OMB Number: 4040-0001
Expiration Date: 06/30/2016

APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

3. DATE RECEIVED BY STATE	**State Application Identifier**

1. TYPE OF SUBMISSION*

❍ Pre-application ● Application ❍ Changed/Corrected Application

4.a. Federal Identifier

b. Agency Routing Number

c. Previous Grants.gov Tracking Number

2. DATE SUBMITTED

Application Identifier A105917

5. APPLICANT INFORMATION

Organizational DUNS*: 605799469

Legal Name*: University of Washington
Department: Office of Sponsored Programs
Division: Research
Street1*: 4333 Brooklyn Ave NE
Street2: Box 359472
City*: Seattle
County:
State*: WA: Washington
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 98195-9472

Person to be contacted on matters involving this application

Prefix: First Name*: Lynette Middle Name: Last Name*: Arias Suffix:

Position/Title: Director, Office of Sponsored Programs
Street1*: 4333 Brooklyn Ave NE
Street2: Box 359472
City*: Seattle
County:
State*: WA: Washington
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 98195-9472
Phone Number*: 206-543-4043 Fax Number: Email: osp@uw.edu

6. EMPLOYER IDENTIFICATION NUMBER *(EIN) or (TIN)** 91-6001537

7. TYPE OF APPLICANT* H: Public/State Controlled Institution of Higher Education

Other (Specify):

Small Business Organization Type ❍ Women Owned ❍ Socially and Economically Disadvantaged

8. TYPE OF APPLICATION*

● New ❍ Resubmission
❍ Renewal ❍ Continuation ❍ Revision

If Revision, mark appropriate box(es).

❍ A. Increase Award ❍ B. Decrease Award ❍ C. Increase Duration
❍ D. Decrease Duration ❍ E. Other *(specify)* :

Is this application being submitted to other agencies?* ❍Yes ●No What other Agencies?

9. NAME OF FEDERAL AGENCY*
National Institutes of Health

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER
TITLE:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*
Systems analysis and improvement approach to improve pediatric HIV testing and linkage to care

12. PROPOSED PROJECT

Start Date* Ending Date*
04/01/2016 03/31/2019

13. CONGRESSIONAL DISTRICTS OF APPLICANT
WA-007

SF 424 (R&R) APPLICATION FOR FEDERAL ASSISTANCE

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Prefix: First Name*: Anjuli Middle Name: Dawn Last Name*: Wagner Suffix:
Position/Title: Graduate Student Research Assistant
Organization Name*: University of Washington
Department: Epidemiology
Division: School of Public Health
Street1*: 1959 NE Pacific Street
Street2: Box 357236
City*: Seattle
County:
State*: WA: Washington
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 98195-9472
Phone Number*: 978-460-2331 Fax Number: Email*: anjuliwagner@gmail.com

15. ESTIMATED PROJECT FUNDING

a. Total Federal Funds Requested*	$189,710.00
b. Total Non-Federal Funds*	$0.00
c. Total Federal & Non-Federal Funds*	$189,710.00
d. Estimated Program Income*	$0.00

16.IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?*

a. YES ○ THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:
DATE:

b. NO ● PROGRAM IS NOT COVERED BY E.O. 12372; OR

○ PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

17. By signing this application, I certify (1) to the statements contained in the list of certifications* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances * and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001)

● I agree*

** The list of certifications and assurances, or an Internet site where you may obtain this list, is contained in the announcement or agency specific instructions.*

18. SFLLL or OTHER EXPLANATORY DOCUMENTATION File Name:

19. AUTHORIZED REPRESENTATIVE

Prefix: First Name*: Lynette Middle Name: Last Name*: Arias Suffix:
Position/Title*: Director
Organization Name*: University of Washington
Department: Sponsored Programs
Division: Research
Street1*: 4333 Brooklyn Ave NE
Street2: Box 359472
City*: Seattle
County:
State*: WA: Washington
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 98195-9472
Phone Number*: 206-543-4043 Fax Number: Email*: osp@uw.edu

Signature of Authorized Representative*
Diane Wentz

Date Signed*
09/02/2015

20. PRE-APPLICATION File Name:

21. COVER LETTER ATTACHMENT File Name:1247-FINAL_Cover_Letter_v2.pdf

424 R&R and PHS-398 Specific Table Of Contents

OMB Number: 4040-0010
Expiration Date: 06/30/2016

Project/Performance Site Location(s)

Project/Performance Site Primary Location

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	University of Washington
Duns Number:	6057994690000
Street1*:	1959 NE Pacific Street
Street2:	
City*:	Seattle
County:	
State*:	WA: Washington
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	98195-7236
Project/Performance Site Congressional District*:	WA-007

Project/Performance Site Location 1

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	University of Nairobi
DUNS Number:	3664987440000
Street1*:	Ngong Road
Street2:	PO Box 19676
City*:	Nairobi
County:	
State*:	
Province:	
Country*:	KEN: KENYA
Zip / Postal Code*:	00202-0000
Project/Performance Site Congressional District*:	XX-000

File Name

Additional Location(s)

Funding Opportunity Number: PA-14-149. Received Date: 2015-09-02T11:24:31.000-04:00

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved?* ● **Yes** ❍ **No**

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ❍ Yes ● No

If YES, check appropriate exemption number: _ 1 _ 2 _ 3 _ 4 _ 5 _ 6

If NO, is the IRB review Pending? ● **Yes** ❍ **No**

IRB Approval Date:

Human Subject Assurance Number 00006878

2. Are Vertebrate Animals Used?* ❍ **Yes** ● **No**

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ❍ Yes ❍ No

IACUC Approval Date:

Animal Welfare Assurance Number

3. Is proprietary/privileged information included in the application?* ❍ **Yes** ● **No**

4.a. Does this project have an actual or potential impact - positive or negative - on the environment?* ❍ **Yes** ● **No**

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ❍ Yes ❍ No

4.d. If yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic place?* ❍ **Yes** ● **No**

5.a. If yes, please explain:

6. Does this project involve activities outside the United States or partnership with international collaborators?* ❍ **Yes** ● **No**

6.a. If yes, identify countries:

6.b. Optional Explanation:

	Filename
7. Project Summary/Abstract*	1240-FINAL_Abstract.pdf
8. Project Narrative*	1241-FINAL_Narrative.pdf
9. Bibliography & References Cited	1242-FINAL_Bibliography.pdf
10.Facilities & Other Resources	1243-FINAL_Facilities_Resources.pdf
11.Equipment	1244-FINAL_Equipment.pdf
12. Other Attachments	1245-FINAL_Epi_Degree_Schwartz.pdf 1246-FINAL_LOS_Packet.pdf

Funding Opportunity Number: PA-14-149. Received Date: 2015-09-02T11:24:31.000-04:00

ABSTRACT:

This implementation science research project aims to evaluate innovative strategies to expand pediatric HIV diagnosis and linkage to care. Over 90% of the 3.2 million HIV-infected children in the world live in sub-Saharan Africa, many of whom are undiagnosed. In the absence of treatment, pediatric HIV has a far more aggressive course than adult infection and the benefits of antiretroviral treatment are limited when treatment is deferred until children are symptomatic. Children born before the scale up of PMTCT programs, and children who slip through the cracks in the PMTCT cascade remain untested and at risk for severe illness and death. Targeted HIV testing for the children of HIV-infected adults in care is an efficient case detection strategy that identifies a high prevalence of pediatric HIV; however, pediatric HIV testing rates remain low. A health systems-level approach to optimizing the delivery and tracking of pediatric HIV testing services in the pediatric HIV testing and care cascade may complement and improve current pediatric HIV diagnosis approaches. This study will 1) identify health facility level factors associated with high and low pediatric HIV testing rates, and 2) adapt and test the *Systems Analysis and Improvement Approach (SAIA)* previously used to enhance PMTCT (R01, PI: Sherr) to determine whether it can improve pediatric HIV testing rates and linkage to care. In Aim 1, we will use routinely collected pediatric HIV testing indicator data and remote surveys through a partnership with the National AIDS and STI Control Programme (NASCOP); we will compare high and low pediatric HIV-testing facilities to identify potentially modifiable facility-level characteristics, which can be evaluated during the adapted SAIA intervention. In Aim 2, we will conduct a cluster randomized controlled trial (cRCT) in Kenya using the 12 sites from the SAIA trial. The SAIA approach involves classical industrial engineering methods—cascade analysis, process mapping, and continuous quality improvement—and has been successful in optimizing PMTCT delivery services. We will collect routine, monthly pediatric HIV testing and linkage to care indicator data for each facility and compare the change in a) testing rates and b) linkage to care between intervention and control facilities during pre-intervention, intervention, and post-intervention periods. If found to be effective and sustainable, this low-cost and flexible intervention may provide a new tool for optimizing pediatric HIV testing and linkage to care.

PROJECT NARRATIVE

There is urgent need to optimize and scale efficient pediatric HIV case detection strategies to limit the morbidity and mortality associated with undiagnosed pediatric HIV infection. Pediatric HIV testing uptake is low and there is need for low cost, flexible, and sustainable interventions to improve pediatric HIV detection and prompt linkage to treatment. This project aims to determine whether and which health systems engineering methods at the facility-level can increase the uptake and linkage to care of HIV testing for children born to HIV-infected adults.

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children pre- and post-highly active antiretroviral therapy and revaccination. *Pediatr Infect Dis J* 2009,**28**:295-299.

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FACILITIES AND OTHER RESOURCES: UNIVERSITY OF WASHINGTON, SEATTLE

The University of Washington and its affiliate institutions provide an excellent environment for training and research characterized by recent growth, diversity and excellence in all types of health-related research and education. The University has been the top public university in federal research funding every year since 1974 and among the top five universities, public and private, in federal funding since 1969. Of this, the largest share comes from the National Institutes of Health (NIH) and the Department of Health and Human Services (DHHS), indicating the depth and breadth of University's health research program.

Offices:

Ms. Wagner's work for this fellowship will be based between Dr. Sherr's research group and Dr. John-Stewart's research group. ***Dr. Sherr's*** group is based at the Department of Global Health academic office on the University campus where Dr. Sherr and team have access to offices and support. This main departmental office space contains the following resources available to staff and students: Ethernet, printers, scanners fax machines, stationary supply room, and mail room. ***Dr. John-Stewart's*** group is based at the Global Center for Integrated Health of Women, Adolescents, and Children (Global WACh), and Kenya Research and Training Center (KRTC) central offices at the University of Washington's Ninth and Jefferson Building (NJB). This office occupies approximately 1900 square feet and includes office space for the PI, research faculty, staff, and for fellows and trainees writing manuscripts and preparing grant proposals. The co-location of trainees and program faculty/staff in this office facilitates communication and coordination between these individuals. The Global WACh and KRTC share common facilities with the International Clinical Research Center, the International AIDS Research and Training Program (IARTP), the International Training and Education Center for Health (I-TECH), the Northwest AIDS Education and Training Center, the STD Prevention and Training Center, the Northern Pacific Fogarty Global Health Fellows and Scholars Training Program, the Disease Control Priorities Network, the Program in Education and Research in Latin America (PERLA), and the Global Medicines Program, and all have access to the Department of Global Health's 10 conference rooms, two of which have videoconferencing capabilities, a classroom equipped for distance learning, and high-speed internet, both wired and wireless. Two offices on the University of Washington campus, located in the Health Sciences Building conveniently near the main library, have been provided exclusively for KRTC trainees by the Department of Epidemiology, School of Public Health. The Department of Global Health also has offices at the main University of Washington campus, in the Harris Hydraulics building. Eleven conference rooms on the 12th and 13th floors of the Ninth and Jefferson Building are available for use**.** All include data, phone, and projector connections; six include wall-mounted LCD monitors; four include Polycom videoconferencing capabilities; and one is a fully-equipped classroom for distance learning, including data connections, ceiling-hung projector and screen, lectern with data connections and in-room audio, a ceiling-mounted camera, press-to-talk boundary microphones, Polycom videoconferencing, and two-way audio from lectern to a control room with live webcasting, webinar, and lecture capture capability. One videoconferencing suite includes a dedicated Polycom videoconferencing system with 80-port hub, wall-mounted camera configured for enhanced telepresence, and two wall-mounted LCD monitors. This system enables video connections from up to 80 H.323-compliant videoconferencing clients as well as voice-only participants.

Ms. Wagner's training will be supported by the following centers and services:

• ***Center for AIDS Research (CFAR)*** is an NIH-funded infrastructure program that advances the prevention, detection, and treatment of HIV infection and AIDS by fostering collaborative and interdisciplinary research, supporting career development in early-stage investigators, and providing cutting-edge core support to researchers and scientists at our affiliated institutions. CFAR members include more than 550 UW and affiliated faculty, research scientists, and predoctoral and postdoctoral students. Led by King K. Holmes, MD, PhD.

• ***Kenya Research and Training Center*** provides an academic forum to support both trainees and investigators in the planning, implementation, analysis, and presentation of research conducted in Kenya. Led by Carey Farquhar, MD, MPH, and Scott McClelland, MD, MPH.
• ***Global Center for Integrated Health of Women, Adolescents and Children (Global WACh)*** is a joint effort among the UW departments of Global Health, Pediatrics, and Obstetrics & Gynecology. The center makes scientific discoveries, cultivates leaders, and bridges disciplines to advance the tightly connected health and well-being of women, adolescents, and children. Led by Grace John-Stewart, MD, MPH, PhD.
• ***Health Alliance International (HAI)*** is a UW-affiliated, non-governmental organization that partners with ministries of health to strengthen government primary health care and foster social, economic, and health equity for all. HAI consists of over 150 field staff in Mozambique, Timor-Leste, and Côte d'Ivoire, and 22 staff at headquarters in Seattle, including seven UW DGH faculty. Led by James Pfeiffer, MPH, PhD.

Global Center for Integrated Health of Women, Adolescents, and Children (Global WACh)
Established in 2011, the mission of the UW Global Center for Integrated Health of Women, Adolescents and Children (Global WACh) is to improve global health by cultivating excellence in research, education, and leadership focused on the lifecycle of women, adolescents, and children. Global WACh is currently home to over 23 research grants with an annual combined budget of over $6.8 million, housed in three sponsoring departments: Global Health, Pediatrics, and Obstetrics and Gynecology. Since 2012, the center has awarded over $170,000 in seed grants to foster new discovery, interdisciplinary collaboration, and career development of scientists dedicated to improving the health of women, adolescents and children (WACh). The center has also developed a graduate certificate in WACh health, and has graduated over 11 students from five different programs in two years. There are currently 10 students enrolled from six programs. Four new courses were created in order to develop new WACh leaders by providing a high-quality engaging curriculum that fosters interdisciplinary approaches to improve health. Global WACh has also sponsored working groups focused on nutrition, family planning, and data collection methods, and continues to coordinate the Kizazi mentoring group in order to accelerate the development and publication of WACh research.

Global WACh also directs a peer-mentoring group open to international trainees, faculty, and others. This group is called Kizazi, a Kiswahili word for "Generations," and it reflects a mentorship model for researchers addressing the health of women, adolescents and children. Participants include clinical and research faculty and students from master's and doctoral programs throughout the UW. The format of the meeting is informal, and groups are purposefully kept intimate to allow members to present frequently, and to encourage presentation of new ideas and works in progress. Presentations often feature students and junior investigators seeking feedback on thesis proposals, grant applications, analysis plans, human subjects applications, manuscripts, data analyses, and practice talks for upcoming conferences. Kizazi members have published 60+ peer-reviewed manuscripts, celebrated the graduation of 5 MPH and 4 PhD students, been awarded 14 career development grants, and have completed 6 trials/cohort studies in Kenya. The numerous conference presentations include CROI, IAS, ISSTDR, Pediatrics Workshop (DC), American Society of Tropical Medicine and Hygiene, North American Forum on Family Planning, Society for Clinical Trials, CFAR Symposium, ITHS National Retreat, Dominque Dormont Maternal-Child Transmitted Infections, and Keystone Symposia. Other notable activities teaching/ lecturing in UW courses and training workshops, serving as student mentors and advisors, and contributing to health promotion projects in the community.

Kenya Research and Training Center

The Kenya Research Program (KRTC) supports both trainees and investigators in the planning, implementation, analysis, and presentation of research conducted in Kenya. Created in 2006 by Drs. Grace John-Stewart (Global Health), Carey Farquhar (Infectious Diseases, Medicine), and Barbra Richardson (Biostatistics), KRTC is comprised of senior UW and Kenyan faculty with an established history of mentoring US and international trainees, and junior US and Kenyan faculty, fellows, and students, including Fogarty-funded Kenyan students. It began as an informal weekly meeting as an opportunity for students and faculty to brainstorm about current and planned research in Kenya, and has evolved into a well-established Center, with 27 UW faculty, 18 US-based staff and ~80 Kenyan-based staff, and over 30 post-and pre-doc trainees at present. The faculty, appointed at US and Kenyan institutions including the University of Washington, Fred Hutchinson Cancer Research Center, University of Nairobi, Kenyatta National Hospital, Kenya Medical Research Institute, and the Kenya National AIDS and STI Control Programme (NASCOP), collectively work with ~$15 million annually in research funding.

With a 30-year history of working in Kenya (the first MOU with University of Nairobi was signed in 1985), the KRTC has developed strong collaborative relationships with various institutions including University of Nairobi, Kenyatta National Hospital, Kenya Medical Research Institute, Kenyan Ministry of Health, Coptic Mission, Walter Reed, and more. The impact of the Kenya Research Program on HIV prevention and treatment in Kenya and East Africa is measureable, with >550 peer-reviewed publications, >40 currently active projects, and >30 clinical trials completed.

In addition to providing a pool of faculty mentors, research projects, and peer mentoring and support, KRTC also contributes core administrative support including assistance with IRB applications, assistance with travel arrangements and housing in Kenya, furnishing safety information and support for overseas travel, and other international research and training-related services.

