

**A. SPECIFIC AIMS.**

The primary aim of the VUKA Family Program study is to meet the urgent need for theory-driven, empirically-informed, effective, and sustainable HIV prevention and care approaches for the unprecedented numbers of perinatally HIV-infected (PHIV+) youth in South Africa (SA). This study aims to 1) increase our understanding of behavioral and health risks in this emerging population, and 2) examine the impact of a family/household-level intervention, the VUKA Family Program (VUKA), on youth overall health and mental health, and reduce behavioral risk. VUKA (which means WAKE UP in Zulu) is informed by a robust program of HIV prevention and care research conducted by CHAMP (Collaborative HIV Prevention and Adolescent Mental Health Project) investigators (McKay, Mellins, Bhana, Petersen, Holst, Abrams) in the US and internationally.

Aim #1 (Primary): To identify the behavioral (e.g., ART adherence, attendance at clinic medical appointments, involvement in sexual and drug use possibility situations), health (e.g., level of viremia, general health), and psychosocial (e.g. mental health, connection to protective adult resources, coping) risks of this emerging population of PHIV+ youth in South Africa.

Aim #2 (Primary): To examine the impact of VUKA on youth behavioral, health and psychosocial outcomes relative to those who receive standard care within South African public medical clinics. Hypotheses: Compared to standard care, children exposed to VUKA will show greater improvements in all three overlapping outcomes: a) behavior; b) health; and c) psychosocial risks.

Aim #3 (Secondary): To investigate how outcomes are mediated by theoretical constructs as represented in the Social Action Theory (SAT) model (self-regulation, social/family regulation, and contextual factors).

Aim #4 (Secondary): To elucidate multi-level factors that influence implementation, and integration of VUKA (e.g. staff delivery skill, perceptions of burden, clinic organizational challenges, time and space constraints) in publicly funded, pediatric HIV care sites in KwaZulu-Natal, SA. We draw upon the PRISM model (Practical, Robust Implementation and Sustainability Model) which emphasizes how interventions interact with the characteristics of recipients (settings, staff and youth/family members) to influence implementation and integration outcomes.

**B. STUDIES AND RESULTS.**Overview.

This study is a randomized controlled trial to examine the effectiveness, implementation, and integration processes associated with VUKA with a sample of 360 PHIV+ early adolescents (9 to 14 years of age) registered at 4 publicly financed pediatric HIV clinics in KwaZulu-Natal, South Africa. Youth and their family members will be randomly assigned to one of two study conditions: 1) VUKA or 2) standard of care (SOC), with research assessments at 3 time points: baseline, 3 months (post-test) and 12 months (follow-up) from baseline. In order to promote sustainability in low resources settings, VUKA has been designed to align with the training and skill levels of lay HIV counselors who are almost universally employed in public health clinic settings across Africa. VUKA is a cartoon-based intervention developed with intensive input from SA investigators, graphic artists, medical staff, adult caregivers and HIV+ adolescents. It is one of the few available interventions to promote the well-being of children growing up with HIV infection in low-middle income countries that is theory-driven, evidence-informed and has promising pilot results.

Ethics clearance and study site access

The project received initial IRB approval to proceed with non-human subjects activities from New York University on 9 July 2012. Full ethics approval for human subjects activities from the Institutional Review Boards (IRBs) of New York University was then received on 26 March 2013 and from Columbia University on 21 March 2013. Final approval from Human Sciences Research Council (HSRC) was received on 18 July 2012. The KwaZulu Natal Department of Health has given approval for access to 4 sites: The RK KHAN Hospital (RKK) and Prince Mshiyeni Memorial Hospital (PMMH) and 2 additional sites are in the process of being identified by the National Department of Health.

Study activities

Drs. McKay and Mellins along with the NICHD program officer have made one site visit at the study start up with Drs. Bhana, Chhagan and Petersen. Weekly calls have taken place throughout the year to review all study procedures, changes in South African policies, new developments, etc. Drs. McKay, Mellins and Ms. Small (one of the US project managers) will visit South Africa again in July for intervention start up.

Staff

A South Africa-based Project Manager has been employed to oversee the daily study operations and on site running of the study and South Africa-based Research Assistant has been employed to extend research support to the PI and project manager. Experienced US-based project management staff has also been hired.

#### Data Collection Systems

The initial protocol had described a paper-based system for collecting youth, caregiver and health data, however the investigators have opted for a more efficient paperless data collection system using hand held devices (tablets) which will be used to capture data at the site level.

ART adherence is an important study outcome measure and adherence will be assessed with *Wisepill*, an electronic monitoring system (similar to MEMS caps) and also by self-report. *Wisepill* devices have been delivered to the study team. The study team has undergone training on how to use the *Wisepill* devices as well as how to navigate the *Wisepill* web console to monitor patient usage of the device. Dr. Mellins and US consultant, Reuben Robins, have used *Wisepill* in Cape Town, South Africa as part of an adult adherence intervention and have facilitated adaptation for VUKA in collaboration with the developer of *Wise Pill*.

