SUMMARY STATEMENT

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(Privileged Communication) ***Release Date:*** **08/21/2015**

Application Number: **1 R21 HD084274-01A1**

Principal Investigators (Listed Alphabetically):
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MEDINA-MARINO, ANDREW PHD

Applicant Organization: UNIVERSITY OF CALIFORNIA LOS ANGELES

Review Group: **BSPH**
Behavioral and Social Science Approaches to Preventing HIV/AIDS Study Section
AIDS

Meeting Date: **07/09/2015** ***RFA/PA:*** **PA13-303**
Council: **OCT 2015** ***PCC:*** **MPIDB-DR**
Requested Start: **09/01/2015**
Dual IC(s): **AI**

Project Title: **Pilot Study of STI Screening and Treatment for PMTCT**

SRG Action: **Impact Score: 10 Percentile: 3 +**
Next Steps: **Visit http://grants.nih.gov/grants/next_steps.htm**
Human Subjects: **30-Human subjects involved - Certified, no SRG concerns**
Animal Subjects: **10-No live vertebrate animals involved for competing appl.**
Gender: **2A-Only women, scientifically acceptable**
Minority: **5A-Only foreign subjects, scientifically acceptable**
Children: **1A-Both Children and Adults, scientifically acceptable**
Clinical Research - not NIH-defined Phase III Trial

Project Year	Direct Costs Requested	Estimated Total Cost
1	125,000	160,949
2	150,000	193,138
TOTAL	275,000	354,087

ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.

1R21HD084274-01A1 Klausner, Jeffrey

RESUME AND SUMMARY OF DISCUSSION: This outstanding applicant proposes investigating the feasibility and acceptability of implementing point of care screening for gonorrhea (NG) and Chlamydia (CT) infections in pregnant women in Tshwane, South Africa at their first antenatal care visit to prevent mother to child transmission of HIV as well as adverse birth outcomes. Women found infected with NG and or CT will, with their consent, be rapidly placed in treatment and treatment will be extended to their male partners as well. Research by this team has demonstrated the impact of NG & CT infections on MTCT of HIV as well as untoward birth events. The evidence for conducting this study is compelling and underscores its significance. In fact, the feasibility of this approach has been tested in Peru, raising confidence about a similar outcome in South Africa. The PI enjoys national and international reputation in this domain; his equally well qualified team of collaborators have the complementary expertise to ensure the success of this project. This resubmission was very responsive to prior critiques and the application has been further strengthened. The proposed study promises a very high public health impact in South Africa, a region with the highest rate of MTCT in the world. The data garnered will provide insight into the prevalence of NG & CT among HIV infected pregnant women in Tshwane, as well as estimates of the frequency of adverse birth outcomes and their association with CT and NG screening and treatment. It will also provide estimates of the frequency of HIV MTCT and its association with CT and NG screening and treatment in the area. This application is truly comprehensive in the breadth of measures it will consider and in the rigor of its design. Comments were made about a lack of details in the collection and analyses of the qualitative component of the study; these, however, did not in any way dampen this committee's wholehearted support for an application it assesses as potentially having extremely high impact on antenatal care of women in South Africa and in low to middle income regions with high rates of HIV.

DESCRIPTION (provided by applicant): The proposed study will help fill critical gaps in the understanding of how bacterial STIs may impact mother-to-child-transmission (MTCT) of HIV infection and infant morbidity and mortality in the era of combination antiretroviral therapy in pregnant women. We propose a study to investigate screening for Neisseria gonorrhoeae (NG) and Chlamydia trachomatis (CT) infections, and the potential impact of a screening program on the MTCT of HIV infection. Recent research by our group, including in South Africa, has demonstrated that NG and CT infections doubled the risk of mother-to-child HIV transmission. South Africa's estimated preterm delivery rate of 8 per 100 live-births results in more than 80,000 preterm births annually, associated with about 60% infant mortality. With one of the largest numbers of HIV-infected pregnant women delivering annually in the world (>300,000), both adverse birth outcomes and HIV MTCT are significant public health problems; despite this, few studies have systematically measured the role of STIs and adverse birth outcomes in HIV-infected South African women. There are two specific aims to our proposal. Aim 1: We will determine the acceptability and feasibility of screening and treating HIV-infected pregnant women for NG and CT at first antenatal care visit, in order to: a) determine the proportion of eligible women consenting to testing (acceptability) and NG/CT-infected women receiving treatment within two weeks of specimen collection (feasibility), b) estimate the prevalence of CT and NG in HIV-infected pregnant women in Tshwane District, South Africa; and c) examine correlates of CT and/or NG infection and CT/NG treatment outcomes among pregnant women in the study. Aim 2: We will describe longitudinal birth and infant outcomes for HIV-infected pregnant women screened for CT and NG, in order to: a) estimate the frequency of adverse birth outcomes and their association with CT and NG screening and treatment; and b) estimate the frequency of HIV MTCT and its association with CT and NG screening and treatment. This pilot study is designed to determine the feasibility and acceptability of routinizing CT/NG screening and treatment of HIV-infected pregnant women, including treatment of partners to prevent re-infection. It has the potential to significantly inform programs aimed at the prevention of HIV MTCT in South Africa and to directly impact clinical and public health practices