KRTC faculty are engaged in service and training, as well as research projects which focus primarily on infections (HIV, STDs, helminths, TB, malaria, CMV, EBV, HSV-2, pediatric diarrhea/bacteremia). More than 30 research grants provide a diverse pool of potential projects for trainees to design clinical trials, observational studies, data analyses using historical data, clinical or molecular epidemiology, and/or implementation science projects.

Relevant Schools and Departments at the University of Washington

School of Public Health

The UW School of Public Health is ranked among the top ten public health schools in the U.S., and has had over 10,000 graduates in the past 40 years. The School houses the Departments of Epidemiology, Global Health, Biostatistics, Environmental and Occupational Health Sciences, and Health Services, and offers interdisciplinary programs in Health Administration, Maternal and Child Health, Nutritional Sciences, Pathobiology, and Public Health Genetics. More than 30 centers and institutes bring together faculty from throughout the School to collaborate and do research across disciplines. The School partners with a number of health organizations including the Bill & Melinda Gates Foundation, Fred Hutchinson Cancer Research Center, Group Health Research Institute, Seattle Children's Hospital, U.S. Department of Veterans Affairs, PATH, and local and regional health departments across a five-state region.

Department of Epidemiology

The Department of Epidemiology is consistently rated as one of the top epidemiology departments in the United States. The department offers MPH, MS, and PhD degrees in epidemiology, with approximately 165 graduate students at any one time. There is a wide range of faculty expertise, with 70 faculty and an additional

~100 health professionals and scientists holding adjunct and affiliate appointments in the department. Faculty research is highly interdisciplinary and encompasses a broad range of topics, including cancer, HIV/AIDS, sexually transmitted diseases, cardiovascular disease, maternal and child health, injury, trauma and violence, women's health, diseases of aging, and Alzheimer's disease. In addition to infectious agents, faculty research focuses on behavioral, nutritional, genetic, metabolic, environmental and medical factors associated with disease risk and disease outcome. The department maintains close collaborative ties with a number of other institutions and programs in the area, including Public Health Seattle-King County, the Fred Hutchinson Cancer Research Center, Group Health Research Institute, Harborview Injury Prevention and Research Center, the Veteran's Administration, and the University of Washington School of Medicine.

Department of Global Health

The Department of Global Health (DGH) was established in 2007 through a generous gift and endowment from the Bill & Melinda Gates Foundation, and complementary Washington State resources. UW DGH bridges the schools of Medicine and Public Health, with a mandate to harness the expertise and interdisciplinary power of all 16 UW schools and colleges. Currently, the department has more than 330 faculty representing 15 of 16 UW schools and colleges and 41 departments. It is the second largest department at the University in terms of funding for research and training programs, and includes more than 30 centers, programs, initiatives, and the Institute for Health Metrics and Evaluation (IHME). The Department offers a wide selection of programs, including MPH and PhD degrees, Health Metrics & Evaluation Fellowships, and Graduate Certificate Programs in Global Health, Global Health of Women, Adolescents, and Children (Global WACh), Global Injury and Violence Prevention, and HIV and STIs. A Global Health Minor is also open to students from across campus. Current and emerging focus areas include: health metrics and evaluation, infectious diseases, workforce development, health system strengthening and implementation science, climate change, global trauma and violence, global medicines safety, women, children and adolescent health, and a strong cross-cutting focus on social justice and equity.

Department of Medicine

The University of Washington's Department of Medicine is one of the best-funded departments of medicine in the nation, ranking in the top 10 of most funded departments of medicine in the United States since 2006. The Department has more than 1,000 full-time faculty members who are active in all levels of training—medical school, four residency pathways, and subspecialty fellowship programs. The Department's residencies and fellowships are considered among the best programs in the country. Department of Medicine faculty members are leaders of major multidisciplinary and translational research centers at the University of Washington, including Center for AIDS and STD, Center for Lung Biology, Center for Research in Reproduction and Contraception, Diabetes and Obesity Center of Excellence, Fred Hutchinson Cancer Research Center (FHCRC), Institute for Stem Cell and Regenerative Medicine, Institute of Translational Health Sciences, Kidney Research Institute, and affiliated with a number of research centers and projects including the AIDS Clinical Trials Unit, AIDS Vaccine Evaluation Unit, Center of Excellence in Women's Health, HIV Prevention Trials Unit, and Virology Research Clinic. Research partners include the Fred Hutchinson Cancer Research Center, Puget Sound Blood Center, Group Health Center for Health Studies, and other centers of advanced study, and research takes place in multidisciplinary centers affiliated with the Department, as well as laboratories at UW Medical Center, Harborview Medical Center, VA Puget Sound Health Care System, and Fred Hutchinson Cancer Research Center.

Division of Allergy and Infectious Diseases, Department of Medicine

The Division of Allergy and Infectious Diseases has over 75 full-time faculty members, 50 clinical faculty members, and 15 adjunct or affiliate faculty members. Faculty have been nationally and internationally recognized for their work in a variety of subspecialties, including phagocyte biology and function, HIV/AIDS and other sexually transmitted diseases and infections, viral diseases, immuno-compromised hosts, bacterial pathogenesis, geographic medicine, urinary tract infections, and the molecular biology of infectious diseases. The Division offers two fellowship training programs which are closely integrated with a number of local hospitals, clinics, and research institutions to provide a wide variety of clinical and research experience. Research training is offered in 9 areas of special emphasis: Clinical Epidemiology of Infectious Diseases, Clinical Trials, Human Immunodeficiency Virus Infection, Immunocompromised Host, Infectious Disease Immunology, Leukocyte Biology and Function, Pathogenesis of Bacterial, Fungal, and Parasitic Diseases,

Pathogenesis of Viral Diseases, and Sexually Transmitted Diseases. Affiliations include Fred Hutchinson Cancer Research Center , Harborview Medical Center, Seattle Cancer Care Alliance, Seattle Children's Hospital, University of Washington Medical Center, and VA Puget Sound Health Care System.

Library:
The University of Washington Health Sciences Library is available to all faculty, trainees, and staff. The library has been selected by the National Library of Medicine to serve as the Regional Medical Library for a five-state region. The library has extensive computer and informatics capability, with a large number of medical journals available online.

Computing Facilities:
The University of Washington leads the region in providing state-of-the-art access to networked information and innovative, cost-effective computing tools for a wide variety of applications. University-supported resources include Ethernet access and various databases including the Current Index to Statistics, Medline, the UW library catalog, and the Library of Congress. The University also negotiates group-discounted site licenses for software that are widely used by the University community. UW Information Technology also offers Nebula Managed Desktop Services, which includes delivery and installation of the Nebula software suite, phone support, private and shared file server space, security (patching, anti-virus, hot fixes), power management, drive mappings, printer installs, file restores, and basic set-up and troubleshooting for Outlook email and calendaring. The UW Information Technology service has partnered with Google to provide “UW Google Apps”, a service that provides access to many web-based applications that are integrated with UW email accounts, including Google Apps Email with over 7 GB of storage, Google Calendar, Google Talk, Google Docs, and other applications. UW Learning and Scholarly Technologies (LST) offers free workshops on software such as Adobe Creative Suite and Adobe Photoshop, and online curriculum in computing fundamentals, design and graphics, digital audio and video, document creation, spreadsheets and databases, and web publishing. UW LST also offers its own free online suite of web-based communication and collaboration applications for use in teaching, learning, research, and everyday work, including an online survey tool, file sharing, and shared work space.

Two Xerox WorkCentre copiers are available, with multifunction capability including copy, print, color and B&W scanning, and fax; as well as a stand-alone Muratec F-114 fax machine.

The Global WACh and KRTC central office at the Ninth & Jefferson Building has 9 desktop PCs and 5 HP Laserjet printers for use by faculty, staff, and trainees. Additional equipment includes an HP Laserjet fax machine and a Xerox Omnifax machine that has scanning capabilities. The KRTC/IARTP trainee offices at the School of Public Health have a total of 4 desktop computers and 2 printers that are networked to each computer. In addition, long-term trainees will be provided with a personal laptop computer at the beginning of the academic year to ensure adequate computer access.

Clinical:
N/A

Animal:
N/A

UNIVERSITY OF NAIROBI, NAIROBI, KENYA

Offices:
The Departments of Paediatrics, Microbiology, and Obstetrics/Gynecology at the University of Nairobi currently provide office space for study physicians, nurses, and data management personnel. Additional office space is available at the Institute for Tropical and Infectious Diseases (UNITID). There are three offices within the Departments of Medical Microbiology, Pediatrics, and Obstetrics/Gynecology and 9 offices plus access to shared space in the UNITID building. These offices occupy more than 160 square meters.

UNITID building

Library:

The Medical Library supports undergraduate and postgraduate students in the College of Health Sciences (CHS). There is capacity for 300 students in the study cartels and group work tables spread throughout the library wings. There is a Wi-Fi network that has 40 APS, 10,000 connections, and 8200 data points. The CHS supports access to online journals, currently providing access to over 2,000 titles.

There are 2 computer labs, one for undergraduate students (see photo right) and one for postgraduate students, each with approximately 20 computers. The computer lab will have an additional approximately 15 computers and the distance learning room will be equipped with materials for recording classes and providing them on the internet or via mobile networks to students.

Computing facilities:
Collaborative research in Nairobi is supported by a local area network (LAN) connected to the internet. Accounts have been activated to allow researchers access to electronic biomedical journals. Computing equipment at the University of Nairobi/KNH sites includes 8 desktop and two laptop computers and 3 printers for data entry, analysis, interpretation, presentation, and internet access. The Nairobi data office, located in the University of Nairobi Institute of Tropical and Infectious Diseases (UNITID) building, has 3 computers.

Clinical:
N/A

Laboratories:
N/A

Animal: N/A

EQUIPMENT

Computing Equipment

University of Washington: Anjuli Wagner's work for this grant will be primarily based at the IARTP & Kenya Research Training Center (KRTC) central office at the Ninth & Jefferson Building, which has 5 desktop PCs/Macs, 10 laptop computers, and 5 HP Laserjet printers for use by faculty, staff, and fellows. Additional equipment includes an HP Laserjet fax machine and a Xerox Omnifax machine that has scanning capabilities.

University of Nairobi: Collaborative research in Nairobi is supported by a local area network (LAN) connected to the internet. Accounts have been activated to allow researchers access to electronic biomedical journals. Computing equipment at the University of Nairobi sites includes 8 desktop and two laptop computers and 3 printers for data entry, analysis, interpretation, presentation, and internet access. The Nairobi data office, relocated to a new University of Nairobi Institute of Tropical and Infectious Diseases (UNITID) building in 2006, recently purchased 3 new computers.

Computer resources, in both Washington and Kenya are equipped with software for statistical analysis (STATA 12), bibliographic development software (EndNote), and the Microsoft Office Suite. Computers in Washington are equipped with Adobe Design Suite for CRF development and Atlas.ti for qualitative data coding and analysis.

SCHOOL OF PUBLIC HEALTH
UNIVERSITY of WASHINGTON
Department of Epidemiology

August 31, 2015

To: NIH Review Committee

From: Stephen M. Schwartz, PhD
Professor and Graduate Program Director

Re: Anjuli Wagner degree status

I am writing to certify that Ms. Anjuli Wagner has completed all required PhD coursework and credits, has completed her qualifying exam and general exam, and scheduled a date for her dissertation defense (November 13, 2015). If her defense is successful (and given Ms. Wagner's outstanding performance to date, I have no doubt that it will be), she will be awarded her PhD at the end of December, 2015. Thus, she will have her doctoral degree prior to the start date of the proposed F32 fellowship.

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NATIONAL AIDS & STI CONTROL PROGRAM
Kenyatta National Hospital Grounds
P.O. Box 19361, 00202
Nairobi

When replying please quote
Ref: NASCOP/ADMIN/ART/2015/24

Date: 31st August 2015

Anjuli Wagner, MPH
PhD Candidate
Department of Epidemiology
University of Washington
SEATTLE

Dear Ms. Wagner

RE: SUPPORT FOR PROPOSED STUDY ON SYSTEMS ANALYSIS AND IMPROVEMENT APPROACH TO IMPROVE PEDIATRIC HIV TESTING AND LINKAGE TO CARE

Your proposal to conduct a study on *Systems analysis and improvement approach to improve pediatric HIV testing and linkage to care* (SAIA-PEDS) is noted.

NASCOP has noted that this project aims to determine facility-level characteristics associated with high and low pediatric testing rates, as well as test whether the previously developed SAIA (systems analysis and improvement approach) methodology is effective in increasing the number of older children receiving HIV testing.

In line with NASCOP efforts to detect pediatric HIV infections and promptly link those infected to care, this proposed study is welcome.

In addition NASCOP notes that this proposal is an extension of the Counseling and Testing for Children at Home (CATCH) Study, which was presented at the Paediatric HIV steering committee that was held in March 2013.

This is to inform you that NASCOP supports the proposed study for submission for approval and subsequent implementation if approved. You are required to provide updates on the outcome of the proposal approval process, implementation of study and subsequently disseminate the findings to the Ministry of Health and other relevant stakeholders.

Dr. Irene Mukui
Head: National AIDS & STI Control Program

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
SCHOOL OF MEDICINE
DEPARTMENT OF PAEDIATRICS AND CHILD HEALTH

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Kenyatta National Hospital
P.O. Box 19676
NAIROBI
KENYA

August 27, 2015

Dear NIH Review Committee,

I am writing in support of Ms. Anjuli Wagner's application for the NRSA Individual Postdoctoral Fellowship (F32). I am a professor of Pediatrics and Child Health and have worked in PMTCT research and program scale up. Most recently, I have served as the Kenyan site PI for the SAIA (*Systems Analysis and Improvement Approach (SAIA) to Optimize PMTCT trial*) on which Ms. Wagner's proposed study is based. I look forward to seeing this important project implemented and offering support to Ms. Wagner during her career development as she grows into an independent investigator.

The SAIA intervention involved the following steps at each intervention facility a) quantifying the number of women who dropped out of the cascade at each step, b) mapping the clinic flow process, and c) testing small changes for system improvement iteratively through continuous quality improvement (CQI). This evaluation was in line with the *Kenyan Quality Improvement Model for Health.* In the SAIA trial in Kenya, we saw a substantial improvement in maternal antiretroviral coverage as a result of the operations research intervention. This type of low cost, facility-focused intervention is innovative and sustainable; it empowers healthcare workers to make changes inspired by their observations and insight, shifts the culture within a facility to one of teamwork and continuous improvement, and builds long-term capacity for change.

There has been considerable success in early infant diagnosis in Kenya; however, the same success is not replicated in the diagnosis and treatment of older children. The *Kenya AIDS Strategic Framework* has identified this gap, but no studies have been carried out to evaluate strategies of testing children beyond research settings. These children remain undiagnosed, and when they do present for care it is often in the context of severe co-infection, resulting in high mortality. Targeted strategies to identify these children and refer them for care and treatment before they require hospitalization is a critical component of efforts to successfully provide HIV treatment to HIV-infected children.

Ms. Wagner's previous research has shown that **targeted testing for the children of HIV-infected adults in care is an efficient case detection strategy, revealing underlying pediatric HIV prevalence between 8 and 15%.** However, uptake of testing services has been low, often due to lack of routine systems to offer testing and track children over time. In PMTCT settings, we have developed strong systems to identify and track HIV-exposed infants, and note those who are not tested in a timely fashion. Bringing the same systematic approach to testing of older children beyond the age range for PMTCT coverage could help to close the gap in pediatric HIV testing.

Approaches that have been successful in optimizing PMTCT may have direct impact for pediatric HIV testing as well; testing the translatability of proven interventions across systems is an efficient approach to innovation. As site PI of the SAIA trial in Kenya, I have seen the impact of taking a health systems research approach to improving HIV care. The SAIA approach applies the scientific method to optimizing health systems flow and function in a sustainable way. Employing implementation science to bring proven interventions to scale will be the next frontier in realizing the benefit of global health innovations.

UNIVERSITY OF NAIROBI
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Kenyatta National Hospital
P.O. Box 19676
NAIROBI
KENYA

Kenya has recently devolved health care from national to county government; the SAIA approach is particularly appropriate now as devolution presents an opportunity to invest in locally-motivated strategies for health services delivery optimization. Finally, Global Fund and PEPFAR have provided the Kenyan government with funds to Accelerate Child Treatment (ACT), earmarking funds for pediatric case detection. **This confluence of need, will, and funds means that innovations to help scale up pediatric HIV testing are well-poised to be adopted at local and national levels.**

Ms. Wagner proposes to identify facility-level factors associated with high and low pediatric testing rates to identify potential areas for change at the clinic level in her first aim. In her second aim, she proposes to adapt and test the SAIA intervention to pediatric HIV testing to determine whether it increases rates of pediatric HIV testing in 12 facilities throughout Kenya. This proposal is in line with the *Kenya AIDS Strategic Framework Research Strategy*, which identified translation of research into standards of care as a priority.

Anjuli has completed her PhD coursework in Epidemiology at the University of Washington and her dissertation focused on this same subject of pediatric HIV testing. The proposed study is the natural next phase of the research that she has already completed. She has an excellent team of mentors—Drs. Kenneth Sherr (implementation science), Grace John-Stewart (pediatric HIV), Peter Cherutich (implementation science and senior policymaker in Ministry of Health), James Hughes (biostatistics), and Shan Liu (industrial engineering and operational research)—who are leaders in their fields. The conduct of this study will help nurture Anjuli into the next generation of leaders in pediatric HIV. I am committed to give necessary support and guidance in the achievement of study objectives and Ms. Wagner's training.

Thank you for considering this application and please contact me if you have any questions.

Sincerely,

Professor Ruth Nduati, MBChB, MMed (Paeds), MPH
Professor of Pediatrics and Child Health
University of Nairobi

MINISTRY OF HEALTH

Telephone: 2729502
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Email: pcheru2013@gmail.com

Kenyatta National Hospital Grounds
P. O. Box 19361 – 00202
Nairobi.

