SUMMARY STATEMENT
(Privileged Communication)

PROGRAM CONTACT:

███████████████████

Principal Investigator

REBEIRO, PETER F

Applicant Organization: VANDERBILT UNIVERSITY MEDICAL CENTER

Release Date: 04/26/2017
Revised Date:

Application Number: 1 K01 AI131895-01A1

Review Group:	**AIDS**
	Acquired Immunodeficiency Syndrome Research Review Committee
	AIDS - EXP. REV.

Meeting Date:	03/22/2017	**RFA/PA:**	PA16-190
Council:	MAY 2017	**PCC:**	A27F
Requested Start:	07/01/2017		

Project Title:	The HIV Care Continuum and Health Policy: Changes through Context and Geography
SRG Action:	Impact Score: ██
Next Steps:	Visit https://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.
	1A-Both ███████, scientifically acceptable
Minority:	1A-Minorities and non-minorities, scientifically acceptable
Children:	3A-No children included, scientifically acceptable

Project Year	Direct Costs Requested	Estimated Total Cost
1		
2	██████	██████
3		
4		
5		
TOTAL	████	████

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.

1K01AI131895-01A1 Rebeiro, P

RESUME AND SUMMARY OF DISCUSSION: This exceptional resubmission application for a Mentored Research Scientist Development Award (K01) entitled "The HIV Care Continuum and Health Policy: Changes through Context and Geography" was submitted by Vanderbilt University Medical Center with Dr. Peter Rebeiro as the Principal Investigator (PI) and Dr. Timothy Sterling as the Primary Mentor. The proposed research goal is to compare influences of health care policy implementation on the HIV Care Continuum (HIVCC), a framework that captures the different stages of HIV medical care, by using existing data available from the North American AIDS Cohort Collaboration on Research and Design (NA-ACCORT) and the Central and South America Network for HIV Epidemiology (CCASAnet). The results of this study may help to inform policy makers about the impact of current health policy decisions on the HIVCC and may guide future policy decision making regarding the Affordable Care Act (ACA) and Medicaid expansion provisions specifically. The Specific Aims are: 1) To describe disparities in three National HIV/AIDS Strategy (NHAS) specific HIVCC outcomes across North America: proportions of the population clinically retained; using antiretroviral therapy (ART); or virally suppressed, and to describe temporal trends in these three outcomes accounting for geographic, contextual, and health policy differences; 2) To measure the effect of ACA implementation on HIVCC outcomes using data from NA-ACCORD clinical cohorts and cohorts that provide uniform access to care and states opting not to expand Medicaid as comparators; 3) To measure the effect of ACA implementation on HIV disease status at entry and clinical endpoints related to competent HIV care in the NA-ACCORD.

This improved application is from an outstanding candidate with epidemiology and biostatistics expertise who is already recognized as an emerging expert in the field of HIV epidemiology, evidenced by a strong publication record in this area. Dr. Rebeiro is very responsive to previous critiques, and he addresses and satisfactorily answers all concerns raised by the reviewers. The choice of two local biostatistician mentors is a positive addition, and the overall mentoring team and support letters are outstanding. The collaborations with Dr. McGowan and Drs. Grange and Moore of CCASAnet and NA-ACCORD add important expertise, and meetings with representatives of the Health Resources and Services Administration and the Center of Disease Control are a plus. Vanderbilt University provides an excellent environment and Dr. Rebeiro will receive strong institutional support. Improvements to the Research Plan and to the Career Development Plan add to the strength of this application. The aims are well-constructed and the presented preliminary data support high confidence in the success of the proposed research. The topic of the proposed research is timely and critical to understanding HIV care disparities. Robust NA-ACCORD and CCASAnet cohort data are an excellent source for the proposed research. The revised selection of relevant coursework presents an outstanding addition to the application.

One minor concern is the challenge of comparing data across countries and cohorts. No major weaknesses were noted.

Based upon the evaluation of scientific and technical merit, this application received an Overall Impact/Priority score of 10.

DESCRIPTION (provided by applicant):
PROJECT SUMMARY (ABSTRACT). The HIV Care Continuum is a compelling epidemiologic framework describing the movement of people living with HIV/AIDS through care, including diagnosis, linkage and retention in care, use of antiretroviral therapy (ART), and ultimately, viral suppression.