in low and middle-income countries relating to maternal-child health, especially relating to bacterial STIs.

PUBLIC HEALTH RELEVANCE: This pilot study will enhance knowledge of the prevalence of maternal and congenital infections and birth outcomes in high risk populations in low and middle-income countries, and explore how gonorrhea and chlamydia may influence mother-to-child transmission (MTCT) of HIV. It has the potential to significantly inform programs aimed at the prevention of HIV MTCT in South Africa and to directly impact clinical and public health practices in low and middle-income countries relating to maternal-child health, especially relating to bacterial STIs.

CRITIQUE 1:

Significance: 1
Investigator(s): 1
Innovation: 3
Approach: 2
Environment: 1

Overall Impact: This is a highly responsive resubmission of a new R21 application that seeks to determine the feasibility, acceptability, and potential impact of adding molecular point-of-care (POC) diagnostic screening and treatment for Neisseria gonorrhoeae (NG) and Chlamydia trachomatis (CT) infections among HIV-infected female clients at two clinics in South Africa. The accomplished team has demonstrated the feasibility in a different setting in Peru and now seeks to study the potential for implementation in Africa. The study has the potential to significantly inform PMTCT programs on the feasibility and potential impact of POC NG and CT screening and treatment on adverse birth outcomes and vertical HIV transmission. The study is clearly designed and described and is feasible. The investigators have been very responsive to the prior critiques and the changes made have significantly strengthened the application. There remain some minor concerns around the non-random comparison group and the use of self-report for partner treatment success and the added qualitative interview areas could use some expansion. Overall, an improved application that could be quite high-impact if successful.

1. Significance:

Strengths

- NG and CT have a significant impact on mother to child HIV transmission in Africa.
- Research will help bridge the knowledge gap of NG and CT prevalence as diagnosed by molecular methods among HIV infected women in South Africa.
- Point of Care (POC) molecular diagnostics are a potential reality for better-resourced African municipalities.
- Study has the potential to significantly inform PMTCT programs on the feasibility and potential impact of POC NG and CT screening and treatment on vertical transmission.
- Addition of qualitative interviews of subjects adds to the significance of data to be collected in this pilot.

Weaknesses

- None Noted

2. Investigator(s):

Strengths

- Dr. Klausner is an internationally recognized expert in STIs and HIV.
- Dr. Medina-Marino has been the Laboratory Branch Chief for CDC-South Africa and experience within PEPFAR focusing on strengthening public health laboratory systems and disease surveillance programs for HIV/AIDS, TB and opportunistic infections.
- Addition of Dr. Margot Uys, an implementation science expert in PMTCT is a strength.
- Study has OB/GYN consultant.

Weaknesses

- None Noted

3. Innovation:

Strengths

- POC screening for NG and CT in the context of PMTCT is novel.

Weaknesses

- No innovations in approach or study design are attempted, however this is a developmental pilot R21.

4. Approach:

Strengths

- Methods and procedures are clearly described and practical.
- Prior studies in Peru add to project feasibility.
- List of potential confounders related to adverse birth outcomes to be collected is comprehensive.
- Qualitative interviews with patients are now included to help assess acceptability.
- Patient appointment reminders and tracking efforts are well described and a strength.
- Inclusion of partner referral and treatment has now been addressed
- Rescreening for NG and CT infection at week 32 of pregnancy is now included.
- Sample size calculation of estimate precision is reasonable
- Description of propensity score matching procedures is now included.

Weaknesses

- Self-report of successful partner treatment is a highly suspect measure are very susceptible to social-desirability response bias.
- Qualitative areas of investigation are somewhat limited to technical aspects of the specimen collection. It would be of value to include discussions of patients' motivation and barriers to engage in STI testing and issues around partner testing as well.