#### Site visits

The project staff has held meetings with ARV clinic managers of both RK KHAN Hospital and the Prince Mshiyeni Memorial Hospital to introduce the study to the managers and ensure their support and approval for future site visits and staff contact sessions. Several meetings have been held with lay counselors at both sites to explain the purpose of the study and encourage the lay counselors participation in the VUKA family sessions. The study team has conducted intensive clinic observations to document roles and responsibilities of the clinic staff, duties of the counselors and patient flow through the clinic. These observations have been conducted to determine how best to place VUKA within the clinic and to gauge the best times for recruitment, VUKA sessions and data collection. All three of the South African investigators have met numerous times with South African Department of Health officials to ensure stakeholder buy-in and that VUKA complies with all DOH regulations concerning pediatric treatment and care. Dr. Chhagan in particular is head of Maternal and Child Health at UKZN and will ensure that VUKA curricula and adherence assessment remain relevant to current antiretroviral regimens and treatment overall.

#### Finalization of batteries for caregiver and adolescents

The batteries to measure psychosocial outcomes in caregivers and adolescents have been finalized and programming of these instruments onto the tablets is underway. This involved review of the VUKA pilot data, input from staff and other investigators in South Africa, and adaptations to ensure a battery that was feasible and culturally acceptable.

#### Recruitment and enrollment

Ten RK KHAN counselors were trained on facilitation skills and conducting VUKA sessions on 16 May 2013. The remaining three counselors will be trained shortly as will all the counselors at Prince Mshiyeni. The first two cohorts of participants have been approached (20 youth and their adult caregivers) and expressed interest in enrollment at RK KHAN. Informed consent process is in process and baseline data collection efforts are underway. At Prince Mshiyeni, the first cohort of participants has been approached (10 youth and their adult caregivers) with the same expressed interest in enrollment. Informed consent and baseline assessments are underway. The first groups will begin in July, 2013.

### **C. SIGNIFICANCE**

An increasing number of adolescents born with HIV in South Africa are on antiretroviral treatment and have to confront complex issues related to coping with a chronic, stigmatizing and transmittable illness. Very few evidence-based mental health and health promotion programs for this population exist in South Africa. This study builds on a previous collaboratively designed and developmentally-timed family-based intervention for early adolescents (CHAMP). The VUKA intervention is one of the few pilot tested interventions.

### **D. PLANS.**

Study set up at the first 2 sites will be complete by the end of Year 1 and recruitment of patients into the study has commenced. In Year 2, enrollment will continue. In addition, the team will be investigating factors that could hinder or enable the sustainability of the VUKA at the sites namely, the organizational culture and attitudes of staff in relation to

adolescents and also to interventions such as VUKA. Two further study sites will be identified by the South African Department of Health in Year 2 of the study.

#### **E. HUMAN SUBJECTS.**

No changes in human subjects protocol and projections have been made. The total sample size for the study is 360 HIV+ pre/early adolescent youth, aged 9-14 years. Inclusion criteria are:

- a) Child perinatal HIV infection;
- b) Child aware of their HIV+ status;
- c) Child on ART;
- d) Participants are Zulu (the vast majority of patients) or English speaking;
- e) Capable of consent (caregiver) or assent (child).

#### **F. PUBLICATIONS.**

McKay MM, Alicea S, Elwyn L, McClaim ZRB, Parker G, Small L, Mellins CA. Addressing the need for theory-driven programs capable of impacting poverty-impacted children's health, mental health and prevention needs: CHAMP and CHAMP+, evidence-informed, family-based interventions to address HIV risk and care. *Journal of Clinical Child and Adolescent Psychology*. In press. PMC Journal – PMC in process.

Bhana A, Mellins CA, Petersen I, Alicea S, Myeza N, Holst H, Abrams E, Johns S, Chhagan M, Nestadt DF. The VUKA Family Program: Piloting a family-based psychosocial intervention to promote health and mental health among HIV+ early adolescents in South Africa. *AIDS Care*. In press. PMC Journal – PMC in process.

Nestadt DF, Alicea S, Petersen I, John S, Myeza NP, Nicholas SW, Cohen LG, Holst H, Bhana A, McKay MM, Abrams EJ, Mellins CA. HIV+ and HIV– youth living in group homes in South Africa need more psychosocial support. *Vulnerable Children and Youth Studies*, 2013;1-11. Epub ahead of print. NIHMSID: NIHMS468416

Mellins CA, Malee K. Understanding the mental health of youth living with perinatal HIV infection: Lessons learned and current challenges. *Journal of the International AIDS Society*, in press (June or July publication). PMC Journal - PMC in process.

#### VUKA presentations

Mellins CA. Behavioral Challenges in Perinatally HIV Youth. Invited paper at symposium at the 20<sup>th</sup> Conference on Retroviruses and Opportunistic Infections (CROI), Atlanta, Abstract #118 March 2013.

Mellins CA, Bhana A, Petersen I, Holst H, Alicea S, Myeza N, Abrams EJ, John S, Leu CS, Chhagan M, McKay M. The VUKA Family Project: A family-based Mental Health and HIV Prevention Program for Perinatally HIV-infected Youth. Poster presentation at the XIX International AIDS Conference, Washington DC July 2012. Abstract # TUPE316.

Mellins, CA, Ongoing follow up of HIV positive children within an integrated approach – future issues and challenges. Invited talk. The Road to Melbourne: Young Children Born into HIV-affected Families Meeting 1 (New York): Early intervention: Evidence and Entry Points. Unicef/UNAIDS/ Coalition for Children Affected by AIDS. May 30-31. New York City.

McKay, MM, Family strengthening and HIV prevention: Challenges to implementation and sustainability. Grand Rounds presentation at Columbia University HIV Center for Clinical and Behavioral Studies. June 6. New York City.

**F. PROJECT GENERATED RESOURCES:** No resources have been generated from this grant.