22nd August 2015

August 22, 2015

Ruth L. Kirschstein National Research Service Award (F32)

Dear Review Committee,

I am writing to offer my strongest support of Ms. Anjuli Wagner's proposed postdoctoral work, entitled *'Systems Analysis and Improvement Approach to Improve Pediatric HIV Testing and Linkage to Care (SAIA-PEDS)'*. During her postdoctoral training, I will provide Ms. Wagner with mentorship on the design of implementation science projects, assistance liaising with national and local HIV policymakers and implementers, and support in the dissemination of the study results to relevant stakeholders.

Over the past several years, Ms. Wagner has developed a strong passion for implementation science. During our initial meeting about this proposed project, her enthusiasm and passion were evident, as well as her understanding of the additional training that she would need in order to complete this project effectively. I am thrilled to join Ms. Wagner's mentorship team, which has been carefully crafted to include mentors who offer subject- and method-specific expertise.

Ms. Wagner sought my mentorship based on my interdisciplinary academic training—I was the first graduate from the Implementation Science PhD program at the University of Washington—

extensive field experience in Kenya, and experience as a policymaker. I currently serve as the Deputy Director of Medical Services for the Ministry of Health in Kenya and previously have been Program Manager of HIV Testing, Program Manager of Male Circumcision, and Head of HIV Prevention within the National AIDS and STI Control Programme (NASCOP) of Kenya over the past 12 years. Between 2006 and 2012, I worked to scale up voluntary medical male circumcision (VMMC) across Kenya. My team strategically employed implementation science methods to inform our roll out of services, which enabled our VMMC program to be the most successful in sub-Saharan Africa. Given my training and experience as a policymaker, I feel that I am well qualified to mentor Ms. Wagner in her proposed work.

Ms. Wagner plans to determine health facility-level characteristics associated with high and low pediatric testing and linkage to care rates in her first aim, and then use a cluster-randomized trial design to determine whether a systems analysis and optimization approach (SAIA trial methodology) improves testing and linkage to care rates. Her proposed project utilizes routinely collected HIV testing indicators in Aim 1, and is nested in a larger R01 led by Dr. Kenneth Sherr for Aim 2; the addition of Ms. Wagner's postdoctoral aims to this project increase the impact of this R01 grant. Using routinely collected program data from the National AIDS and STI Control Programme (NASCOP) is an innovative strategy for integrating implementation science into program roll-out. While ambitious, I feel after careful discussion with Ms. Wagner and the rest of her committee, that the proposed work is surely feasible in the timeframe of her postdoctoral studies. The dissemination of her results in both academic and programmatic circles can ensure that HIV-infected children in Kenya benefit from this important study.

Finally, I've been impressed with the experience Ms. Wagner has already garnered through her work abroad. She has spent a great deal of time conducting public health research projects in resource-limited settings, including work done in Kenya, India, Ghana, and other countries. I feel that her field experience has helped her to understand the often-messy reality of conducting theoretically elegant studies in resource-limited settings. Anjuli is aware of the setting-specific challenges to conducting her postdoctoral work, and is addressing those anticipated challenges in the design phase of her dissertation. Additionally, the success of Anjuli's previous projects speaks to her ability to drive projects through to execution in the field; this is not always easily accomplished.

During her time in Kenya and Seattle, I will provide implementation science and dissemination mentorship to Ms. Wagner through bi-monthly in-person or Skype meetings. I will also mentor her during her time in attachment with NASCOP, providing connections and contextual support within this national policymaking organization.

In summary, given Ms. Wagner's innovative and well-designed project, carefully crafted mentorship team, and overwhelming passion for her project, I am eager to offer her support and mentorship as she embarks on this novel and high-impact study.

Yours faithfully,

Dr Peter Cherutich, MBChB, MPH, PhD, OGW
Deputy Director of Medical Services
Ministry of Health, Kenya

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National Institutes of Health

Dear F32 Review Committee,

RE: Systems Analysis and Improvement Approach to Improve Pediatric HIV Testing and Linkage to Care (SAIA-PEDS)": Letter of Support for Ms. Anjuli Wagner

I am writing in strong support of Ms. Wagner's application for the NRSA Individual Postdoctoral Fellowship. This proposal presents an important opportunity to innovate strategies to increase uptake of pediatric HIV testing by focusing on modifiable health system factors and standardized interventions to promote change.

In Kenya, roughly 60% of HIV infected children are currently undiagnosed; children with undiagnosed infections are at extremely high risk of mortality. Diagnosing HIV-infected children by the time they are already in hospital is too late. Strategies to target the asymptomatic children of HIV-infected children are efficient, but have historically had low uptake due to lack of systematic implementation of screening and follow-up.

The SAIA approach has been tested in the context of PMTCT and has resulted in increases in ARV coverage among pregnant women in Kenya. The same approach may be effective in increasing the number of children of unknown status who complete testing promptly.

Ms. Wagner and her interdisciplinary team propose to determine whether there are modifiable facility-level characteristics that are associated with high and low rates of pediatric testing, and to further test whether the SAIA approach to change is effective in increasing rates among low-performing facilities.

I feel confident in the ability of Ms. Wagner and her multidisciplinary mentorship and field team to address this question in a thoughtful and rigorous manner. Her team has a strong history of conducting studies in maternal and child health in Kenya and a >20 year history of collaboration between the University of Washington and the University of Nairobi. I look forward to supporting Ms. Wagner and her team in conducting this important seed study and in the future work it inspires.

Thank you for considering this application and please contact me if you have any additional questions.

Sincerely,

Dr. John Kinuthia, MBChB, MMed, MPH
Head, Research and Programs
Kenyatta National Hospital

DEPARTMENT OF BIOSTATISTICS
UNIVERSITY of WASHINGTON
School of Public Health

Ruth L. Kirschstein National Research Service Award (F32)

August 27, 2015

Dear Review Committee,

It is with great enthusiasm that I write to support Ms. Anjuli Wagner's proposed postdoctoral work, entitled *'Systems Analysis and Improvement Approach to Improve Pediatric HIV Testing and Linkage to Care (SAIA-PEDS)'*. Over the course of her training, I will serve as a member of Ms. Wagner's mentorship team, offering mentorship in the design and analysis of cluster randomized trials and analysis of facility, and time-series data. I plan to aid her in conducting statistically sound, yet interpretable, analyses that are not only published in respected peer-reviewed journals, but also are understandable to public health policy-makers and practitioners alike. I am excited to support Anjuli as she pursues this innovative project and develops the skills necessary to become an independent investigator in her field.

I first met Anjuli three years ago when she approached me about mentoring her on the statistical analysis of her doctoral dissertation based on my expertise in the analysis of implementation science studies. Ms. Wagner's doctoral work focused on the analysis of individual-level data—she investigated the individual-level barriers and facilitators to testing children for HIV—and she is in the process of submitting these analyses for publication. During the course of her doctoral work, I have watched Anjuli become more interested in addressing upstream barriers and facilitators to pediatric HIV testing on the health systems level, focusing on facility-level data and interventions. This strong shift from traditional epidemiologic inquiry to relatively new health systems research will require substantial training to gain a new set of methodologic skills for appropriate design and analysis. Additionally, the shift from observational to randomized controlled trial data (in Aim 2), and utilization of routine program data (in Aim 1) will offer Ms. Wagner another opportunity to gain new analysis skills. I have helped Ms. Wagner select a series of statistics courses that will prepare her for these new methods.

It was clear from our first meeting that Anjuli has the detail-oriented skills necessary to conduct this project in a rigorous scientific fashion and the dedication and passion to see this project to completion. Throughout her project, I will provide statistical mentorship to Ms. Wagner. I am excited for the opportunity to continue working with and mentoring Anjuli as she pursues her project. I believe the results from this project will have a positive future impact on the lives of children in Kenya.

This project, while ambitious, is feasible. Aim 1 of Ms. Wagner's proposal will use already available facility-level indicator data from facilities throughout Kenya, collected and housed at the National AIDS and STI Control Programme (NASCOP) headquarters. The use of these routinely available indicators is a very clever way of utilizing program data to answer meaningful implementation science questions. Aim 2 of Ms. Wagner's proposal is also feasible, as it is nested within a larger R01, run by Dr. Kenneth Sherr, Anjuli's sponsor. The inclusion of operations research, quality improvement, surveillance data utilization, and cluster randomized controlled trial methods makes this proposal especially robust; instruction in these different, yet complementary, disciplines will leave Anjuli in a strong position to undertake future multidisciplinary research.

Ms. Wagner has had experience with a range of diverse public health research projects in resource-limited settings; this field experience has directly informed the realistic goals and timeframe she has developed for this project and has shown that she is capable of adapting to often challenging field

DEPARTMENT OF BIOSTATISTICS
UNIVERSITY of WASHINGTON
School of Public Health

settings. I am confident that Ms. Wagner's previous international research experience and her wide and dedicated network of academic support at the University of Washington and the University of Nairobi leave her well equipped to undertake this critical research.

In summary, I am highly enthusiastic about Anjuli's postdoctoral work because of the project's innovation and importance, her carefully crafted mentorship team, and the opportunities for growth that the methodologic training will provide her. I am excited to offer guidance and mentorship throughout her training for this novel and potentially high-impact study.

Sincerely,

James P. Hughes, Ph.D
Professor of Biostatistics

Box 357232 Seattle, WA 98195-7232 Phone: 206-543-1044 FAX: 206-543-3286 www.biostat.washington.edu

August 27, 2015

Dear Ruth L. Kirschstein National Research Service Award (F32) Review Committee,

It gives me great pleasure to write in support of Ms. Anjuli Wagner's fellowship application to enable her proposed postdoctoral work, entitled *Systems Analysis and Improvement Approach to Improve Pediatric HIV Testing and Linkage to Care.* During the course of the fellowship, I will serve as a member of Anjuli's mentorship team, offering mentorship for her first and second aims in relation to operations research and system flow optimization. Anjuli's enthusiasm for her work, combined with an innovative multi-disciplinary project and a stellar mentorship team, makes her an outstanding applicant for this fellowship.

Anjuli's proposed postdoctoral project will identify health-systems level factors associated with high and low pediatric HIV testing rates (Aim 1), and use a systems engineering approach to optimize pediatric HIV testing systems based on the SAIA trial (Aim 2). Her first aim focuses on determining the facility-level factors that impact rates of pediatric HIV testing and linkage to care. These may be factors such as number of health care workers, patient volume, routine availability of HIV test kits, physical location of testing space, documentation practices to follow up on linkage to care, etc. Identifying those factors which are associated with high testing and are modifiable will be instrumental to inform her second aim, applying systems improvement model to improve testing rates. In her second aim, Anjuli proposes to adapt the SAIA trial approach—which utilizes several classical operations research tools including cascade analysis, flow mapping, and continuous quality improvement (CQI). These methods have emerged from industrial engineering, which has strong methods to investigate systems optimization. It is truly exciting to see such a promising young epidemiologist embrace this important skill set.

In addition to developing skills in methodology that is increasingly being requested in competitive health sciences applications, Anjuli has a research question that is quite novel. While Anjuli's doctoral research focused on *individual* level factors that affect pediatric HIV testing uptake, there is an absence of research on strategies to modify *health systems* to offer pediatric HIV testing services in a more efficient way with high coverage and fidelity. I look forward to working with Anjuli as she addresses this novel question in a Kenyan setting.

While Anjuli is in Seattle and during her time in Nairobi, I plan to meet with her every month to provide mentorship on her project either in person or through Skype calls. To build her capacity for systems optimization modeling, she will take two courses, Introduction to Optimization Models, and my course, Healthcare Modeling & Decision-making in the Department of Industrial Engineering.

In summary, I am thrilled to mentor Anjuli as she pursues this novel, well supported and critically important research project in Kenya. I look forward to watching her develop further systems engineering methods to one day become a competitive independent investigator.

Sincerely,

Shan Liu, PhD
Assistant Professor, Industrial & Systems Engineering
University of Washington
Box 352650
Office. phone: (206) 543-7593, Email: liushan@uw.edu

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: First Name*: Anjuli Middle Name Dawn Last Name*: Wagner Suffix:

Position/Title*: Graduate Student Research Assistant
Organization Name*: University of Washington
Department: Epidemiology
Division: School of Public Health
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County:
State*: WA: Washington
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 98195-9472

Phone Number*: 978-460-2331 Fax Number: E-Mail*: anjuliwagner@gmail.com

Credential, e.g., agency login: ANJWAGNER

Project Role*: PD/PI Other Project Role Category:

Degree Type: BA, MPH Degree Year: 2012

	File Name
Attach Biographical Sketch*:	1234-FINAL_Wagner_biosketch.pdf
Attach Current & Pending Support:	

Tracking Number: GRANT11984279 Funding Opportunity Number: PA-14-149 . Received Date: 2015-09-02T11:24:31.000-04:00

PROFILE - Senior/Key Person

Prefix: | First Name*: Kenneth | Middle Name | Last Name*: Sherr | Suffix:

Position/Title*: Associate Professor
Organization Name*: University of Washington
Department: Global Health
Division: School of Public Health
Street1*: 4534 11th Ave NE
Street2: Box 357965
City*: Seattle
County:
State*: WA: Washington
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 98105-0000

Phone Number*: 1-206-221-7635 | Fax Number: | E-Mail*: ksherr@uw.edu

Credential, e.g., agency login: ksherr

Project Role*: Other (Specify) | Other Project Role Category: Sponsor

Degree Type: BA, MPH, PhD | Degree Year: 2009

	File Name
Attach Biographical Sketch*:	1235-FINAL_Sherr_biosketch.pdf
Attach Current & Pending Support:	

PROFILE - Senior/Key Person

Prefix: | First Name*: Grace | Middle Name | Last Name*: John-Stewart | Suffix:

Position/Title*: Professor
Organization Name*: University of Washington
Department: Global Health
Division: School of Public Health
Street1*: 325 9th Ave
Street2: Box 359909
City*: Seattle
County:
State*: WA: Washington
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 98104-0000

Phone Number*: 206-543-4278 | Fax Number: | E-Mail*: gjohn@uw.edu

Credential, e.g., agency login: GRACEJOHN

Project Role*: Other (Specify) | Other Project Role Category: Co-sponsor

Degree Type: MD, MPH, PhD | Degree Year: 2000

	File Name
Attach Biographical Sketch*:	1236-FINAL_John-Stewart_biosketch.pdf
Attach Current & Pending Support:	

PROFILE - Senior/Key Person

Prefix: First Name*: James Middle Name P. Last Name*: Hughes Suffix:

Position/Title*: Professor
Organization Name*: University of Washington
Department: Biostatistics
Division: School of Public Health
Street1*: 329 9th Ave
Street2: Box 359931
City*: Seattle
County:
State*: WA: Washington
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 98104-0000

Phone Number*: 206-744-3633 Fax Number: E-Mail*: jphughes@uw.edu

Credential, e.g., agency login: JPHUGHES

Project Role*: Other (Specify) Other Project Role Category: Advisor

Degree Type: MS, PhD Degree Year: 1993

File Name

Attach Biographical Sketch*: 1237-FINAL_Hughes_biosketch.pdf

Attach Current & Pending Support:

PROFILE - Senior/Key Person

Prefix: First Name*: Shan Middle Name Last Name*: Liu Suffix:

Position/Title*: Assistant Professor
Organization Name*: University of Washington
Department: Indust. & Systems Engineering
Division: College of Engineering
Street1*: 3900 Northeast Stevens Way
Street2: Box 352650
City*: Seattle
County:
State*: WA: Washington
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 98195-2650

Phone Number*: 206-543-1427 Fax Number: E-Mail*: liushan@uw.edu

Credential, e.g., agency login:

Project Role*: Other (Specify) Other Project Role Category: Advisor

Degree Type: SM, PhD Degree Year: 2013

File Name

Attach Biographical Sketch*: 1238-FINAL_Liu_biosketch.pdf

Attach Current & Pending Support:

PROFILE - Senior/Key Person

Prefix:	First Name*: Peter	Middle Name	Last Name*: Cherutich	Suffix:

Position/Title*:	Deputy Director of Medical Services
Organization Name*:	Ministry of Health
Department:	Ministry of Health
Division:	
Street1*:	Afya House, Cathedral Road
Street2:	PO Box 30016-00100
City*:	Nairobi
County:	
State*:	
Province:	
Country*:	KEN: KENYA
Zip / Postal Code*:	00000-0000

Phone Number*:	Fax Number:	E-Mail*:
254-20-2717077		ps@health.go.ke

Credential, e.g., agency login: PCHERU

Project Role*:	Other Project Role Category:
Other (Specify)	Advisor

Degree Type:	Degree Year:
MBChB, MPH, PhD	2015

	File Name
Attach Biographical Sketch*:	1239-FINAL_Cherutich_biosketch.pdf
Attach Current & Pending Support:	

OMB No. 0925-0001/0002 (Rev. 08/12 Approved Through 8/31/2015)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.

Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: Wagner, Anjuli Dawn

eRA COMMONS USER NAME (agency login): ANJWAGNER

POSITION TITLE: Graduate Student Research Assistant

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
Tufts University	BA	05/2009	Community Health, Peace & Justice Studies
University of Washington	MPH	12/2012	Epidemiology
University of Washington	PHD	12/2015	Epidemiology

A. Personal Statement

My research goal is to use implementation science approaches to improve HIV prevention and treatment in resource-limited settings. I aim to focus my implementation research questions on issues that are directly relevant to national Ministry of Health programs and policy. My undergraduate work in Community Health, graduate work in Epidemiology, and extensive research experience in global settings, provide an excellent background for this research. During my undergraduate career, I gained valuable comprehensive hands-on experience that included study planning, processing lab specimens, data analysis, and manuscript preparation in infectious diseases projects in Ghana and India,

During Masters and PhD Epidemiology training at the University of Washington, I worked under the mentorship of Drs. Grace John-Stewart and Jennifer Slyker on a series of pediatric and adolescent HIV testing studies in Kenya. My dissertation utilized qualitative, quantitative, and cost-effectiveness methods to determine acceptability, feasibility, and cost-effectiveness of offering pediatric HIV testing to adults attending HIV Care and Treatment programs in Kenya in the Counseling and Testing for Children at Home (CATCH) Study. I received an F31 NRSA training grant from NIMH to undertake this work.