- There is still concern over the non-randomized comparison group for aim 2. Selection bias will likely be present for those attending two ANC visits at the time of enrollment compared to the intervention group (only 1 ANC visit). It is noted that this was done for practical recruitment issues and is only a minor weakness.

5. Environment:

Strengths

- UCLA School of Medicine and the Department of Epidemiology, School of Public Health are all exemplary research institutions with excellent track records in HIV research.
- South African collaborating institutions are strong and show support for the research.

Weaknesses

- None Noted

Protections for Human Subjects:

- Acceptable

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Not Applicable (No Clinical Trials)

Inclusion of Women, Minorities and Children:

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- Inclusion/Exclusion of Children under 21: Including ages < 21 justified scientifically
- Acceptable

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Resubmission:

- The resubmission application is seen to be highly responsive. Only minor concerns remain.

Applications from Foreign Organizations:

Justified

- Acceptable

Budget and Period of Support:

Recommend as Requested:

CRITIQUE 2:

Significance: 1
Investigator(s): 1
Innovation: 2
Approach: 2
Environment: 1

Overall Impact: This revised proposal – to screen for STIs during pregnancy in a region in South Africa with very high HIV prevalence - responded to all critiques in the summary statement. Where the original reviewers scored the proposal as very strong with minor weaknesses (fit to acceptability and feasibility, partner screening, retesting, further explanation of propensity score matching and differential inclusion for controls) those weaknesses have been addressed.

1. Significance:

Strengths

- Addresses problem of vertical transmission among the largest population of HIV+ pregnant women in the world (>300,000)
- Address STIs during pregnancy
- Focus on STIs appropriate, doubling the possibility of vertical transmission and influencing other outcomes (preterm births and high infant mortality).

Weaknesses

- None Noted

2. Investigator(s):

Strengths

- Excellent team of NIH experienced and collaborating researchers in US and SA, bolstered by new biostatistician.
- Close working relationship of SA organization and local health authorities.

Weaknesses

- Biostatistician is undoubtedly qualified but no evidence of experience with propensity score matching.

3. Innovation:

Strengths

- First test of point of care screening for STIs

- Use of propensity score matching in this application important in SA context

Weaknesses

- None noted

4. Approach:

Strengths

- Point of care diagnostic for CT and NG and couple treatment
- Long term outcomes followed in case and controls
- Qualitative interviews to explore feasibility and acceptability

Weaknesses

- Non-equivalent controls for study efficiency (but this is the reason for PS approach)
- Qualitative component with providers should be extended to patients as originally suggested, especially for reactions to self-swab and partner participation and response. Could engage a local SA social scientist or student.

5. Environment:

Strengths

- FPD founded by SAMA, strong relationship to government and excellent research environment. UCLA among the top 2 or 3 institutions for HIV/AIDS research in the US.

Weaknesses

- None noted.

Protections for Human Subjects:

Acceptable Risks and/or Adequate Protections

- None noted

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Not Applicable (No Clinical Trials)

Inclusion of Women, Minorities and Children:

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- Inclusion/Exclusion of Children under 21: Including ages < 21 justified scientifically
- None

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Resubmission:

- Very responsive to previous critiques

Resource Sharing Plans:

Acceptable

Budget and Period of Support:

Recommend as Requested:

Additional Comments to Applicant (Optional):

- Demonstrating more senior SA participation on the study team would be a plus, and should be considered if this proposal moves forward.

CRITIQUE 3:

Significance: 1
Investigator(s): 1
Innovation: 3
Approach: 2
Environment: 1

Overall Impact: This is a well written proposal to determine the acceptability and feasibility of screening and treating (as indicated) HIV-infected pregnant women for Chlamydia (CT) and Gonorrhea (GN) at their first antenatal care visit and to describe birth outcomes of those screened compared to those who have not been screened (in order to determine the impact of screening on birth outcomes). The research would be conducted in Tshwane District, South Africa, where the investigators have a strong history of conducting research. This resubmission has been largely responsive to previous reviewer comments (though see below). A strong case is made for the significance of CT and GN screening, which is not currently conducted, and the harmful impacts on birth outcomes of untreated CT and GN infection. The study is not particularly innovative, though the provision of screening at POC is somewhat innovative and could be implemented in other similar settings. Still, the study is important. This is a strong investigative team with excellent institutional support. There are a few concerns regarding the data collection / analysis plans but in general enthusiasm for the project is high; there is considerable potential for high impact.

