



Complications & Comorbidities Scientific Committee
IMPAACT Network Meeting
June 12, 2019

Complications and Comorbidities Scientific Committee

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Sarah Bouisson

SLG Liaison: Grace John-Stewart

Finish Line = Long healthy life!





Complications & Comorbidities - 4 Focus Areas

- **Neurobehavioral impairment**
 - mental health, cognition
- **Vaccines (non-HIV)**
- **Chronic inflammation/immune activation**
- **Long Term Complications**
 - HIV and ART



Summary of Priorities by Region

Priorities	Asia	Africa	South America	U.S.
Cognitive impairment				
Psychiatric & mental health (depression, anxiety)				
HIV & HCV co-infection				
HIV & aging				
Long term effects of children born to women on option B+				
Lipodystrophy (prevention & resolution)				
Long term complications (HIV & ART)				
Immune activation & inflammation				

A white sticky note with a red pushpin at the top left corner is pinned to the right side of the table. The note has the handwritten text "What's the plan?" in black ink.

Neurobehavioral Studies

Completed recent studies:

IMPAACT 1104S: Longitudinal Developmental and Neuropsychological Assessment of the P1060 Clinical Trial Cohort

IMPAACT 2002: Depression among adolescents (US)

Neuropsychological performance in African children with HIV enrolled in a multisite antiretroviral clinical trial

Michael J. Boivin^a, Linda Barlow-Mosha^b, Miriam C. Chernoff^c, Barbara Laughton^d, Bonnie Zimmer^e, Celeste Joyce^f, Mutsa Bwakura-Dangarembizi^g, Mmule Ratswana^h, Nasreen Abrahamsⁱ, Lee Fairlie^h, Hermien Gous^h, Portia Kamthunzi^j, Katie McCarthy^k, Itziar Familiar-Lopez^a, Patrick Jean-Phillippe^l, Joan Coetzee^d, Avy Violari^f, Mark C. Cotton^d, Paul E. Palumbo^m, the IMPAACT P1104s Study Team

Objective and design: Children with HIV infection (HIV+) are at neuropsychological





Neurobehavioral Studies

NWCS 602	Neurobehavioral and neuropsych outcomes & inflammation/immune activation (among suppressed)	US
Bearden	Inflammation and neurocognitive outcomes in the broad population (PHACS/1074)	US
2016	Group intervention for Treatment of Depression among HIV+ youth in low resource settings	INTL
2015	CSF evaluation of individuals with evidence of decreased neurocognitive function*	US

In development:

CAP 548: impact of computerized cognitive rehabilitation training on neurocognitive function. Target population: graduates of P1104s and, possibly, additional, similar patients at P1104s sites. (Boivin R01)

Future planning:

INTERVENTIONS!!

*Cure protocol

Vaccines



2011	Phase I Placebo-Controlled Study of the Infectivity, Safety and Immunogenicity of a Single Dose of a Recombinant Live-Attenuated RSV Vaccine, LID Δ M2-2 1030s, Lot RSV#010A, Delivered as Nose Drops to RSV Seronegative Infants 6 to 24 Months of Age	US
2012	Phase I Placebo-Controlled Study of the Infectivity, Safety and Immunogenicity of a Single Dose of a Recombinant Live-Attenuated RSV Vaccine, LID cp Δ M2-2, Lot RSV#009B, Delivered as Nose Drops to RSV Seronegative Infants 6 to 24 Months of Age	US
2013	Phase I Placebo-Controlled Study of the Infectivity, Safety and Immunogenicity of a Single Dose of a Recombinant Live-Attenuated RSV Vaccine, D46/NS2/N/ Δ M2-2-HindIII, Lot RSV#011B, Delivered as Nose Drops to RSV-Seronegative Infants 6 to 24 Months of Age	US
2018	Phase I Study of the Infectivity, Safety and Immunogenicity of Two Recombinant Live-Attenuated Respiratory Syncytial Virus (RSV) Vaccines (RSV Δ NS2/ Δ 1313/I1314L and RSV 276) With Different Modes of Attenuation, Delivered in a Single Dose as Nose Drops to RSV-Seronegative Infants and Children 6 to 24 Months of Age	US

Next steps: move into efficacy trial

Vaccines

In development: RSV vaccine study among pregnant women (Weinberg)- on hold

Future:

Other vaccines?

Other diseases?

Inflammation



	Neurobehavioral and neuropsych outcomes & inflammation/immune activation (among suppressed)	US
Bearden	Inflammation and neurocognitive outcomes in the broad population (PHACS/1074)	US
Agwu	ASA vs. Fish Oil Statin → decrease risk of cardiovascular disease	US

In development:

CS5020: Low dose ASA for prevention of preterm birth in women with HIV

Future planning:

move promising interventions into our populations

-Microbiome working group

-Revisit statins?



Complications-Completed studies

1074	Long-term follow-up study*	US
1076	Impact of Oral Alendronate on Bone Mineral Density in HIV+ Children & Adolescents with Low Bone Mineral Density [⊥]	US/ INTL
1063	Safety of Atorvastatin for PI-assoc. high LDL cholesterol*	US
1079	PK of Artemisinin antimalarial therapy within the context of ART	INTL
1084s	Toxicity Related to Tenofovir: Bone & Kidney Substudy of PROMISE*	INTL

*Manuscripts submitted/ in development; [⊥]Analysis ongoing



Complications & Comorbidities— ongoing studies

PHACS

Pediatric HIV/AIDS Cohort Study/ 219C*

US

In planning/development:

Assessment of DTG/other INSTs and weight gain in PHACS cohort
STI working group

Future planning:

- Hep C treatment among co-infected pregnant women?
- identify important co-morbidities to target, based on new data in HIV+ adults or other chronic diseases
- move promising interventions into our populations

*Available to query for specific questions



Let's Get It
STARTED!