My proposed F32 postdoctoral research will focus on health systems processes to improve pediatric HIV testing, While the F32 proposal retains my interest in pediatric HIV testing, it represents a completely new direction in terms of implementation science methods. My proposed training plan will provide me with methodologic expertise in operations research, quality improvement, and design and analysis of cluster-randomized trials. These methods will allow me to grow as an implementation scientist by shifting from an individual-level focus to a facility-level focus. Recently, I was awarded the Magnuson Scholar Award, which recognizes one student from the University of Washington School of Public Health who has exceptional potential for scientific contributions. The Magnuson award included funding that I plan to use to support the proposed F32 research project. My F32 sponsors, Drs. Kenneth Sherr and Grace John-Stewart, are internationally recognized researchers in implementation science and pediatric HIV, respectively, with over 35 years of combined global health research experience , and extensive experience mentoring graduate and postdoctoral students. Through my choice of mentors, research methods, and training plan, I will gain the necessary skills to execute implementation science projects aimed at optimizing HIV-related prevention and treatment programs in resource-limited settings.

1. Drake AL, **Wagner A**, Richardson B, John-Stewart G. Incident HIV during pregnancy and postpartum and risk of mother-to-child HIV transmission: a systematic review and meta-analysis. PLoS Med. 2014 Feb;11(2):e1001608. PubMed PMID: 24586123; PubMed Central PMCID: PMC3934828.
2. **Wagner A**, Slyker J, Langat A, Inwani I, Adhiambo J, Benki-Nugent S, Tapia K, Njuguna I, Wamalwa D, John-Stewart G. High mortality in HIV-infected children diagnosed in hospital underscores need for faster diagnostic turnaround time in prevention of mother-to-child transmission of HIV (PMTCT)

programs. BMC Pediatr. 2015 Feb 15;15:10. PubMed PMID: 25886564; PubMed Central PMCID: PMC4359474.

3. **Wagner AD,** Njuguna IN, Mugo C, Inwani I, Maleche-Obimbo E, Sherr K, Wamalwa D, John-Stewart G, Slyker J. Targeted HIV testing in home or clinic for older children of HIV-infected adults in care increases pediatric HIV testing rates and reveals high prevalence of previously undiagnosed HIV infection. International AIDS Society; 2015 July; Vancouver, BC, Canada.

4. Njuguna IN, **Wagner AD**, Otieno V, Cranmer L, Adhiambo J, Benki-Nugent S, Maleche-Obimbo E, Slyker J, Wamalwa D, John-Stewart G. System Gaps Result in Late Diagnosis and Treatment of Children With HIV in Hospital. Conference on Retroviruses and Opportunistic Infections; 2015; Seatte, WA, USA. c 00 .

B. Positions and Honors

Positions and Employment

2007 - 2007	Research Assistant, Tufts University, Medford
2008 - 2009	Research Assistant, Tufts University, Medford
2009 - 2009	Research Assistant, Tufts University, Medford
2009 - 2010	Teaching Assistant, Tufts University, Medford
2010 - present	Research Assistant, University of Washington
2010 - 2011	Research Assistant, University of North Carolina
2012 - 2014	Teaching Assistant, University of Washington

Other Experience and Professional Memberships

Honors

2005	Atkinson Scholarship, Sudbury Foundation
2006	Atkinson Scholarship, Sudbury Foundation
2007	Atkinson Scholarship, Sudbury Foundation
2008	Atkinson Scholarship, Sudbury Foundation
2008	Summer Scholars Scholarship, Tufts University
2009	Atkinson Opportunity Grant, Sudbury Foundation
2009	Audrey Butvay Gruss Science Award, Tufts University
2009	Honos Civicus, Tufts University
2009	Presidential Award for Citizenship and Public Service, Tufts University
2009	Phi Beta Kappa, Tufts University
2013	Outstanding Teaching Assistant Award, School of Public Health, University of Washington
2015	Magnuson Scholar Award, School of Public Health, University of Washington

C. Contribution to Science

1. **Urogenital schistosomiasis diagnosis and prevention:** During my undergraduate training, I received a university-sponsored fellowship to conduct global health research under Drs. Karen Kosinski and David Gute focusing on developing more sensitive testing strategies for urogenital schistosomiasis detection and prevention in children in rural Ghana. Our team used a community-based participatory research (CBPR) approach to design, implement, and evaluate a structural prevention intervention. Our diagnostic study noted that repeat screening using urine dipsticks and egg filtration improved sensitivity of screening substantially, particularly among lightly infected children, with implications for accurately assessing infection status in intervention evaluation settings. Our structural intervention using a water recreation area reduced annual cumulative incidence substantially from 13.4% to 3.7%. In conjunction with mass drug administration, structural prevention interventions may have a role in limiting the morbidity associated with repeat pediatric urogential schistosomiasis. This work resulted in two publications and several poster presentations. As a result of this project, I was awarded both the Audrey Butvay Gruss Science Award

(given to one undergraduate female scientist) and the Presidential Award for Citizenship and Public Service (awarded to 4 students) at Tufts University.

a. **Wagner A**. Urinary Schistosomiasis Prevention in Rural Ghana. Tufts University Undergraduate Research & Scholarship Symposium; 2008 April; Medford, MA, USA.
b. Kosinski KC, Bosompem KM, Stadecker MJ, **Wagner AD**, Plummer J, Durant JL, Gute DM. Diagnostic accuracy of urine filtration and dipstick tests for Schistosoma haematobium infection in a lightly infected population of Ghanaian schoolchildren. Acta Trop. 2011 May;118(2):123-7. PubMed PMID: 21354093.
c. Kosinski KC, Adjei MN, Bosompem KM, Crocker JJ, Durant JL, Osabutey D, Plummer JD, Stadecker MJ, **Wagner AD**, Woodin M, Gute DM. Effective control of Schistosoma haematobium infection in a Ghanaian community following installation of a water recreation area. PLoS Negl Trop Dis. 2012;6(7):e1709. PubMed PMID: 22815999; PubMed Central PMCID: PMC3398975.

2. **Pediatric and adolescent HIV testing strategies:** Over the past 5 years, my Masters and PhD work has focused on pediatric and adolescent HIV testing and prevention of mother-to-child transmission of HIV. My Masters thesis contrasted the efficiency of case detection of infant HIV infections between PMTCT and hospital settings, noting high prevalence of HIV infection as well as high mortality among hospital-diagnosed infants. These findings highlighted the importance of identifying HIV-infected infants and children prior to the development of symptomatic disease. This gave way to my doctoral work in the Counseling and Testing for Children at Home (CATCH) Study, which examined the acceptability, feasibility, and cost-effectiveness of targeted pediatric HIV testing through home- versus clinic-based testing using traditional epidemiologic, qualitative, and cost-effectiveness methods. This study noted that routine offering of HIV testing to HIV-infected adults with untested children significantly increased the number of children tested and identified 8% HIV prevalence among previously untested children. I was involved in the design, grant-writing, and management of this study, spending 3-4 months in Kenya annually and was responsible for site selection; staff hiring, training, oversight; data collection tool development, database design, data management; budget monitoring; coordination of study analyses; dissemination of study results to stakeholders at local, national, and international levels. During the past 5 years, I have been involved in writing 13 grants; 6 of which have been funded to conduct adolescent and child HIV studies. I have been involved in the design of these studies and have played a central role in implementation and analysis.

a. **Wagner A**, Njuguna I, Mugo C, Inwani I, Maleche-Obimbo E, Sherr K, Wamalwa D, John-Stewart G, Slyker J. Targeted HIV testing in home or clinic for older children of HIV-infected adults in care increases pediatric HIV testing rates and reveals high prevalence of previously undiagnosed HIV infection. 7th International Workshop on HIV Pediatrics; 2015 June; Vancouver, BC, Canada. c 00 .
b. **Wagner A**, Slyker J, Langat A, Inwani I, Adhiambo J, Benki-Nugent S, Tapia K, Njuguna I, Wamalwa D, John-Stewart G. High mortality in HIV-infected children diagnosed in hospital underscores need for faster diagnostic turnaround time in prevention of mother-to-child transmission of HIV (PMTCT) programs. BMC Pediatr. 2015 Feb 15;15:10. PubMed PMID: 25886564; PubMed Central PMCID: PMC4359474.
c. **Wagner AD**, Njuguna IN, Mugo C, Inwani I, Maleche-Obimbo E, Sherr K, Wamalwa D, John-Stewart G, Slyker J. Targeted HIV testing in home or clinic for older children of HIV-infected adults in care increases pediatric HIV testing rates and reveals high prevalence of previously undiagnosed HIV infection. International AIDS Society; 2015 July; Vancouver, BC, Canada.

3. **HIV acquisition during pregnancy and postpartum:** I have been involved with studies of acute maternal HIV infection occurs and its contribution to pediatric HIV infection. I worked on the Mama Salama project, which aimed to estimate the incidence, and risk factors for maternal incident HIV infection during pregnancy and postpartum. This work resulted in two abstracts, as well as a recently published and frequently cited meta-analysis. The meta-analysis noted high rates of HIV acquisition among pregnant and postpartum women and a 3-4 fold higher risk of mother-to-child transmission of HIV among acutely infected women compared to chronically infected women. The importance of unrecognized maternal acute HIV in pregnancy/postpartum was underscored in a subsequent analysis in a pediatric cohort. We found among newly HIV diagnosed hospitalized children, the system gap that contributed the greatest number of undiagnosed pediatric infections was incident maternal HIV following a negative HIV test during antenatal care. I was involved in the design, data collection, and analysis for these manuscripts and abstracts.

a. Njuguna IN, **Wagner AD**, Otieno V, Cranmer L, Adhiambo J, Benki-Nugent S, Maleche-Obimbo E, Slyker J, Wamalwa D, John-Stewart G. System Gaps Result in Late Diagnosis and Treatment of Children With HIV in Hospital. Conference on Retroviruses and Opportunistic Infections; 2015; Seatte, WA, USA. c 00 .

b. John-Stewart G, Drake A, Kinuthia J, Slyker J, **Wagner A**, Richardson B. Responding to Risk in Pregnancy. Conference on Retroviruses and Opportunistic Infections; 2010; Boston, MA, USA. c 00 .

c. Kinuthia J, Odem-Davis K, **Wagner A**, Drake A, Matemo D, Unger J, Ambler G, Merkel M, McClelland RS, John-Stewart G. Sexual behavior and vaginal practices during pregnancy and postpartum: Implications for HIV prevention strategies. 7th International AIDS Society (IAS) Conference on HIV Pathogenesis, Treatment and Prevention; 2013 July; Kuala Lumpur, Malaysia. c 00 .

d. Drake AL, **Wagner A**, Richardson B, John-Stewart G. Incident HIV during pregnancy and postpartum and risk of mother-to-child HIV transmission: a systematic review and meta-analysis. PLoS Med. 2014 Feb;11(2):e1001608. PubMed PMID: 24586123; PubMed Central PMCID: PMC3934828.

Complete List of Published Work in MyBibliography:

http://www.ncbi.nlm.nih.gov/sites/myncbi/1FCVxacPrlJkh/bibliography/47811055/public/?sort=date&direction=ascending.

D. Scholastic Performance

YEAR	SCIENCE COURSE TITLE	GRADE
	TUFTS UNIVERSITY	
	--Health Sciences--	
2005	Intro to Community Health	A-
2007	Fundamental Epidemiology	A
2007	Human Nutrition	A
2008	Occupational and Env. Health	A-
2008	Intro. Global Health	A
2008	Community Health Internship	A
2008	Community Health Internship Sem	A
2008	Principles of Biostatistics	A
2009	Epidemiological Methods	A
2009	Regression Methods	A
	UNIVERSITY OF WASHINGTON	
	--Health Sciences--	
2010	Epidemiologic Methods I	3.9
2010	AIDS Multidisciplinary Approach	CR**
2010	Global Health Seminar	CR**
2010	Applied Biostatistics I	4.0
2010	Epidemiologic Program Seminar	CR**
2011	Epidemiologic Data Analysis	CR**
2011	Epidemiologic Methods II	3.7
2011	Application of Epidemiologic Methods	3.8
2011	Applied Biostatistics II	3.8
2011	Epidemiology of Infectious Disease	3.9
2011	Society and Health	3.7
2011	Vaccines	4.0
2011	Categorical Analysis Epidemiology	3.9
2011	Epidemiology Seminar	CR**
2012	Maternal and Child Health	3.9
2012	Survival Data Analysis Epidemiology	4.0

YEAR	OTHER COURSE TITLE	GRADE
	TUFTS UNIVERSITY	
2005	Globalization	B+
2005	Intro Peace/Justice Studies	A-
2005	Spanish Comp/Conversation II	A
2006	Concepts of the Cosmos	A+
2006	Elementary Italian I	A
2006	Social Movements	A
2006	Educ for Peace/Justice	A
2006	Main Current Spanish Lit II	A-
2006	Black Freedom in Haiti	A
2006	Kathak Dance	A
2006	Inner Peace, Outer Action	A
2006	Intro to Sociology	A
2006	Sociology of War & Peace	A-
2006	Survey Latin American Lit	A
2007	Health Care in America	A
2007	Mahayana Buddhist Sem	A
2007	Int'l Research Colloquium	P*
2007	Wealth, Poverty & Inequality	A-
2007	Health, Ethics & Policy	A+
2008	Women & Health	A
2008	Internship for Social Change	A-
2008	Interpersonal Conflict & Neg	A
2009	Community Health Indep Study	P*
2009	Gospel Choir	A+
2009	Peace, Justice & Social Change	A
	UNIVERSITY OF WASHINGTON	
2011	Responsible Conduct of Int'l Res.	CR**
2011-2	Masters Thesis	CR**

YEAR	SCIENCE COURSE TITLE	GRADE	YEAR	OTHER COURSE TITLE	GRADE
2012	Exposure Measurement	CR**	2012-5	Doctoral Dissertation	CR**
2012	Writing Research Proposals	CR**			
2012	Qualitative Research Methods	3.9			
2012	Doctoral Dissertation Seminar	CR**			
2013	Correlated Data Analysis	S***			
2013	Advanced Epidemiologic Methods	4.0			
2013	Economic Evaluation in Health	S***			
2014	Implementation Science Methods	3.9			
2015	Psychiatric Epidemiology	CR**			

*Courses at Tufts University graded with a P (pass) or NP (no pass). Passing is a C+ or better
** Courses at University of Washington graded as CR (credit) or NC (no credit). Credit is granted if students meet attendance and participation requirements for seminar series, complete assigned coursework and meet attendance and participation requirements for full courses, and make sufficient progress on thesis project for thesis credits. The attendance and participation requirements vary by course.
*** Courses at University of Washington graded as S (satisfactory) or NS (not satisfactory). Satisfactory is granted if students earn grades of 2.7 or above, while 2.6 or below is recorded as not satisfactory.

OMB No. 0925-0001/0002 (Rev. 08/12 Approved Through 8/31/2015)

BIOGRAPHICAL SKETCH

NAME: Sherr, Kenneth

eRA COMMONS USER NAME: ksherr

POSITION TITLE: Associate Professor, Department of Global Health,
Adjunct Associate Professor, Department of Industrial and Systems Engineering
Adjunct Associate Professor, Department of Epidemiology
University of Washington, Seattle, WA, USA
Director of Implementation Science, Health Alliance International

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
Kenyon College, Gambier, OH	B.A.	05/1995	Anthropology/Sociology
University of Washington, Seattle, WA	MPH	03/2000	Health Services
University of Washington, Seattle, WA	PhD	08/2009	Epidemiology

A. Personal Statement

In this F32 postdoctoral fellowship application, Ms. Anjuli Wagner proposes to use health systems research tools to improve the uptake of targeted pediatric HIV testing in Keya. I am well suited to serve as Ms. Wagner's primary mentor given my training and experience in implementation science, with a focus on HIV and reproductive health services in Kenya and Mozambique. As country director for Health Alliance International in Mozambique, I led the design and implementation of a range of HIV prevention, care and treatment services, including targeted HIV testing in youth friendly health centers, and later managed broad scale-up of these services through the primary healthcare framework through support from PEPFAR, UNICEF, the World Bank, and other agencies. As faculty of the Department of Global Health at the University of Washington and Director of the UW/FHCRC Center for AIDS Research's Scientific Working Group on Implementation Science, I have been involved in developing implementation science methodologies and capacity, including a 5-credit graduate level course on the Fundamentals of Implementation Science in Global Health, a PhD program in implementation science, and numerous short-courses on related material in Mozambique, Kenya, Peru, Timor Leste and Seattle. As Principal Investigator of the Systems Analysis and Improvement Approach (SAIA) Trial, I led the development and pilot testing of the project intervention (through a CFAR New Investigator Award), and subsequently the cluster randomized trial that assessed intervention impact in three countries. Ms. Wagner proposes to adapt and test the SAIA methodology as it applies to pediatric HIV testing in Kenya; I will be able to mentor her directly in the study's design, implementation, and analysis. Finally, I have a strong record of mentoring students, with 3 postdoctoral mentees, 7 doctoral mentees, and 9 masters students, and 20 graduate supervisees. In sum, my demonstrated record of successful and productive health systems research in an area highly related to this project, as well as my management and leadership experience with health programs and academic involvement in implementation science, prepare me to serve as Ms. Wagner's primary sponsor for her postdoctoral fellowship.