1. Significance:

Strengths

- CT and GN appear to be prevalent among pregnant women in this area and associated with increased chance of HIV MTCT; identifying and treating these diseases has potential to further improve goals MTCT related goals
- Screening as part of standard protocol at first antenatal visits is a relatively simple way to detect CT and GN, but is not currently practiced; there is reason to think that making it standard practice could have significant impact on health of women and children
- Understanding the association between CT/GN and birth outcomes would make a significant contribution to research literature and clinical practice
- It appears that the CT/NG screening, though not currently used in low and middle resourced settings as standard practice, could be relatively easy to implement in such settings
- Understanding factors associated with CT/NG in this population may provide insights that can be built on to develop future interventions (beyond treatment at antenatal clinics) to address risk of CT/NG

Weaknesses

- None Noted

2. Investigator(s):

Strengths

- Very strong research team that has conducted some preliminary research that serves as strong foundation for research proposed here
- Good support of and collaboration with local provincial and district health departments that should facilitate conduct of the research
- Appropriate complementarity of skills and expertise

Weaknesses

- None Noted

3. Innovation:

Strengths

- Providing CT and GN screening in the context of antenatal clinic, at point of care, seems innovative

Weaknesses

- There is nothing particularly innovative about the analytical methods
- There is nothing particularly innovative about the effort to study the impact of CT/GN on birth outcomes, but it remains an important line of research

4. Approach:

Strengths

- Acceptability and feasibility study is well designed with clear measures of both; also will provide insight into prevalence of CT/GN in this population and insight into factors associated with CT/NG infection

- Appropriate procedures in place to provide follow up care to infected women and options for encouraging treatment of women's husbands/partners
- Use of roving teams to further assure infected women and their partners receive treatment is appropriate and important
- Procedures for ensuring retention and follow-up are well conceived
- Quantitative data analysis plans are appropriate (except see below re: factors associated with CT/NG infection)
- Suggestion box is an interesting way to collect qualitative data

Weaknesses

- There is virtually no discussion of what types of data and analyses will be used to assess correlates of prevalent CT and /or NG infection (aim 1c)
- It is still not clear why the different eligibility criteria for the comparison group (the rationale provided is that this is necessary to fit follow-up times but not clear what this means); still, plan to analyze data by ANC visit number will help compensate for this
- Plans for qualitative data collection are barely described, plan for qualitative data analysis is not described at all
- The rationale for face-to-face interviews related to health outcomes is not entirely clear since most of the data collected would seem to be included in medical records

5. Environment:

Strengths

- Environment is very strong and will support the study

Weaknesses

- None Noted

Protections for Human Subjects:

Acceptable Risks and/or Adequate Protections

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Not Applicable (No Clinical Trials)

Inclusion of Women, Minorities and Children:

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- Inclusion/Exclusion of Children under 21: Including ages < 21 justified scientifically
- all foreign women, includes 18-21

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Resubmission:

- largely responsive to previous concerns

Applications from Foreign Organizations:

Justified

- subcontract

Resource Sharing Plans:

Acceptable

Budget and Period of Support:

Recommend as Requested:

THE FOLLOWING SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW OFFICER TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE, OR REVIEWERS' WRITTEN CRITIQUES, ON THE FOLLOWING ISSUES:

PROTECTION OF HUMAN SUBJECTS: ACCEPTABLE

INCLUSION OF WOMEN PLAN (G2A): ACCEPTABLE

INCLUSION OF MINORITIES PLAN (M5A): ACCEPTABLE

INCLUSION OF CHILDREN PLAN (C1A): ACCEPTABLE

COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested.

+ Derived from the range of percentile values calculated for the study section that reviewed this application.

NIH has modified its policy regarding the receipt of resubmissions (amended applications). See Guide Notice NOT-OD-14-074 at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-074.html. The impact/priority score is calculated after discussion of an application by averaging the overall scores (1-9) given by all voting reviewers on the committee and multiplying by 10. The criterion scores are submitted prior to the meeting by the individual reviewers assigned to an application, and are not discussed specifically at the review meeting

or calculated into the overall impact score. Some applications also receive a percentile ranking. For details on the review process, see http://grants.nih.gov/grants/peer_review_process.htm#scoring.

MEETING ROSTER

Behavioral and Social Science Approaches to Preventing HIV/AIDS Study Section
AIDS and Related Research Integrated Review Group
CENTER FOR SCIENTIFIC REVIEW
BSPH
July 09, 2015 - July 10, 2015

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* Temporary Member. For grant applications, temporary members may participate in the entire meeting or may review only selected applications as needed.

Consultants are required to absent themselves from the room during the review of any application if their presence would constitute or appear to constitute a conflict of interest.