Health policies may profoundly influence outcomes along the Care Continuum, and these effects may be modified across regions and through individual contexts. In observational cohorts, retention in clinical care, ART use, and viral suppression proportions have varied depending on available data and the population under study. The US National HIV/AIDS Strategy (updated to 2020) and the revised 2013 World Health Organization ART guidelines also reference milestones in the Care Continuum. Because the Patient Protection and Affordable Care Act (ACA) and other national health policies in North and Latin American countries aim to improve healthcare access and reduce health disparities, describing the effect of policy and contextual factors on Care Continuum outcomes in these settings is of great interest to epidemiologists, clinicians, and policy makers. This research seeks to quantify health policy, sociodemographic, contextual, and geographic patterns and correlates of HIV Care Continuum outcomes among HIV-infected persons in the United States (US), Canada, and Mexico. Contextual factors include psychiatric illness, regional poverty, residential urbanicity, and other individual and environmental characteristics. The North American AIDS Cohort Collaboration on Research and Design (NA- ACCORD) and Caribbean, Central and South America network for HIV epidemiology (CCASAnet) provide rich data sources in which to conduct this work. Aim 1 will quantify disparities in Care Continuum outcomes in North and Latin America, assessing health system, demographic, risk, contextual, and geographic differences. Because research into the influence of contextual factors and health system characteristics on Care Continuum outcomes in longitudinal cohorts with clinical care data have been sparse or geographically limited, this analysis will be novel and of significant importance. Aims 2 and 3 will provide inferences about the ACA's effects on improving healthcare among HIV-infected individuals in care in the US. The state-led expansion of Medicaid coverage under the ACA will be used as a quasi-experiment to assess effects on Care Continuum and other HIV disease outcomes, comparing pre-ACA (pre-2014) to ACA implementation periods.

PUBLIC HEALTH RELEVANCE

PUBLIC HEALTH RELEVANCE STATEMENT (NARRATIVE). HIV remains a massive public health challenge both domestically and internationally; the HIV Care Continuum is a widely used and powerful epidemiologic framework applicable to those suffering from HIV, and the influence of public health and health system policies across the Continuum may be profound. By assessing the dynamic process of the HIV Care Continuum in discrete stages, and examining disparities by health policy, geography, and individual context, transitions that demand improvement and specific targets for public health and clinical interventions can more easily be identified. The US National HIV/AIDS Strategy (updated to 2020) and revised 2013 World Health Organization ART guidelines also reference milestones in the Care Continuum; because the Patient Protection and Affordable Care Act (ACA) and other national health policies implemented in North and Latin American countries aim to improve healthcare access and reduce health disparities in accord with these milestones, describing the effect of policy and individual contextual factors on Care Continuum outcomes, as this study aims to do, will be of great interest and utility to epidemiologists, clinicians, and policy makers.

CRITIQUES: The written critiques of individual reviewers are provided in essentially unedited form below. These critiques were prepared prior to the meeting and may not have been revised afterwards. The "Resume and Summary of Discussion" above summarizes the final opinions of the committee.

CRITIQUE 1

Candidate:	1
Career Development Plan/Career Goals & Objectives:	1
Research Plan:	1
Mentor/Co-Mentor(s), Consultant(s), and Collaborator(s):	1

Environment and Institutional Commitment to the Candidate: 1

Overall Impact:

This is an exceptional application from an outstanding applicant. Dr. Rebeiro has worked productively with these data and published in excellent journals. He responded well to the prior review critiques and addressed all concerns of the Study Section. His career development plan is improved and clearly outlines the courses in health policy and economics he intends to take. In addition, he has added courses in advanced biostatistics and added mentors in this area. Given the shifting landscape of healthcare in the U.S., this application appears particularly relevant.

1. Candidate:

Strengths

- The candidate is outstanding and has a Ph.D. in Epidemiology from Johns Hopkins University.

- He has published extensively in this area and is recognized as an emerging expert in this field.

- He works closely with some of the leaders in HIV care research.

- Dr. Rebeiro will undoubtedly be a successful NIH-funded investigator who will make important contributions to health outcomes research in HIV.

Weaknesses

- None noted.