1. **SHERR K**, Gimbel S, Rustagi A, Nduati R, Cuembelo F, Farquhar C, Wasserheit J, Gloyd S. Systems analysis and improvement to optimize pMTCT (SAIA): A cluster randomized trial. *Implementation Science*. 2014;9:55. PMC Journal – In Process.
2. Gimbel S, Voss J, Mercer MA, Zierler B, Gloyd S, Coutinho M, Floriano F, Cuembelo F, Einberg J, **SHERR K**. The prevention of mother-to-child transmission of HIV cascade analysis tool: Supporting health managers to improve facility-level service delivery. BMC Research Notes. 2014;7:743.
3. Gerdts S, Wagenaar B, Micek M, Farquhar C, Karagianis M, Amos J, Gimbel S, Pfeiffer J, GLoyd S, **SHERR K**.* Linkage to HIV Care and Antiretroviral Therapy by HIV Testing Service Type in Central Mozambique: A Retrospective Cohort Study. *J Acquir Immune Defic Syndr.* 2014;66:e37-e44. PMCID: PMC4020956.
4. Gimbel S, Voss J, Rustagi A, Mercer M, Zierler B, Gloyd S, Coutinho J, Cuembelo F, **SHERR K**. What does high and low have to do with it? Performance classification to identify health system factors associated with effective prevention of mother-to-child transmission of HIV delivery in Mozambique. *J Int AIDS Soc*. 2014;17:18828. PMCID: PMC3965711.

B. Positions and Honors

Positions and Employment

1995-1996 Immunization Outreach Advisor, Save the Children, Inquisivi, Bolivia
1997-1998 HIS/Immunization Advisor, Minnesota International Health Volunteers, Ssembabule, Uganda
1999-2000 Research Assistant, Health Alliance International, Seattle, WA
1999-2000 Teaching Assistant, Research Methods for Developing Countries (EPI/HSERV 539) and Problems in International Health (EPI/HSERV 531), University of Washington, Seattle, WA
2000-2004 Mozambique Country Director, Health Alliance International, Manica and Sofala, Mozambique
2002-2003 Care Partner and Technical Consultant, Clinton Foundation Initiative for Universal HIV Care, Maputo, Mozambique
2003-2004 Chief Technical Advisor, HIV/AIDS Care and Treatment Initiative, Ministry of Health/Medical Care Department, Maputo, Mozambique
2004-2006 Technical Advisor, Health Alliance International, Seattle, WA
2006-2008 Mozambique Country Director, Health Alliance International, Maputo, Mozambique
2008- Director of Implementation Science, Health Alliance International, Seattle, WA
2009-2014 Assistant Professor, Department of Global Health, University of Washington, Seattle, WA
2010-2014 Adjunct Assistant Professor, Departments of Epidemiology and Industrial and Systems Engineering, University of Washington, Seattle, WA
2014- Associate Professor, Department of Global Health, University of Washington, Seattle, WA
2014- Adjunct Associate Professor, Departments of Epidemiology and Industrial and Systems Engineering, University of Washington, Seattle, WA

Other Experience and Professional Memberships

2001 Technical Expert, WHO/AFRO panel on development of HIV Counseling & Testing guidelines
2002 Task Force Member, Ministry of Health/Clinton Foundation committee responsible for development of the National HIV/AIDS Care and Treatment Plan
2010 Moderator, Panel on Health Systems and Implementation Science, Consortium of Universities for Global Health Annual meeting, Seattle, WA
2011 Evaluating the Scale-up for the Millenium Development Goals, Rockefeller Foundation Center, Bellagio, Italy
2011-2012 Guest Editor, *BMC Health Services Research* supplement entitled 'Improving primary health care to achieve population health impact: the African Health initiative'
2012 Scientific Committee Member, XIV Jornadas de Saúde (Mozambique's National Medical Conference)
2013 Participant, 6th NIH Meeting on Dissemination and Implementation Research: A Working Meeting on Research Training
2013-2014 Study Section Member, Mozambique Ministry of Health/National Institutes of Health Small Grants Initiative
2014-2015 Scientific Committee Member, XV Jornadas de Saúde, Moçambique
2014 Scientific Advisory Panel, 7th Annual Conference on the Science of Dissemination and Implementation, NIH & Academy Health
2014- Member, Health Systems Global
2015- Scientific Advisory Member, National Institutes of Health Clean Cookstove Implementation Science Network
2015 Study Section Member, National Institutes of Health ZRG1 (AARR F90:) and ZRG1 (HDM-Y (58) R: Systems Science and Health in the Behavioral and Social Sciences).

Honors

1994-1995 Dean's List, Kenyon College, OH
1995 Distinction on Senior Thesis, Kenyon College, OH
1999 Shedd International Service Awardee, University of Washington, WA
1999 FLAS Title IV Language Fellow (French), University of Washington, WA
1999-2000 Mortar Board Scholar, University of Washington, WA
1999 Hatterlee Merit Scholar, University of Washington, WA
2008 International AIDS Society Young Investigator Award
2011 NIH/FIC Independent Scientist in Global Health Award
2012 UW/FHCRC CFAR New Investigator Award

C. Contribution to Science

Systems Analysis and Improve HIV Prevention, Care and Treatment. Patient loss to follow-up along the HIV prevention, care and treatment cascades impedes programmatic effectiveness. Research on HIV prevention, care and treatment cascades can deepen our understanding of obstacles contributing to loss to follow-up, and help identify and iteratively test strategies to address this loss to follow-up. A recent research focus has been in the application of industrial and systems analysis techniques to describe, highlight inefficiencies, and improve complex service cascades in HIV prevention, care and treatment. This work has included the development and application of cascade analysis tools that describe linkages from HIV testing with follow-up services, as well as leakage from follow-up services, for prevention of mother-to-child HIV transmission (pMTCT) and adult combination antiretroviral therapy. This research has led to measurable improvements in cascade process outcomes, and a generalizable model to assess and improve complex HIV prevention, care and treatment services. I have served as the primary investigator, co-investigator, or mentor on these studies.

1. **SHERR K**, Gimbel S, Rustagi A, Nduati R, Cuembelo F, Farquhar C, Wasserheit J, Gloyd S. Systems analysis and improvement to optimize pMTCT (SAIA): A cluster randomized trial. *Implementation Science*. 2014;9:55. PMC Journal – In Process.
2. Gimbel S, Voss J, Mercer MA, Zierler B, Gloyd S, Coutinho M, Floriano F, Cuembelo F, Einberg J, **SHERR K**. The prevention of mother-to-child transmission of HIV cascade analysis tool: Supporting health managers to improve facility-level service delivery. *BMC Research Notes*. 2014;7:743.
3. Micek M, **GIMBEL-SHERR K**, Baptista A, Matediana E, Montoya P, Pfeiffer J, Melo A, Gimbel-Sherr S, Johnson W, Gloyd S. Loss to follow-up of adults in public HIV care systems in central Mozambique: identifying obstacles to treatment. *J Acquir Immune Defic Syndr*. 2009;52(3):397-405. PMCID: PMC2784145.
4. Gerdts S, Wagenaar B, Micek M, Farquhar C, Karagianis M, Amos J, Gimbel S, Pfeiffer J, GLoyd S, **SHERR K**. Linkage to HIV Care and Antiretroviral Therapy by HIV Testing Service Type in Central Mozambique: A Retrospective Cohort Study. *J Acquir Immune Defic Syndr.* 2014;66:e37-e44. PMCID: PMC4020956.

Human Resources for Health and HIV Care and Treatment. Health workforce scarcity impedes the effective delivery of HIV prevention, care and treatment interventions. Generation of an evidence-base on interventions to address trained health personnel shortages has been prioritized since the concerted efforts to scale-up HIV care and treatment services. My doctoral dissertation focused on this area of research, specifically on evaluating the quality of care and role of non-physician clinicians in the provision of antiretroviral therapy. These papers provided an evidence-base supporting engaging mid-level providers in HIV care and treatment in Mozambique, received a new investigator award at the 2009 International AIDS Society meeting in Mexico City, and has been included in multiple systematic reviews on task sharing. Additional research in this area has focused on modeling the human resource and budgetary needs to take HIV care and treatment to national scale. My role in this research has been as primary investigator, or co-investigator.

1. **SHERR K**, Pfeiffer J, Mussa A, Vio F, Gimbel S, Micek M, Gloyd S. The role of non-physician clinicians in the rapid expansion of HIV care in Mozambique. *J Acquir Immune Defic Syndr.* 2009;52:S20-23.
2. **SHERR K**, Micek M, Gimbel S, Gloyd S, Hughes J, John-Stewart G, Manjate R, Pfeiffer J, Weiss N. Quality of HIV care provided by non-physician clinicians and physicians in Mozambique: a retrospective cohort study. *AIDS*. 2010;24:S59-66. PMCID: PMC3372417.
3. Gimbel-Sherr S, Micek M, **GIMBEL-SHERR K**, Koepsell T, Hughes J, Thomas K, Pfeiffer J, Gloyd S. Using nurses to identify HAART eligible patients in the Republic of Mozambique: results of a time-series analysis. *Hum Resour Health*. 2007;5:7. PMCID: PMC1817650.
4. Hagopian A, Micek M, Vio F, **GIMBEL-SHERR K**, Montoya P. What if we decided to take care of everyone who needed treatment? Workforce planning in Mozambique using simulation of demand for HIV/AIDS care. *Hum Resour Health*. 2008;6:3. PMCID: PMC2276232.

Research Methods to Assess the Effect of Health Systems Strengthening. Robust health systems are essential for the delivery of efficacious interventions, and there are substantial gaps in the literature on how to strengthen health systems. A body of my research over the last 7 years has been devoted to developing models for strengthening health systems (supported by the Doris Duke Charitable Foundation's African Health Initiative), and to develop novel approaches to evaluate health system strengthening interventions. My role in this research has been as primary investigator, mentor for junior researchers, or co-investigator.

1. **SHERR K**, Requejo J, Basinga P. Implementation research to catalyze advances in health systems strengthening in sub-Saharan Africa: the African Health Initiative. *Biomedical Central Health Services Research*. 2013;13(Suppl2):S4. PMCID: PMC3668282.

2. Fernandes Q, Wagenaar B, Anselmi L, Pfeiffer J, Gloyd S, **SHERR K**. Effects of health-system strengthening on under-5, infant, and neonatal mortality: 11-year provincial-level time-series analysis in Mozambique. *Lancet Global Health.* 2014;2:e468-77.
3. Bryce J, Requejo J, Moulton L, Ram M, Black R, *et al.* A common evaluation framework for the African Health Initiative. *Biomedical Central Health Services Research*. 2013;13(Suppl2):S10. PMCID: PMC3668298.
4. **SHERR K**, Cuembelo F, Michel C, Gimbel S, Micek M, Kariaganis M, Pio A, Manuel J, Pfeiffer J, Gloyd S. Strengthening integrated primary health care in Sofala, Mozambique. *Biomedical Central Health Services Research*. 2013;13(Suppl2):S1. PMCID: PMC3668215.

Primary Health Care: Strengthening the Information and Commodity Building Blocks. Complementing efforts to evaluate and strengthen health systems has been focused efforts to improve health system building blocks, notably in the areas of health management information systems and commodity management systems. My research in this area has led to improvements in provincial, district and facility-level management of essential health system building blocks. My role in this research has been as primary investigator, mentor for junior researchers, or co-investigator.

1. Wagenaar B, **SHERR K**, Fernandes Q, Wagenaar A. Using routine health information systems for well-designed health evaluations in low-and middle-income countries. *Health Policy and Planning*. 2015 Apr 16.
2. Gimbel S, Micek M, Lambdin B, Lara J, Karagianis M, Cuembelo F, Gloyd S, Pfeiffer J, **SHERR K**. An assessment of routine primary care health information system data quality in Sofala, Mozambique. *Population Health Metrics.* 2011;9:12. PMCID: PMC3112390.
3. Mutale W, Chintu N, Amoroso C, Awoonor-Williams K, Philips J, Baynes C, Michel C, Tayor A, **SHERR K**. Improving health information systems for decision making across five sub-Saharan countries: implementation strategies from the African Health Initiative. *Biomedical Central Health Services Research*. 2013;13(Suppl2):S9. PMCID: PMC3668230.
4. Wagenaar B, Gimbel S, Hoek R, Pfeiffer J, Michel C, Manuel JL, Cuembelo F, Quembo T, Afonso P, Porthé V, Gloyd S, **SHERR K**. Effects of a health information system data quality intervention on concordance in Mozambique: Time-series analyses from 2009-2012. *Pop Health Metrics*. 2015 Mar 26;13:9.

From Pilot to Scale: Providing Evidence for Policy and Strategy Development. Translating effective pilot interventions to national scale, and providing data for the development of national policy and strategy, are essential steps to lead to population-level impact of health services. I have been a co-investigator, or primary investigator, on multiple studies designed to translate pilot initiatives into national programs, and to provide timely data for policymakers to develop national policy.

1. Gloyd S, Montoya P, Floriano F, Chadreque MC, Pfeiffer J, **GIMBEL-SHERR K**. Scaling-Up Antenatal syphilis screening in Mozambique: transforming policy to action. *Sex Transm Dis*. 2007; 34(7): S31-36.
2. Brentlinger PE, **SHERR K**, Mercer MA, Gloyd S. Scaling-up and sustaining insecticide-treated net coverage. *Lancet Infect Dis*. 2003; 3(8): 467.
3. **SHERR K**, Mussa A, Chilundo B, Gimbel S, Pfeiffer J, Hagopian A, Gloyd S. Brain drain and health workforce distortions in Mozambique. *PLoS ONE*. 2012;7:4. PMCID: PMC3338796
4. Mussa A, Pfeiffer J, Gloyd S, **SHERR K**. Vertical funding, non-governmental organizations, and health system strengthening: perspectives of public sector health workers in Mozambique. *Human Resources for Health*. 2013;11:26. PMCID: PMC3691708.

Complete List of Published Work in MyBibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/kenneth.sherr.1/bibliography/44040386/public/?sort=date&direction=descending

D. Research Support

Ongoing Research Support

1R01HD0757-01 Sherr (PI) 09/30/2012-06/30/2016
Systems Analysis and Improvement to Optimize pMTCT in Kenya, Mozambique, and Côte d'Ivoire: A Cluster Randomized Trial
National Institutes of Health, National Institute of Child Health and Human Development
The goal of this research award is to identify determinants of pMTCT program performance, and to implement and assess a systems analysis and improvement approach for pMTCT programs.
Role: PI

1K02TW009207-01 Sherr (PI) 09/16/2011-07/30/2016

Health Systems Strengthening to Improve Health Outcomes: Applying Implementation Science in Central Mozambique
National Institutes of Health, Fogarty International Center
The goal of this career development award is to develop professional skills related to systems analysis and health systems improvement in central Mozambique.
Role: PI

AID-656-A-15-003 Sherr (PI) 10/27/2014-10/30/2017
Strengthening Data Systems to Improve Delivery of Health Services in Mozambique
The goal of this project is to develop and implement a fellowship training program in strategic information, and improve the delivery of routine malaria services through iterative process improvement approaches.
Role: PI

Royalty Research Fund Sherr (PI) 07/01/2014-06/30/2015
Prevalence, risk and protective factors, care seeking, and the sociocultural context for common mental disorders in Sofala Province, Mozambique
The goal of this research project is to assess the burden of common mental health disorders in central Mozambique, including risk factors, care pathways, and health system capacity to screen and care for patients with mental health disorders.
Role: PI

2009059 Sherr (PI) 08/01/2009-06/30/2016
Strengthening Integrated Primary Health Care and Workforce Training in Sofala Province, Mozambique
Doris Duke Charitable Foundation Population Health Implementation Training (PHIT) Partnership Grant
The goal of this project is to implement and evaluate a comprehensive Primary Health Care strengthening approach in Sofala, Mozambique.
Role: PI

AI027757 Holmes (PI) 05/2012-05/2015
Systems analysis and improvement to optimize PMTCT in central Mozambique.
New Investigator Award through the UW/FHCRC Center for AIDS Research.
The goal of this New Investigator Award is to develop and implement a systems analysis and improvement approach for prevention of mother-to-child transmission of HIV services in Sofala, Mozambique.
National Institutes of Health, National Institute of Allergy and Infectious Diseases (award through the Developmental Core of the UW/FHCRC Center for AIDS Research).
Role: Implementation Science Scientific Working Group Director

Completed Research Support

AI027757 Holmes (PI) 05/2012-05/2015
Systems analysis and improvement to optimize PMTCT in central Mozambique. New Investigator Award through the UW/FHCRC Center for AIDS Research. The goal of this New Investigator Award is to develop and implement a systems analysis and improvement approach for prevention of mother-to-child transmission of HIV services in Sofala, Mozambique.
National Institutes of Health, National Institute of Allergy and Infectious Diseases (award through the Developmental Core of the UW/FHCRC Center for AIDS Research).
Role: Implementation Science Scientific Working Group Director

2005053 Gloyd (PI) 01/01/2006-12/31/2008
HAART Delivery Models: A quasi-experimental study
Doris Duke Charitable Foundation's Operations Research for AIDS Care and Treatment in Africa (ORACTA)
The goal of this study was to compare how the structure and composition of clinic service delivery teams affected the quality and effectiveness of HIV care and treatment in central Mozambique.
Role: Co-I

OMB No. 0925-0001/0002 (Rev. 08/12 Approved Through 8/31/2015)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.

Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: John-Stewart, Grace C

eRA COMMONS USER NAME (agency login): GRACEJOHN

POSITION TITLE: Director

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
University of Michigan	BS	07/1983	Chemistry and Cellular Molecular Biology
University of Michigan, Ann Arbor, Michigan	MD	07/1987	Medicine
University of Washington, Seattle, WA	MPH	06/1996	Epidemiology
University of Washington, Seattle, WA	PHD	06/2000	Epidemiology
University of Michigan, Ann Arbor, MI	Resident	06/1991	Internal Medicine/Pediatrics
University of Michigan, Ann Arbor, MI	Resident	06/1992	Chief Resident Pediatrics
University of Washington, Seattle, WA	Fellow	06/1996	Infectious Diseases Fellowship

A. Personal Statement

Over the past >20 years, my research has focused on HIV transmission and pathogenesis in women and children. The first studies I conducted were designed to define risk and timing of mother-to-child HIV transmission, particularly to understand breastmilk transmission of HIV. These studies included clinical trials and molecular epidemiology studies. This research informed policy and guidelines and contributed to interventions to prevent transmission with antiretrovirals. Our group has contributed comprehensively to PMTCT across a spectrum of research that has included clinical trials, molecular epidemiology, implementation science, and large-scale evaluations. In addition, through mentorship I have sought to catalyse new research and young investigators to advance studies of co-infection (herpes viruses, TB) in mothers and children. The work we do with women and children also led naturally to studies on HIV progression, reproductive health and outcomes in women and detailed studies on pathogenesis and interventions to improve outcomes in HIV-infected and HIV-exposed uninfected children. **Overall, my research has been disseminated in >215 peer-reviewed publications.** For Ms. Anjuli Wagner's proposed F32, I will provide expertise in study design and analysis, with specific focus on pediatric HIV diagnosis and management. Additionally, I will provide mentorship for Ms. Wagner's career development as she gains new implementation science research skills. I will be available to meet with Ms. Wagner weekly in-person or via Skype.

1. **John GC**, Nduati RW, Mbori-Ngacha D, Overbaugh J, Welch M, Richardson BA, Ndinya-Achola J, Bwayo J, Krieger J, Onyango F, Kreiss JK. Genital shedding of human immunodeficiency virus type 1 DNA during pregnancy: association with immunosuppression, abnormal cervical or vaginal discharge, and severe vitamin A deficiency. J Infect Dis. 1997 Jan;175(1):57-62. PubMed PMID: 8985196; PubMed Central PMCID: PMC3372419.
2. Nduati R, **John G**, Mbori-Ngacha D, Richardson B, Overbaugh J, Mwatha A, Ndinya-Achola J, Bwayo J, Onyango FE, Hughes J, Kreiss J. Effect of breastfeeding and formula feeding on transmission of HIV-1: a randomized clinical trial. JAMA. 2000 Mar 1;283(9):1167-74. PubMed PMID: 10703779.
3. Mbori-Ngacha D, Nduati R, **John G**, Reilly M, Richardson B, Mwatha A, Ndinya-Achola J, Bwayo J, Kreiss J. Morbidity and mortality in breastfed and formula-fed infants of HIV-1-infected women: A randomized clinical trial. JAMA. 2001 Nov 21;286(19):2413-20. PubMed PMID: 11712936; PubMed Central PMCID: PMC3358136.
4. Slyker JA, Casper C, Tapia K, Richardson B, Bunts L, Huang ML, Wamalwa D, Benki-Nugent S, **John-Stewart G**. Accelerated suppression of primary Epstein-Barr virus infection in HIV-infected infants initiating lopinavir/ritonavir-based versus nevirapine-based combination antiretroviral therapy. Clin Infect Dis. 2014 May;58(9):1333-7. PubMed PMID: 24550373; PubMed Central PMCID: PMC3982841.

B. Positions and Honors

Positions and Employment

1993 - 2005	Visiting Research Scientist, University of Nairobi, Nairobi
1996 - 1997	Acting Instructor, University of Washington, Seattle, WA
1997 - 2002	Assistant Professor, University of Washington, Seattle, WA
2008 -	Director, International Core, UW CFAR
2009 -	Professor, University of Washington, Departments of Global Health, Epidemiology, Medicine, and Pediatrics, Seattle, WA
2011 -	Director, Global Center for Integrated Health of Women, Adolescents and Children (Global WACh)
2011 - 2014	Director, Kenya Research Program

Selected Other Experience and Professional Memberships

1993 -	Member, WHO Collaborative HIV/STD Center Nairobi
2008 - 2012	AIDS Clinical Epidemiology Study Section Full Member, NIH
2011 - 2011	External reviewer, IMPAACT
2012 - 2012	Ethics Review Panel, NIH PROMISE
2012 - 2014	DSMB Member, Fluconazole/FC Phase IIB RCT, NIAD
2013 -	Full Member, NIH T32/K Study Section
2013 -	DSMB Charter Member, NIAID
2014 -	Scientific Advisory Group, IMPAACT
2014 -	Scientific Advisory Board, INFANT study
2014, 2015	D43 Study Section Chair, NIH Fogarty

Selected Honors

1981	William Branstrom Award, University of Michigan
1982, 1983	James B Angell Scholar, University of Michigan
1983	Merck Award (Outstanding Graduate Chemistry), University of Michigan
1991	Galen's Bronze Beeper Award, University of Michigan
1991	Resident Initiative Award (James M Simpson Award), University of Michigan
1991	Board Certified, Pediatrics, ABP
1992	Board Certified Internal Medicine, ABIM
1996	Young Investigator Award, IAS
1996	Board Certified, Infectious Diseases, AB Infectious Diseases
2002	Elizabeth Glaser Scientist Award, Elizabeth Glaser Pediatric AIDS Foundation
2009	Science in Medicine Lecture, University of Washington
2009	Distinguished Faculty Lecturer in Public Health, University of Washington

C. Contribution to Science

1. Our group has contributed molecular epidemiologic studies to understand how mother-to-child HIV transmission occurs. We found that maternal genital and breastmilk HIV contributed independent of systemic plasma HIV RNA levels, that cellular and cell-free virus were associated with transmission. Higher maternal-infant HLA-relatedness (concordance) also increased transmission, while infant and maternal HIV-specific T-cell responses were associated with lower transmission. Other genetic polymorphisms (CCR5, SDF-1, TLRs) also influence MTCT.

    a. Richardson BA, **John-Stewart GC**, Hughes JP, Nduati R, Mbori-Ngacha D, Overbaugh J, Kreiss JK. Breast-milk infectivity in human immunodeficiency virus type 1-infected mothers. J Infect Dis. 2003 Mar 1;187(5):736-40. PubMed PMID: 12599046; PubMed Central PMCID: PMC3382109.

b. Mackelprang RD, **John-Stewart G**, Carrington M, Richardson B, Rowland-Jones S, Gao X, Mbori-Ngacha D, Mabuka J, Lohman-Payne B, Farquhar C. Maternal HLA homozygosity and mother-child HLA concordance increase the risk of vertical transmission of HIV-1. J Infect Dis. 2008 Apr 15;197(8):1156-61. PubMed PMID: 18462163; PubMed Central PMCID: PMC2689391.

c. Lohman-Payne B, Slyker JA, Moore S, Maleche-Obimbo E, Wamalwa DC, Richardson BA, Rowland-Jones S, Mbori-Ngacha D, Farquhar C, Overbaugh J, **John-Stewart G**. Breast milk cellular HIV-specific interferon γ responses are associated with protection from peripartum HIV transmission. AIDS. 2012 Oct 23;26(16):2007-16. PubMed PMID: 22948269; PubMed Central PMCID: PMC3718292.

d. Beima-Sofie KM, Bigham AW, Lingappa JR, Wamalwa D, Mackelprang RD, Bamshad MJ, Maleche-Obimbo E, Richardson BA, **John-Stewart GC**. Toll-like receptor variants are associated with infant HIV-1 acquisition and peak plasma HIV-1 RNA level. AIDS. 2013 Sep 24;27(15):2431-9. PubMed PMID: 24037211; PubMed Central PMCID: PMC4124859.

2. We have studied mechanisms of antiretroviral effect in prevention of MTCT (PMTCT). We found that nevirapine results in much longer suppression of plasma and breastmilk HIV RNA than other regimens, that all regimens have less impact on HIV DNA than RNA in breastmilk, and that nevirapine provides substantial infant prophylactic benefits. Genital suppression of virus occurs rapidly within a week of zidovudine initiation. These studies provide evidence that informs the most effective currently used PMTCT strategies.

a. Mbori-Ngacha D, Richardson BA, Overbaugh J, Panteleeff DD, Nduati R, Steele M, **John-Stewart G**. Short-term effect of zidovudine on plasma and genital human immunodeficiency virus type 1 and viral turnover in these compartments. J Virol. 2003 Jul;77(13):7702-5. PubMed PMID: 12805473; PubMed Central PMCID: PMC164813.

b. Chung MH, Kiarie JN, Richardson BA, Lehman DA, Overbaugh J, **John-Stewart GC**. Breast milk HIV-1 suppression and decreased transmission: a randomized trial comparing HIVNET 012 nevirapine versus short-course zidovudine. AIDS. 2005 Sep 2;19(13):1415-22. PubMed PMID: 16103773; PubMed Central PMCID: PMC3381340.

c. Chung MH, Kiarie JN, Richardson BA, Lehman DA, Overbaugh J, Kinuthia J, Njiri F, **John-Stewart GC**. Highly active antiretroviral therapy versus zidovudine/nevirapine effects on early breast milk HIV type-1 Rna: a phase II randomized clinical trial. Antivir Ther. 2008;13(6):799-807. PubMed PMID: 18839781; PubMed Central PMCID: PMC2859833.

d. Lehman DA, Chung MH, **John-Stewart GC**, Richardson BA, Kiarie J, Kinuthia J, Overbaugh J. HIV-1 persists in breast milk cells despite antiretroviral treatment to prevent mother-to-child transmission. AIDS. 2008 Jul 31;22(12):1475-85. PubMed PMID: 18614871; PubMed Central PMCID: PMC2765916.

3. We expanded studies to facilitate implementation of PMTCT. This included studies showing that rapid HIV testing and male partner involvement could improve PMTCT, that systems failures had a larger impact than stigma and that maternal HIV incidence within PMTCT programs was contributing substantial infant HIV infections. These studies have supported wider use of rapid HIV testing, engaging male partners in PMTCT and will continue to be important to improve prevention and management of acute maternal HIV in pregnancy/postpartum - together these will be critical to advance elimination of infant HIV and to optimize maternal health outcomes.

a. Malonza IM, Richardson BA, Kreiss JK, Bwayo JJ, **Stewart GC**. The effect of rapid HIV-1 testing on uptake of perinatal HIV-1 interventions: a randomized clinical trial. AIDS. 2003 Jan 3;17(1):113-8. PubMed PMID: 12478076; PubMed Central PMCID: PMC3380077.

b. Aluisio A, Richardson BA, Bosire R, **John-Stewart G**, Mbori-Ngacha D, Farquhar C. Male antenatal attendance and HIV testing are associated with decreased infant HIV infection and increased HIV-free survival. J Acquir Immune Defic Syndr. 2011 Jan 1;56(1):76-82. PubMed PMID: 21084999; PubMed Central PMCID: PMC3005193.

c. Kinuthia J, Kiarie JN, Farquhar C, Richardson BA, Nduati R, Mbori-Ngacha D, **John-Stewart G**. Uptake of prevention of mother to child transmission interventions in Kenya: health systems are more influential than stigma. J Int AIDS Soc. 2011 Dec 28;14:61. PubMed PMID: 22204313; PubMed Central PMCID: PMC3313883.

d. Drake AL, Wagner A, Richardson B, **John-Stewart G**. Incident HIV during pregnancy and postpartum and risk of mother-to-child HIV transmission: a systematic review and meta-analysis. PLoS Med. 2014 Feb;11(2):e1001608. PubMed PMID: 24586123; PubMed Central PMCID: PMC3934828.

4. Our group has also studied pediatric HIV, focusing on detection, progression, treatment outcomes, and disclosure. We have noted higher viral loads among children with early infection compared to later postpartum, response to ART but slower suppression of virus and frequent development of resistance to nevirapine, even in the absence of prior maternal nevirapine exposure. These studies contribute to improving pediatric HIV outcomes.

   a. Wamalwa DC, Farquhar C, Obimbo EM, Selig S, Mbori-Ngacha DA, Richardson BA, Overbaugh J, Emery S, Wariua G, Gichuhi C, Bosire R, **John-Stewart G**. Early response to highly active antiretroviral therapy in HIV-1-infected Kenyan children. J Acquir Immune Defic Syndr. 2007 Jul 1;45(3):311-7. PubMed PMID: 17356470; PubMed Central PMCID: PMC3380073.

   b. Beima-Sofie K, **John-Stewart G**, Shah B, Wamalwa D, Maleche-Obimbo E, Kelley M. Using health provider insights to inform pediatric HIV disclosure: a qualitative study and practice framework from Kenya. AIDS Patient Care STDS. 2014 Oct;28(10):555-64. PubMed PMID: 25216105; PubMed Central PMCID: PMC4183914.

   c. Benki-Nugent S, Eshelman C, Wamalwa D, Langat A, Tapia K, Okinyi HM, **John-Stewart G**. Correlates of age at attainment of developmental milestones in HIV-infected infants receiving early antiretroviral therapy. Pediatr Infect Dis J. 2015 Jan;34(1):55-61. PubMed PMID: 25144793; PubMed Central PMCID: PMC4336221.

   d. Chohan BH, Tapia K, Benki-Nugent S, Khasimwa B, Ngayo M, Maleche-Obimbo E, Wamalwa D, Overbaugh J, **John-Stewart G**. Nevirapine resistance in previously nevirapine-unexposed HIV-1-infected Kenyan infants initiating early antiretroviral therapy. AIDS Res Hum Retroviruses. 2015 Apr 22;PubMed PMID: 25819584.

5. Our group has examined relevant co-infections affecting women and children with HIV. We found that deworming did not significantly improve HIV outcomes. TB co-infection is frequent in mothers and children and latent TB detection by IGRAs predict maternal and infant outcomes. TB-specific immune responses are detectable in breastmilk and mothers have substantial rates of IGRA conversion postpartum. These studies will help to tailor TB prevention approaches in HIV-infected women and their children. We have also conducted studies of CMV, EBV, and HSV in mother-infant cohorts and examined cotrimoxazole prophylaxis. These studies of co-infections in HIV and among mother-infant pairs are important to complement antiretroviral treatment approaches.

   a. Slyker JA, Lohman-Payne BL, Rowland-Jones SL, Otieno P, Maleche-Obimbo E, Richardson B, Farquhar C, Mbori-Ngacha D, Emery VC, **John-Stewart GC**. The detection of cytomegalovirus DNA in maternal plasma is associated with mortality in HIV-1-infected women and their infants. AIDS. 2009 Jan 2;23(1):117-24. PubMed PMID: 19050393; PubMed Central PMCID: PMC2739581.

   b. Jonnalagadda S, Lohman Payne B, Brown E, Wamalwa D, Maleche Obimbo E, Majiwa M, Farquhar C, Otieno P, Mbori-Ngacha D, **John-Stewart G**. Latent tuberculosis detection by interferon γ release assay during pregnancy predicts active tuberculosis and mortality in human immunodeficiency virus type 1-infected women and their children. J Infect Dis. 2010 Dec 15;202(12):1826-35. PubMed PMID: 21067370; PubMed Central PMCID: PMC3058232.

   c. Walson J, Singa B, Sangaré L, Naulikha J, Piper B, Richardson B, Otieno PA, Mbogo LW, Berkley JA, **John-Stewart G**. Empiric deworming to delay HIV disease progression in adults with HIV who are ineligible for initiation of antiretroviral treatment (the HEAT study): a multi-site, randomised trial. Lancet Infect Dis. 2012 Dec;12(12):925-32. PubMed PMID: 22971323.

   d. Cranmer LM, Kanyugo M, Jonnalagadda SR, Lohman-Payne B, Sorensen B, Maleche Obimbo E, Wamalwa D, **John-Stewart GC**. High prevalence of tuberculosis infection in HIV-1 exposed Kenyan infants. Pediatr Infect Dis J. 2014 Apr;33(4):401-6. PubMed PMID: 24378937; PubMed Central PMCID: PMC3959593.

Complete List of Published Work in My Bibliography:
http://www.ncbi.nlm.nih.gov/myncbi/grace.john-stewart.1/bibliography/40347452/public/?sort=date&direction=ascending

D. Research Support

Selected Ongoing Research Support

2014/05/01-2019/04/30
R01 HD080460-02, Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
John-Stewart, Grace C (PI) **Evaluation of mHealth strategies to optimize adherence and efficacy of PMTCT/ART** This randomized trial will compare 2-way vs. 1-way SMS to control for effects on ART adherence, viral suppression and other maternal child outcomes. The intervention was developed in collaboration with computer scientists and involves an innovative delivery platform (Mobile WACHx). Role: PI

2006/09/29-2017/03/31
K24 HD054314-09, Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
John-Stewart, Grace C (PI); **Pediatric HIV-1 in Africa: Pathogenesis and Management** This award supports Dr. John-Stewart to mentor trainees in studies focused on pediatric HIV clinical research. Role: PI

2014/04/10-2016/03/31
R21 HD079637-02, Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
John-Stewart, Grace C (PI); **HIV-1 Counseling and Testing for Children at Home (CATCH)**
This study seeks to improve options to 'catch' HIV-infected infants and children who did not get diagnosed in PMTCT programs. Role: PI

2012/09/21-2016/03/31
R01 HD023412-22S1, National Institute of Child Health and Human Development (NICHD)
John-Stewart, Grace C (PI); **Urgent Versus Post-Stabilization ART in HIV+ Children with Severe Co-infection**
This RCT will compare urgent vs. post-stabilization ART among children newly diagnosed in hospital with HIV. Role: PI

2013/06/01-2018/05/31
P30 AI027757-21, National Institute of Allergy and Infectious Diseases (NIAID)
Holmes, K (PI) Dr. John-Stewart leads the **UW CFAR International Core**. Role: Director, IC

Selected Completed Research Support

- 2013/08/21-2015/05/30; 12007, GAPPS; Eschenbach, David (PI); **Vaginal Microbiome, Metabolome, and Immune Responses in Preterm Birth** Role: Co-Investigator
- 2009/09/15-2014/06/30; P01 HD064915-01, National Institute of Child Health and Human Development (NICHD) Overbaugh, J (PI) ; **Incidence, timing and cofactors that contribute to the HIV risk in pregnancy and postpartum**; Dr. John-Stewart leads Project 1. Role: PI Project 1
- 2010/09/01-2012/08/31; R21 HD058477-02S1, National Institute of Child Health and Human Development (NICHD) John-Stewart, Grace C (PI) **Latent TB Detection and Implications in HIV-1 Infected Women and Their Children**; Role: PI

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BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: James P. Hughes

eRA COMMONS USER NAME (credential, e.g., agency login): JPHUGHES

POSITION TITLE: Professor

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Maine, Orono, Maine	**B.S.**	**1977**	**Wildlife Ecology**
University of Washington, Seattle, Washington	**M.S.**	**1980**	**Biomathematics**
University of Washington, Seattle, Washington	**Ph.D.**	**1993**	**Statistics**

A. Personal Statement

Dr. Hughes is a professor of Biostatistics with extensive experience in both clinical trial and observational studies of HIV and STI prevention. He is a senior statistician in the HIV Prevention Trials Network and is involved in both domestic and international initiatives in that network. He is the PI of an R01 methods grant entitled “Statistical Methods in AIDS Research”. Dr. Hughes is also the director of the Biostatistics and Bioinformatics core of the University of Washington STI Collaborative Research Center. Dr. Hughes has extensive experience teaching statistics and has received the University of Washington School of Public Health Outstanding Teaching Award.

