order to ensure optimal health outcomes, there is a global need to better understand the characteristics of these adolescents and their ability to remain in paediatric care and transition to adult care.

Consensus potential research projects

1. Adolescent transition to adult care: This priority research project could identify important factors in loss to follow up (LTFU) and the interventions/services (such as transition plans) that might ensure a smooth transition to adult programmes.

2. Duration on first-line ART to switch: This research project was seen as a high priority given its potential impact on informing clinical management and improving health outcomes of paediatric populations. Participants noted that it could also include mortality and LTFU data (note that EPPICC and IeDEA were both collecting these data and could leverage that work to produce a global analysis).

3. Pregnancy outcomes of perinatally infected adolescents: Determining pregnancy outcomes among HIV-infected adolescents (including the health status of infants) would require retrospective data collection (descriptive in nature), including characteristics and pregnancy outcomes (HIV diagnosis, birth weight, other standard measures). It was noted that there is not a lot of a data available on this issue at the moment, and it would require substantial work in determining data elements (therefore it was deemed a lower priority than the first two research projects mentioned).

4. Parking lot (potential future projects): An HBV and HCV cross-sectional prevalence blood testing survey using point-of-care assays in selected sites with regional representation would provide important information to clinicians. In discussions, participants noted that the project is likely to require significant costs, and so the decision was to table this project as a potential future project.
CIPHER is providing a grant of US$500,000 to fund these two important projects, the first to include such a broad range of participating paediatric cohorts. The grant will be given to three data centres that will be handling the data collection and analysis for the project. The principal investigator for the project is Dr Mary-Ann Davies (Centre for Infectious Disease Epidemiology and Research, University of Cape Town, South Africa), in partnership with lead investigators Dr Ali Judd (Medical Research Council Clinical Trials Unit at University College London, UK) and Dr George Seage III (Paediatric HIV/AIDS Cohort Study Data and Operations Center, Harvard School of Public Health, USA). Findings of the studies will be published jointly as the CIPHER Cohort Collaboration.

To advise this phase of the initiative, a CIPHER Cohort Executive Committee was established, chaired by Linda-Gail Bekker (Desmond Tutu HIV Centre, University of Cape Town), the IAS Governing Council representative for CIPHER. A Cohort Steering Committee, containing one representative from each of the cohorts/cohort networks present, was established to ensure cohort representation and buy-in for the projects. By the end of 2013, concept notes for each project had been drafted and they are being further developed by working groups.

In addition, the grant includes a capacity-building scholarship for a scholar from the University of Cape Town to study for two months with the HSPH data centre.

The meeting was held on San Servolo Island, Venice, Italy, alongside the 2013 Paediatric European Network for Treatment of AIDS-Infectious Diseases (PENTA-ID) meeting. Following the CIPHER meeting, PENTA graciously invited all 35 of the meeting participants to stay and attend PENTA-ID 2013, allowing for an additional three days of discussion and exchange.

**Project partners:**
- A Prospective Surveillance Study of Long-term Outcomes in HIV-infected Infants, Children and Adolescents (IMPAACT P1074)
- Baylor International Pediatric AIDS Initiative at Texas Children’s Hospital (BIPAI)
- Caribbean, Central and South America Network for HIV Research (CCASAnet)
- Collaborative HIV Paediatric Study (CHIPS)
- East African International Databases to Evaluate AIDS (EA-IeDEA)
- The European Pregnancy and Paediatric HIV Cohort Collaboration (EPPICC) - including PMTCT and Eastern European cohorts
- Identifying Optimal Models for Care in Africa (Optimal Models ICAP)
- International Epidemiologic Database to Evaluate AIDS Central Africa (CA-IeDEA)
- International Epidemiologic Database to Evaluate AIDS Southern Africa (IeDEA-SA)
- International Epidemiologic Database to Evaluate AIDS West Africa Collaboration (WADA and pWADA)
- Médecins Sans Frontières Pediatric Cohorts (MSF)
- Pediatric HIV/AIDS Cohort Study: Adolescent Master Protocol (PHACS AMP)
- Pediatric HIV/AIDS Cohort Study: Surveillance Monitoring for ART Toxicities Study (PHACS SMARTT)
- Pediatric Late Outcomes Protocol (PACTG/IMPAACT 219/219c)
- TREAT Asia Pediatric HIV Observational Database (TApHOD-IeDEA)
CIPHER database