2. Career Development Plan/ Career Goals & Objectives:

Strengths

- The candidate presents a well-developed career development plan that is centered around a multidisciplinary mentorship team and selected course work.

- He will be in direct contact with Health Resources and Services Administration (HRSA) and CDC representatives of HIV/AIDS Divisions.

Weaknesses

- None noted.

3. Research Plan:

Strengths

- The application proposes to use robust databases to study HIV care continuum in the U.S., Canada, and Mexico.

- The goal of Aim 1, to describe disparities in three National HIV/AIDS Strategy (NHAS) HIV care continuum outcomes is particularly important and timely.

Weaknesses

- None noted.

4. Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s):
Strengths

- The candidate is supported by an outstanding group of mentors.
- The lead mentor, Dr. Sterling, is a recognized leader in cohort-related research and a K24 awardee.
- Dr. Rebeiro has added mentors in biostatistics.
- The candidate has outstanding letters of support.

Weaknesses

- None noted.

5. Environment and Institutional Commitment to the Candidate:
Strengths

- Vanderbilt University presents an excellent research environment.
- The applicant is already a faculty member and has received a strong letter of commitment from the Infectious Disease Division Director.

Weaknesses

- None noted.

CRITIQUE 2

Candidate:	1
Career Development Plan/Career Goals & Objectives:	1
Research Plan:	2
Mentor/Co-Mentor(s), Consultant(s), and Collaborator(s):	1
Environment and Institutional Commitment to the Candidate:	1

Overall Impact:
The HIV Care Continuum provides a benchmark for successful public health HIV prevention and treatment programs domestically and internationally. However, access, affordability and social-behavioral context continue to fuel health disparities in the HIV Care Continuum. Dr. Rebeiro's application, with excellent mentorship from national leaders in HIV policy, integrates health policy, geography, and individual context and will identify specific targets for public health and clinical interventions. The didactic training opportunities at Vanderbilt and mentorship from biostatisticians with geospatial expertise ensure the success of this well-trained candidate in the completion of the proposed research. The findings and the process of analysis have a high potential to impact policy and finance decisions to reduce health disparities. The comparative studies can contribute meaningfully to the debate(s) about how best to implement, amend, replace or augment the Patient Protection and Affordable Care Act (ACA). The contrast of international and national health policies in Mexico and Canada is timely and will be of great interest and utility to epidemiologists, clinicians, and policy makers.

1. Candidate

Strengths

- The candidate has trained with Johns Hopkins University mentors and participated in HIV epidemiology and outcomes research consistently, showing his dedication to HIV research.
- The reference letters support his career trajectory and likelihood of long-term success.
- He has extensive training in epidemiologic methods and biostatistics and a clear commitment to policy evaluation and econometrics.

Weaknesses

- None noted.

2. Career Development Plan/Career Goals & Objectives/Plan to Provide Mentoring

Strengths

- The stated goals follow logically from the candidate's previous work and will allow him to further develop in the areas of health policy and epidemiology.
- The candidate will participate in research meetings related to the application topic and attend quarterly meetings with Health Resources and Services Administration.
- Advanced biostatistics courses related to spatial and temporal data analysis and modeling have been added to the career development plan.

3. Research Plan

Strengths

- The planned research in disparities for HIV patient care is important, and the unique use of data from cohorts such as NA-ACCORD and CCASAnet databases is well-suited for the proposed aims.
- Preliminary data and results provide assurance of the candidate's and his mentors' abilities to access and analyze these large longitudinal data sets.
- The use of both state/country level and individual factors to better understand the impact of health policy on the care continuum is a novel and valuable contribution.
- NA-ACCORD data (collected over 10 years from 25 cohorts from all U.S. states, Puerto Rican and Canadian provinces) connected with census-derived data for geographic regions provide a rich source for contextual factors.

Weaknesses

- Comparisons across census data from US Mexico and Canada and even the NA-ACCORD and CCASAnet are recognized challenges that may require additional interpretation

4. Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s)

Strengths

- Local biostatistician mentorship is now provided through the addition of Drs. Fonnesbeck and Shepherd to the internal mentorship team in addition to Dr. Sterling (Director of the Vanderbilt AIDS Center and Epidemiology/Outcomes Unit).