Dr. Hughes has collaborated extensively with Ms. Wagner’s mentorship team, including co-sponsors Drs. Sherr and John-Stewart, on studies related to mother-to-child transmission of HIV and efforts to optimize PMTCT programs. He is an expert in cluster randomized trials, as well as design and analysis considerations in implementation science research. Dr. Hughes was involved in the design and analysis of the SAIA trial, which Ms. Wagner’s proposed project is modeled on. Dr. Hughes looks forward to providing mentorship to Ms. Wagner during her proposed postdoctoral studies.

1. Hussey MA, **Hughes JP**. Design and Analysis of Stepped Wedge Cluster Randomized Trials. *Contemporary Clinical Trials, 28:182-191, 2007.*
2. **Hughes JP**. Using Baseline Data to Design a Group Randomized Trial. *Statistics in Medicine,* 24:1983-1994, 2005.
3. Sherr KH, Micek MA, Gimbel SO, Gloyd SS, **Hughes JP**, John-Stewart GC, Manjate RM, Pfeiffer J, Weiss NS. Quality of HIV care provided by non-physician clinicians and physicians in Mozambique: a retrospective cohort study. AIDS 24, Suppl 1:S59-66, 2010 [PMC 3372417].
4. Richardson BA, John-Stewart GC, **Hughes JP**, Nduati R, Mbori-Ngacha D, Overbaugh J, Kreiss JK. Breastmilk Infectivity in HIV-1 Infected Mothers. *J. Infectious Diseases* 187:736-740, 2003.

B. Positions and Honors.

Employment

Teaching Assistant, Research Assistant, University of Washington, 1977-79
Engineering Technician, Department of Civil Engineering, University of Washington, 1979-80
Systems Analyst Programmer, Department of Health Services, University of Washington, 1980

Mathematical Statistician, Northwest and Alaska Fisheries Center, Seattle, Washington, 1980-81
Research Associate, Department of Biostatistics, University of Washington, 1981-84
Researcher, Department of Biostatistics, University of Washington, 1984-present
Research Assistant, University of Washington, 1992
Research Assistant Professor, Department of Biostatistics, University of Washington, 1993-1999
Associate Director, Biostatistical Core, Center for AIDS Research, University of Washington, 1994 -1997
Director, Biostatistical Core, STD Collaborative Research Center, University of Washington, 1997 - present
Visiting Scientist, CSIRO, Perth, Australia, 1996, 2000
Research Associate Professor, Department of Biostatistics, University of Washington, 1999-2002
Associate Professor, Department of Biostatistics, University of Washington, 2002 – 2005
Professor, Department of Biostatistics, University of Washington, 2005 - present
Member, Fred Hutchinson Cancer Research Center, Seattle, Washington, 2005 - present

Honors

Member, Xi Sigma Pi
IBM Fellowship Award for academic year 1990-91, 1991-92
Z.W. Birnbaum Award (Outstanding Graduate Student, Department of Statistics), 1990
First Place (written), Student Paper Competition, WNAR, Biometric Society, 1992
UW School of Public Health and Community Medicine Outstanding Teaching Award, 2007
American Association for Cancer Research Team Science Award (HPV Research), 2011
UW Department of Biostatistics Prentice Professor 2013-2014.

C. Contributions to Science

1. Statistical Methods for HIV/STI Research

Research to prevent and treat HIV infection and other STI's has grown increasingly sophisticated and the analytic challenges have become correspondingly complex. Biostatisticians play a unique role in this endeavor as they participate in study design and analysis across the entire spectrum of research, from laboratory studies to clinical trials to health service provision. My work on statistical methods for HIV and STI research has ranged from creating new methods for the analysis of clinical data, behavioral data and viral sequence data to the development of novel trial designs (see (2), below). As an example, the so-called "Bayesian method" for determining viral genetic linkage (e.g. Eshleman et al., 2011) is now a standard approach for the analysis of transmission in HIV discordant couples. Similarly, an editorial about my analysis of per-act transmission of HIV (Hughes et al., 2012) noted the "rigorous statistical methods to estimate per coital act transmission probabilities and to assess the effect of covariates". Overall, these analytic methods represent a significant contribution to the fields of HIV and STI research.

1. Hughes JP, Richardson BA: Analysis of a randomized trial to prevent vertical transmission of HIV-1. JASA 95:1032-1043, 2000.
2. Eshleman S, Hudelson S, Redd A,Wang L, Debes R, Chen Y,Martens C, Ricklefs S, Selig E,Porcella S, Piwowar-Manning E, McCauleyM, Hosseinipour M, Kumwenda J, Hakim J, Chariyalertsak S, de Bruyn G, Grinsztejn B, Kumarasamy N, Makhema J, Mayer K, Pilotto J, Santos B, Quinn T, Cohen MS, **Hughes JP**. Analysis of genetic linkage of HIV from couples enrolled in the HIV Prevention Trials Network 052 trial. *Journal of Infectious Diseases*, 204:1918-1926, 2011. [PMC 3209811]
3. **Hughes JP**, Baeten JM, Lingappa JR, Magaret AS, Wald A, de Bruyn G, Kiarie J, Inambao M, Kilembe W, Farquhar C, Celum C. Determinants of per coital act HIV-1 infectivity among HIV-1 serodiscordant couples. *Journal of Infectious Diseases, 205:358-365, 2012.*[PMC: 3256946]
4. **Hughes JP**, Haley DF, Frew PM, Golin CE, Adimora AA, Kuo I, Justman J, Soto-Torres L, Wang J, Hodder S. Changes in Risk Behavior following Study Enrollment in a Cohort of US Women at Risk for HIV. *Annals of Epidemiology* 25:439-44, 2015 [NIHMS 674285]

2. Statistical Methods for Cluster randomized and Stepped Wedge trials

The use of stepped wedge designs in cluster-randomized trials and implementation studies

has become increasingly common in recent years. In a stepped wedge design, instead of randomizing clusters to receive an intervention or not (typical parallel trial design), all the clusters receive the intervention but at a randomly chosen time. This design is particularly useful in implementation research and for evaluating real-world effects during the roll out of a proven intervention. My 2007 paper with student Mike Hussey (Hussey and Hughes, 2007), which laid out the basic methods for designing and analyzing stepped wedge trials, is one of the ten most highly cited papers ever published in Contemporary Clinical Trials. My work in this area is ongoing with a recent publication (Hughes et al., 2015) emphasizing the need to consider treatment effect heterogeneity and approaches to dealing with delayed treatment effects.

1. **Hughes JP**. Using Baseline Data to Design a Group Randomized Trial. *Statistics in Medicine,* 24:1983-1994, 2005.
2. **Hughes JP**, Kulich M. Cluster randomized trials for HIV prevention. *Current Opinions in HIV and AIDS* 1:471-475, 2006.
3. Hussey MA, **Hughes JP**. Design and Analysis of Stepped Wedge Cluster Randomized Trials. *Contemporary Clinical Trials, 28:182-191, 2007.*
4. **Hughes JP**, Granston TS, Heagerty PJ. Current Issues in the design and analysis of stepped wedge trials. *Contemporary Clinical Trials*, in press.[NIHMS 713711]

3. Statistical Collaboration in Clinical Studies of HIV and STI's

The validity and reliability of scientific research depends on careful and correct study design and statistical analysis. Over the course of my career I have collaborated with investigators in a number of scientific fields to provide design clinical studies and provide statistical analyses. My full CV lists over 200 collaborative publications with the greatest emphasis in studies of HIV and other STIs.

1. Celum C, Wald A, **Hughes JP**, Sanchez J, Reid S, Delany-Moretlwe S, Cowan F, Casapia M, Ortiz A, Fuchs J, Buchbinder S, Koblin B, Rose S, Wang J, Corey L, and the HPTN 039 Protocol Team. Twice Daily Acyclovir and HIV-1 Acquisition among HSV-2 Seropositive Women and Men who have sex with Men (MSM): Randomized, Double-blind, Placebo-controlled Trial. *Lancet* 371:2109-2119, 2008. [PMC:2650104]
2. Lingappa JR, Baeten JM, Wald A, **Hughes JP**, Thomas KK, Mujugira A, Mugo N, Bukusi EA, Cohen CR, Katabira E, Ronald A, Kiarie J, Farquhar C, John-Stewart G, Makhema J, Essex M, Were E, Fife K, de Bruyn G, Gray GE, McIntyre J, Manongi R, Kapiga S, Coetzee D, Allen S, Inambao M, Kayitenkore K, Karita E, Kanweka W, Delany S, Rees H, Vwalika B, Margaret MA, Wang R, Kidoguchi L, Barnes L, Ridzon R, Corey L, Celum C for the Partners in Prevention HSV/HIV Transmission Study Team. Daily Acyclovir to Delay HIV-1 Disease Progression Among HIV-1/HSV-2 Co-Infected Persons: A Randomized Trial. Lancet 375:824-833, 2010. [PMC2877592]
3. Hodder SL, Justman J, **Hughes JP**, Wang J, Haley DF, Adimora AA, Del Rio C, Golin CE, Kuo I, Rompalo A, Soto-Torres L, Mannheimer SB, Johnson-Lewis L, Eshleman SH, El-Sadr WM. HIV Acquisition Among Women from Selected Areas of the United States. Annals Inter. Medicine, 158:10-18, 2013. [PMC: 4033695]
4. Golden MR, Kerani RP, Stenger M, **Hughes JP**, Aubin M, Malinski C, Holmes KK. Uptake and Population-Level Impact of Expedited Partner Therapy (EPT) on Chlamydia trachomatis and Neisseria gonorrhoeae: The Washington State Community-level Randomized Trial of EPT. PLoS Medicine 12(1):e1001777, 2015. [PMC 4295847]

A complete list of my published works is available at **My Bibliography**: http://www.ncbi.nlm.nih.gov/sites/myncbi/james.hughes.1/bibliography/43560606/public/?sort=date&direction=ascending.

D. Research Support. List selected ongoing or completed (during the last three years) research projects (federal and non-federal support). Begin with the projects that are most relevant to the research proposed in this application.

Current

5 R01 AI029168 (J Hughes) 5/1/2010 4/30/2014
NIH/NIAID
"Statistical Issues in AIDS Research"

The general goals in this submission include work on methods enabling more effective design and analysis of AIDS clinical trials, on approaches relating to prevalence estimation and prediction, on improving the availability of computer software useful for analysis of clinical data arising in registries, and on approaches to providing confidentiality of AIDS research data.
Role: Principal Investigator

UM1 AI068617 (D Donnell/sub-J Hughes) 6/29/2006 5/31/2013

NIH/NIAID (subcontract from FHCRC)
"Leadership for HIV/AIDS Clinical Trials Networks: HIV Prevention Trials Network"

This application to be the Statistical and Data Management Center (SDMC) describes how the Statistical Center for HIV/AIDS Research & Prevention (SCHARP) will (1) provide leadership for the design, conduct, analysis and publication of Network clinical trials/studies; (2) provide central data management capability that includes randomization, data set and case report form design, central storage, security, processing and retrieval of study results; (3) provide data management and protocol training throughout the Network; (4) provide data-focused clinical trials implementation, and operation; and (5) contribute to cross-Network efforts in developing common data elements and data interfaces.
Role: Consortium PI

P01 AI113173 (J Marrazzo/sub J Hughes) 7/1/2014 6/30/2019 1.2 calendar
NIH $2,171,014
“Sexually Transmitted Infections Collaborative Research Center”

The Sexually Transmitted Infection (STI) Cooperative Research Center (CRC) at the University of Washington (UW) will investigate complex interactions between the human genital microbiome and syndromes and pathogens that contribute to STI-related morbidity. The center consists of 4 projects and 4 cores.The Biostatistics core provides statistical, data management and computational support to the projects.

R01 AI110666 (L Manhart) 4/1/2014 3/31/2019 1.2 calendar
NIH $638,532
"Male Urethritis: Novel Etiologies and Natural History"

This project will describe the natural history (prevalence, incidence, persistence, resolution, recurrence) of infection with each of 3 newly described bacteria among heterosexual men, assess the association of microbial communities in the male urethra with incidence, clinical cure, and recurrence of NGU, and assess the association of male urethral microbial communities with sexual exposures.

RECENT

R01 AI083034 (C Celum) 4/17/2009 3/31/2013
NIH/NIAID
“Multicomponent, Targeted HIV Prevention for Sub-Saharan Africa: PreventionRX”

Develop a coordinated, multi-component HIV prevention package of evidence-based biomedical and behavioral interventions that will be individually-tailored and targeted to maximize coverage and impact on HIV incidence in an African population.
Role: Biostatistician

RC4 AI092552 (C Celum) 9/30/2010 09/29/13
NIH/NIAID
“Interventions to Decrease HIV Infectiousness in Uganda”

Pilot a coordinated, multi-component HIV prevention package of evidence-based biomedical and behavioral interventions in Uganda..
Role: Biostatistician

2 P01 AI057005 (J Mullins) 8/1/2011 6/30/2015
NIH/NIAID
“Immunological and virological events in early HIV infection”

This program project is studying virologic and immunologic events in early HIV infection. The program includes three research projects (and four supporting shared resource cores). Project 1 is using virus isolated from linked HIV-1 transmission partner pairs in the Seattle Primary Infection Clinic (PIC) cohort to define the earliest events in the establishment of HIV-1 infection, focusing on the interactions between CTL responses and viral evolution and fitness. Project 2 is examining fitness costs of CTL escape mutations that occur early after HIV-1 infection in the PIC cohort. Project 3 is analyzing banked specimens from two large cohorts of prospectively followed sero-discordant African heterosexual couples in studies that parallel and complement those in Projects 1 and 2 Role: Biostatistician

OMB No. 0925-0001/0002 (Rev. 08/12 Approved Through 8/31/2015)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: Liu, Shan

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE: Assistant Professor

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Texas at Austin	B.S.	05/2006	Electrical Engineering
Massachusetts Institute of Technology	S.M.	06/2008	Technology and Policy
Stanford University	Ph.D.	06/2013	Management Science & Engineering

NOTE: The Biographical Sketch may not exceed five pages. Follow the formats and instructions below.

A. Personal Statement

My research focus on the evaluation of new medical technologies and healthcare interventions to improve patients' health and enable cost-effective care delivery. I have expertise in methods such as cost-effectiveness analysis, dynamic systems modeling, and optimization under uncertainty. My work have been focusing on developing decision theory and applied mathematical models for the detection, monitoring and treatment of chronic disease when there is rapid technological development. I have worked in interdisciplinary teams to develop methods and tools to support complex technology adoption and policy decisions surrounding the prevention and management of diseases. During the past 6 years, I have developed large-scale, decision-analytic models to assess the screening and treatment guidelines for chronic hepatitis C virus (HCV) infection in the U.S. This body of research answers questions about optimal HCV care management and resource allocation in the presence of uncertainties about cost, health outcomes, and technological progress. My current collaborative research include designing optimal personalized monitoring schedule for depression and population surveillance of chronic disease onset, and modeling the cost-effectiveness of lung cancer diagnostic testing strategies. I have on-going collaborations with the Stanford Center for Primary Care and Outcomes Research, the Veteran Affairs Palo Alto Health Care System, and the Group Health Research Institute in Seattle. I will provide mentorship for Anjuli Wagner in the learning and implementation of modeling methodology, execution of the study, collection and analysis of data, and publication of results.