Part of the cohort initiative was the development of an online searchable database, with an interactive map depicting paediatric HIV cohorts worldwide. To maximize publicity, it was launched during the week of World AIDS Day, on 4 December 2013. The database is intended to act as a dedicated platform for communication and coordination, facilitating harmonization of protocols, data collection, sharing and analysis between cohorts. Cohorts can register, modify and update their entries, and are asked to provide key information about the variables under investigation, as well as the number of participants disaggregated by age group, sex and HIV status. Through the interactive map or the search function, viewers are able to access comprehensive cohort profiles. As a knowledge-sharing tool for researchers, funders and policy makers, the CIPHER database has the potential to spur further research in paediatric HIV and foster enhanced collaboration between cohort studies.

By the end of the first quarter of 2014, the database had a total of 338 visits representing 199 unique visitors. The majority of visits stemmed from Switzerland, the United States and Thailand, respectively. Most of the visits (almost 85%) were derived from direct links (made available in the announcements and the official press release). Other visitors accessed the database through the IAS website (11%), while a small minority of visits came through amfar.org, Google and ias2013.org.

In future, the database will be optimized for search engines along with other improvements. This online resource will be further developed with additional functions, such as the announcement of research grant opportunities, as well as acting as a clearing house for publications and other resources relevant to clinicians and scientists working in the paediatric HIV research field. It is also envisioned that the database will provide an epidemiological tool by offering the most current numbers of cohort participants worldwide.
JIAS special issue: Perinatally HIV-infected adolescents

Given the scarcity of information about perinatally HIV-infected adolescents and the effects of long-term exposure to HIV and ARVs, CIPHER supported a special issue in the Journal of the International AIDS Society (JIAS), “Perinatally HIV-infected adolescents”. It was published on 18 June 2013 and was guest edited by Dr Mark Cotton (Stellenbosch University, South Africa) and Dr Lynne Mofenson (NIH, United States).

This publication covers some of the latest research addressing the unique needs and challenges with respect to the treatment and care of the burgeoning population of perinatally infected children surviving to adolescence. Issues discussed include heart, kidney, lung and bone health, as well as psychosocial well-being, epidemiology, metabolism and neurodevelopment.

By the end of December 2013, abstracts from the special issue had been accessed 6,652 times, while full-text articles had been accessed 3,831 times. These figures demonstrate the high interest generated by this publication, and do not account for the dissemination of 1,000 printed copies.

Events at IAS 2013

IAS conferences represent a key forum for convening stakeholders and addressing issues in HIV. CIPHER held numerous events at the 7th IAS Conference on HIV, Pathogenesis, Treatment and Prevention (IAS 2013), including an announcement of the CIPHER grantees at the 5th International Workshop on HIV Paediatrics, as well as the formal announcement before the first plenary session at IAS 2013. Grantees were also invited to participate in a capacity-building programme, including networking sessions and a JIAS-led abstract writing workshop. The JIAS special issue, “Perinatally HIV-infected adolescents”, was formally launched at IAS 2013 and four closed-door meetings were held back to back on 30 June 2013. These were: a CIPHER Executive Committee meeting; a Scientific and Technical Advisory Committee meeting; a “grantee and mentor session”, including STAC and representatives from ViiV Healthcare, which was an opportunity for grantees to present their research projects; and a CIPHER Database Working Group meeting. Moreover, a press conference was held with ViiV Healthcare, amfAR TREAT Asia and the Elizabeth Glaser Pediatric AIDS Foundation to discuss the key hot topics in paediatric HIV coming out of the conference, for example, the Mississippi baby and the new WHO Consolidated Treatment Guidelines, and to announce the CIPHER grantees.