- Dr. Grave's R01 grant on the Medicaid Expansion Program outcomes is of great relevance for the current application.
- Collaborators from CCASAnet (Dr. McGowan) and NA-ACCORD (Dr. Grange and Dr. Moore) provide additional expertise, and they are committed to the applicant's career.

Weaknesses

- None noted.

5. Environment and Institutional Commitment to the Candidate

Strengths

- The candidate has strong support from the Vanderbilt Institute for Global Health and the Vanderbilt Department of Health Policy (each of which has collaboration with NA-ACCORD and CCASAnet).
- Dr. Rebeiro's position as a faculty member shows clear institutional commitment to the candidate.

Weaknesses

- None noted.

Resubmission

Comments:

- The candidate has addressed all weaknesses identified in the first review.

CRITIQUE 3

Candidate:	1
Career Development Plan/Career Goals & Objectives:	2
Research Plan:	2
Mentor/Co-Mentor(s), Consultant(s), and Collaborator(s):	1
Environment and Institutional Commitment to the Candidate:	1

Overall Impact:

This is a revised K01 grant application. The comments and concerns from the previous reviewers are well addressed. The candidate of this application, Dr. Peter F. Rebeiro, is a Research Assistant Professor in Medicine/Infectious Diseases at Vanderbilt University. Dr. Rebeiro received training in Biology (BA), Biostatistics (MHS), and Epidemiology (ScM, PhD). He has strong experience and a relevant publication track record in HIV epidemiology. His training is broad. His career goal/objective to become a recognized leader in HIV health policy and epidemiology is realistic and sound and the career plan is well-developed. The proposed research plan is based on the candidate's previous research work. The mentor team is very strong. The environment at Vanderbilt University is excellent for research and training in HIV epidemiology.

1. Candidate:
Strengths

- The candidate has a broad training in biology, biostatistics and epidemiology.
- Dr. Rebeiro has relevant experience in HIV epidemiological studies and clinical research.
- He has a strong publication record in HIV epidemiology, which is related to the proposed training and research.

Weaknesses

- None noted.

2. Career Development Plan/ Career Goals & Objectives:
Strengths

- The career development and training plan is well-designed and comprehensive.
- The local biostatistician mentors are a good addition to the application.

Weaknesses

- None noted.

3. Research Plan:
Strengths

- The proposed research in disparities for HIV patient care is of critical importance.
- Accessing the data from large cohorts such as NA-ACCORD and CCASAnet databases is a strength for the proposed project.
- Some preliminary data and results are provided.

Weaknesses

- None noted.

4. Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s):
Strengths

- The mentoring team is strong and appropriate, and mentors are leaders in their research field.
- The local statistical mentors are a good addition.

Weaknesses

- None noted.

5. Environment and Institutional Commitment to the Candidate:
Strengths

- Vanderbilt University presents an excellent environment and the candidate has strong institutional support for the proposed HIV epidemiological research and training.

Weaknesses

- None noted.

THE FOLLOWING RESUME SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW OFFICER TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE ON THE FOLLOWING ISSUES:

PROTECTION OF HUMAN SUBJECTS	**ACCEPTABLE (Code 30)**
DATA AND SAFETY MONITORING PLAN	**NOT APPLICABLE**
INCLUSION OF WOMEN PLAN	**ACCEPTABLE (Code G1A)**
INCLUSION OF MINORITIES PLAN	**ACCEPTABLE (Code M1A)**
INCLUSION OF CHILDREN PLAN	**ACCEPTABLE (Code C3A)**
VERTEBRATE ANIMALS	**NOT APPLICABLE (Code 10)**
BIOHAZARD COMMENT	**NOT APPLICABLE**
TRAINING IN THE RESPONSIBLE CONDUCT OF RESEARCH	**ACCEPTABLE**
FOREIGN INSTITUTION	**NOT APPLICABLE**
SELECT AGENTS	**NOT APPLICABLE**
RESOURCE SHARING PLANS	**NOT APPLICABLE**
AUTHENTICATION OF KEY BIOLOGICAL AND/OR CHEMICAL RESOURCES	**NOT APPLICABLE**

BUDGET AND PERIOD OF SUPPORT: **The budget was recommended as requested**.

Footnotes for 1 K01 AI131895-01A1; PI Name: Rebeiro, Peter F

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.