1. **Liu S**, Brandeau M, Goldhaber-Fiebert JD. Optimizing patient treatment decisions in an era of rapid technological advances. *Healthcare Management Scienc*e. Published ahead online July, 2015. (PMID: 26188961)
2. **Liu S**, Watcha D, Holodniy H, Goldhaber-Fiebert JD. 2014. Sofosbuvir-based treatment regimens for chronic, genotype 1 hepatitis C infections in US incarcerated populations: a cost-effectiveness analysis. *Annals of Internal Medicine*. 161:546-553. (PMID: 25329202, PMCID: PMC4313741)
3. **Liu S**, Cipriano LE, Holodniy M, and Goldhaber-Fiebert JD. 2013. Cost-effectiveness analysis of risk-factor guided and birth-cohort screening for chronic hepatitis C infection in the United States. *PLoS One* 8(3): e58975. doi:10.1371/journal.pone.0058975. (PMID: 23533595, PMCID: PMC3606430)

4. **Liu S**, Cipriano LE, Holodniy M, Owens DK, and Goldhaber-Fiebert JD. 2012. New protease inhibitors for the treatment of chronic hepatitis C: A cost-effectiveness analysis. *Annals of Internal Medicine*. 156: 279-290. (PMID:22351713, PMCID: PMC3586733)

B. Positions and Honors

Positions and Employment

2006-2008	Research Fellow, MIT Microphotonics Center, Cambridge
2008	Research Fellow, United Nations Industrial Development Organization, Beijing
2009-2013	Research Assistant, Center for Primary Care and Outcomes Research, Stanford University
2011-Present	Medical Decision Model Analyst, Veteran Affairs Palo Alto Health Care System
2014-Present	Adjunct Assistant Professor, Radiology, University of Washington
2013-Present	Assistant Professor, Industrial & Systems Engineering, University of Washington

Professional Memberships

2011-Present	Member, Institute for Operation Research and the Management Sciences (INFORMS)
2011-Present	Member, Society for Medical Decision Making (SMDM)
2003-Present	Tau Beta Pi Engineering Honor Society

Honors

Stanford Graduate Fellowship (awarded to top 5% of doctoral students), 2008-2011
MIT Far East Graduate Fellowship, 2006
University of Texas Distinguished College Scholar, 2006
T.C. & Grace T. Ho Endowed Scholarship, 2005–2006

C. Contribution to Science

1. My past collaborative research was focused on the development of large-scale, decision-analytic models to assess screening and treatment guidelines for chronic HCV infection given the availability of new diagnostic and treatment technology. Chronic HCV was difficult to treat and affects approximately 3-4 million Americans with many costly drugs coming on the market. Before year 2013, no consensus existed on screening to detect the estimated 2 million Americans unaware of their infections. My work has led to high-impact publications examining the cost-effectiveness of postponing treatment while periodically monitoring fibrosis progression, and the potential use of new response-guided therapy to target HCV treatment to patients. In addition, I investigated the cost-effectiveness of population screening for chronic HCV, comparing risk-factor guided screening with birth-cohort based screening policies. This work helped to refine the Centers for Disease Control and Prevention (CDC)'s recent recommendations in favor of HCV screening of millions of Americans, and was cited in the USPSTF screening guideline. More importantly, the study showed that birth-cohort screening – which the CDC now recommends – may not be cost-effective if healthcare systems do not have sufficient capacity to ensure high levels of HCV treatment uptake and quality of care. I served as the lead author and/or the primary modeler for these studies.

a. **Liu S**, Cipriano LE, Holodniy M, and Goldhaber-Fiebert JD. 2013. Cost-effectiveness analysis of risk-factor guided and birth-cohort screening for chronic hepatitis C infection in the United States. *PLoS One* 8(3): e58975. doi:10.1371/journal.pone.0058975. (PMID: 23533595, PMCID: PMC3606430)
b. **Liu S**, Cipriano LE, Holodniy M, Owens DK, and Goldhaber-Fiebert JD. 2012. New protease inhibitors for the treatment of chronic hepatitis C: A cost-effectiveness analysis. *Annals of Internal Medicine*. 156: 279-290. (PMID:22351713, PMCID: PMC3586733)
c. **Liu S**, Schwarzinger M, Carrat F, and Goldhaber-Fiebert JD. 2011. Cost effectiveness of fibrosis assessment prior to treatment for chronic hepatitis C patients. *PLoS One* 6(12): e26783. doi:10.1371/journal.pone.0026783. (PMID: 22164204, PMCID: PMC3229483)

d. **Liu S**, Owens DK, Barnett PG, Holodniy M, Lo JJ, Joyce VR, Gidwani R, Asch SM, Goldhaber-Fiebert JD. Effectiveness and cost effectiveness of treatment for hepatitis C infection in non-VA and VA populations. Under review, 2015.

2. A related set of collaborative research was focused on enabling cost-effective delivery of HCV treatment in special-need populations. Prevalence of HCV is high among incarcerated persons and veterans. New, short-duration, high-efficacy therapies may expand treatment eligibility in these populations. Many U.S. healthcare systems are ramping up combined HCV screening and treatment efforts, but these programs are very costly. We are designing the optimal HCV screening and treatment allocation strategies in the near future under budget constraint. Our work has been incorporated into the decision making processes of large health organizations like the Veterans Affairs hospitals. We intend to explore the interaction and tradeoff between treatment programs under resource constraints in integrated healthcare systems with multiple objectives (e.g. equity, efficiency, and fairness), and find the optimal treatment allocation policy for heterogeneous populations within such systems. I served as the lead author, member of the modeling team, or advisor for these studies.

a. **Liu S**, Watcha D, Holodniy H, Goldhaber-Fiebert JD. 2014. Sofosbuvir-based treatment regimens for chronic, genotype 1 hepatitis C infections in US incarcerated populations: a cost-effectiveness analysis. *Annals of Internal Medicine*. 161:546-553. (PMID: 25329202, PMCID: PMC4313741)
b. Goldhaber-Fiebert JD, Barnett PG, Dally S, Asch SM, **Liu S**, Cipriano L, Owens DK, Miake-Lye IM, Beroes JM, Shekelle PG. Assessment of Alternative Treatment Strategies for Chronic Genotype 1 Hepatitis C. VA *Evidence-Based Synthesis Program* Project #05-226, 2013. <http://www.hsrd.research.va.gov/publications/esp/hcv.cfm#.UXOBOqK86So>
c. Cipriano LE, **Liu S**, Goldhaber-Fiebert JD. Budget impacts of hepatitis C treatment: designing fair patient access schemes under budget constraints. Working paper, 2015.
d. Li Y, master thesis in the department of Industrial & Systems Engineering, University of Washington. “Optimizing hepatitis C birth-cohort screening and treatment allocation strategy.” Aug 2015, advised by **Liu S**.

3. My work in methodology development addresses a limitation in standard cost-effectiveness analyses that, if not addressed, can lead to inefficient resource allocations. An overarching, unanswered question is how to best incorporate uncertainties about future technology change into standard medical decision making methodology. As an example, when physicians and patients are making a treatment decision, they can either use the best treatment currently available or wait, based on the belief that better technologies will emerge soon. This decision involves a difficult tradeoff between the deterioration of a patient’s health over time and the rate and magnitude of technological improvement. I have developed models to investigate the impact of timing and uncertainty about future technology innovation on patients’ treatment adoption decisions. Furthermore, the value of additional information about treatment or healthcare intervention may change over time due to the changing patients’ characteristics. The best timing of information collection is an important question in operations. I served as the lead author or a member of the modeling team.

a. **Liu S**, Brandeau M, Goldhaber-Fiebert JD. Optimizing patient treatment decisions in an era of rapid technological advances. *Healthcare Management Scienc*e. Published online July, 2015. (PMID: 26188961)
b. **Liu S**, Cipriano LE, and Goldhaber-Fiebert JD. Combining Statistical Analysis and Markov Models with Public Health Data to Infer Age-Specific Background Mortality Rates for Hepatitis C Infection in the U.S. (Extended Abstract). *Lecture Note in Computer Science Series*, Springer. International Conference on Smart Health, LNCS 8549 proceedings. 2014.
c. **Liu S**, book chapter 8, “Modeling Chronic Hepatitis C during Rapid Therapeutic Advance: Cost-Effective Screening, Monitoring and Treatment Strategies.” *Decision Analytics and Optimization in Disease Prevention and Treatment*. Editors: Shengfan Zhang and Nan Kong. Wiley Series in Operations Research and Management Science. Under review, 2015.
d. Cipriano LE, **Liu S**, Weber TA, Goldhaber-Fiebert JD. Optimal information collection policies in a Markov Decision Process Framework (abstract and working paper). *Value in Health* 17 (3), A190-A191.

4. My current collaborative research is focused on depression management. Depression is a common, complex, and dynamic mental disorder. Mitigating depression has become a national health priority as it affects 1 out of 10 American adults and is the most common mental illness seen in primary care. The emerging use of electronic

health record (EHR) provides an unprecedented information infrastructure to understand depression trajectories. We established a trajectory-based framework for depression diagnosis and prognosis that is adaptable to model population heterogeneity using EHR data. The project aims to design smart personalized monitoring algorithm for major depression onset on the patient level and cost-effective monitoring strategies on the population level. This research will have broad impact in disease trajectory modeling from electronic health record data, individual disease onset prediction, and population-level cost-effective screening and monitoring strategy design. I serve as the principal investigator.

a. Lin Y, Huang S, Simon GE, Liu S. Analysis of depression trajectory patterns using collaborative learning. Working paper, 2015
b. Lin Y, **Liu S**, Huang S. Abstract "Large-scale personalized health surveillance by selective sensing." INFORMS Healthcare Conference, Nashville, Tennessee. July 2015.
c. Lin Y, Huang S, **Liu S**. Abstract "Development and analysis of electronic health record based depression trajectory and monitoring." INFORMS Healthcare Conference, Nashville, Tennessee. July 2015.

5. Applied work in technology assessment for diverse disease conditions is also integral to my research agenda. These research focus on investigating the cost-effectiveness of new medical technologies and their impact on long-term health outcomes. I served as the primary modeler on the team.

a. Pietzsch JB, **Liu S**, Kezirian E, Strollo P. 2015. Long-term cost-effectiveness of upper airway stimulation for the treatment of obstructive sleep apnea: a model-based projection based on the STAR trial. *SLEEP* 2015;38(5):735–744. (PMID: 25348126, PMCID: PMC4402668)
b. Feeley BT, **Liu S**, Garner AM, Zhang AL, Pietzsch JB. The cost-effectiveness of meniscal repair versus partial meniscectomy: a model-based projection. Under review, 2015.

Complete List of Published Work in MyBibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/1r5M3YumnqqQj/bibliography/48499854/public/?sort=date&direction=ascending

D. Research Support

Ongoing Research Support

US Department of Veteran Affairs Palo Alto Health Care System Contract,
Liu (Intergovernmental Personnel Agreement), 06/01/14-05/01/16
Cost-effectiveness analysis of new therapies for the treatment of veterans with chronic hepatitis C
The goal of the study is to build a VA population-specific chronic hepatitis C computer simulation model to analyze the cost-effectiveness of new direct-acting antiviral therapies for the treatment of veterans with chronic hepatitis C.
Role: UW PI; VA IPA

University of Washington Royalty Research Fund, Liu (PI), 06/15/15-06/14/16
Development and Analysis of Electronic Health Record Based Depression Screening and Monitoring Strategies
The goal of the study is to establish a scientific foundation for enabling the development and analysis of depression screening and monitoring strategies that aim to improve the life expectancy and quality of life of American adults who may be living with depression.
Role: PI

NSF CMMI SES 1536407, PI: Wanpracha Chaovalitwongse, Liu (co-PI), 08/15/15-08/14/18
Collaborative Research: Decision Model for Patient-Specific Motion Management in Radiation Therapy Planning
The goal of the study is to develop a new medical decision support paradigm for extracting key characteristics of individual patients to help physicians optimize patient-specific clinical decisions and tailor the treatment plan to specific patients.
Role: co-PI

OMB No. 0925-0001/0002 (Rev. 08/12 Approved Through 8/31/2015)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.

Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: Cherutich, Peter Kipkoech

eRA COMMONS USER NAME (agency login): PCHERU

POSITION TITLE: Deputy Director of Medical Services, Ministry of Health, Kenya

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
University of Nairobi, Nairobi	MBChB	12/1999	Medicine & Surgery
University of Washington, Seattle	MPH	08/2006	Epidemiology & International Health
University of Washington, Seattle	PhD	08/2015	Implementation Science

A. Personal Statement

The goal of Ms. Anjuli Wagner's proposed postdoctoral project is to enhance efficiency and scale of health systems' ability to diagnose and link to care HIV-infected children. I am highly qualified to provide mentorship for this implementation science project as I pioneered the translation of key policies into practice in Kenya in my role as the Director of the National AIDS/STD Control Program (NASCOP). During my tenure at NASCOP I have gained significant experience in program coordination, proposal development, policy development, HIV surveillance and monitoring and evaluation. I was the inaugural chair of the Male Circumcision Taskforce where I provided guidance on the scientific evidence, community engagement and implementation models for this surgical procedure. Through the Taskforce, Kenya has scaled up male circumcision to more men than the rest of Africa combined. My research focus is on the efficiency of health care delivery systems and scaling up most efficacious HIV prevention interventions so as to maximize impact and achieve dramatic reductions in HIV incidence. I have also chaired various technical working groups on HIV Prevention, including Early Infant Diagnosis and Pediatric HIV, and I am the Ministry of Health lead in conceptualizing a new HIV paradigm that incorporates geospatial information. .I recently completed my PhD in Implementation Science in the Department of Global Health at the University of Washington. My research projects utilize implementation science tools to evaluate HIV prevention and care interventions in sub-Saharan Africa. I will provide mentorship to Ms. Wagner in her proposed F32 research regarding incorporating implementation science into national program roll-out. I will meet with Ms. Wagner once a month in-person or by Skype meetings.

1. **Cherutich P,** Inwani I, Nduati R, Mbori-Ngacha D. Optimizing paediatric HIV care in Kenya: challenges in early infant diagnosis. Bull World Health Organ. 2008 Feb;86(2):155-60. PubMed PMID: 18297171; PubMed Central PMCID: PMC2647375.
2. Wamuti BM, Erdman LK, **Cherutich P,** Golden M, Dunbar M, Bukusi D, Richardson B, Ng'ang'a A, Barnabas R, Mutiti PM, Macharia P, Jerop M, Otieno FA, Poole D, Farquhar C. Assisted partner notification services to augment HIV testing and linkage to care in Kenya: study protocol for a cluster randomized trial. Implement Sci. 2015 Feb 13;10:23. PubMed PMID: 25884936; PubMed Central PMCID: PMC4342094.
3. **Cherutich P,** Kaiser R, Galbraith J, Williamson J, Shiraishi RW, Ngare C, Mermin J, Marum E, Bunnell R. Lack of knowledge of HIV status a major barrier to HIV prevention, care and treatment efforts in Kenya: results from a nationally representative study. PLoS One. 2012;7(5):e36797. PubMed PMID: 22574226; PubMed Central PMCID: PMC3344943.
4. Anderson SJ, **Cherutich P,** Kilonzo N, Cremin I, Fecht D, Kimanga D, Harper M, Masha RL, Ngongo PB, Maina W, Dybul M, Hallett TB. Maximising the effect of combination HIV prevention through prioritisation of the people and places in greatest need: a modelling study. Lancet. 2014 Jul 19;384(9939):249-56. PubMed PMID: 25042235.

B. Positions and Honors

Positions and Employment

1999 - 2003 Medical Officer, Ministry of Health
2003 - 2008 Program Manager, HIV Testing, Ministry of Health
2006 - 2012 Program Manager, Male Circumcision, Ministry of Health
2008 - 2012 Deputy Director & Head, HIV Prevention, Ministry of Health
2012 - On Study Leave, Ministry of Health

Other Experience and Professional Memberships

2001 - Member, Kenya Medical Association
2013 - Founding Chairman, Public Health Society of Kenya

Honors

2014 Outstanding PhD Student Department of Global Health, University of Washington
2015 Gilbert S. Omenn PhD Student Award for Academic Excellence, University of Washington

C. Contribution to Science

1. **Scaling up Voluntary Medical Male Circumcision in Kenya:** Male circumcision substantially reduces the risk of HIV acquisition and is recommended by the WHO for HIV prevention. However, scaling up circumcision services is challenging and benefits from a scientific approach to achieving scale, efficiency, and fidelity. During my tenure at NASCOP, I was responsible for implementing voluntary medical male circumcision (VMMC) throughout Kenya. This national program was informed by several implementation science studies, which helped direct decisions regarding clinic flow, staffing requirements, cost-effective outreach strategies, circumcision devices, and populations requiring targeting. VMMC roll-out in Kenya has been an example for other sub-Saharan African countries and is a prime example of incorporating implementation science into program implementation.

    a. Centers for Disease Control and Prevention. Progress in voluntary medical male circumcision service provision Kenya, 2008–2011. *MMWR* 2012; 61:957-61. Reported by **Peter Cherutich**, Athanasius Ochieng, Davies Kimanga, Zebedee Mwandi, Samuel Mwalili, Kipruto Chesang, Nancy Knight.
    b. Mwandi Z, Murphy A, Reed J, Chesang K, Njeuhmeli E, Agot K, Llewellyn E, Kirui C, Serrem K, Abuya I, Loolpapit M, Mbayaki R, Kiriro N, **Cherutich P**, Muraguri N, Motoku J, Kioko J, Knight N, Bock N. Voluntary medical male circumcision: translating research into the rapid expansion of services in Kenya, 2008-2011. PLoS Med. 2011 Nov;8(11):e1001130. doi: 10.1371/journal.pmed.1001130. Epub 2011 Nov 29. Review. PubMed PMID: 22140365; PubMed Central PMCID: PMC3226459.
    c. Curran K, Njeuhmeli E, Mirelman A, Dickson K, Adamu T, **Cherutich P**, Mahler H, Fimbo B, Mavuso TK, Albertini J, Fitzgerald L, Bock N, Reed J, Castor D, Stanton D. Voluntary medical male circumcision: strategies for meeting the human resource needs of scale-up in southern and eastern Africa. PLoS Med. 2011 Nov;8(11):e1001129. doi: 10.1371/journal.pmed.1001129. Epub 2011 Nov 29. Review. PubMed PMID: 22140364; PubMed Central PMCID: PMC3226463.
    d. Jennings L, Bertrand J, Rech D, Harvey SA, Hatzold K, Samkange CA, Omondi Aduda DS, Fimbo B, **Cherutich P**, Perry L, Castor D, Njeuhmeli E. Quality of voluntary medical male circumcision services during scale-up: a comparative process evaluation in Kenya, South Africa, Tanzania and Zimbabwe. PLoS One. 2014 May 6;9(5):e79524. doi: 10.1371/journal.pone.0079524. eCollection 2014. PubMed PMID: 24801073; PubMed Central PMCID: PMC4011679.

2. **HIV testing and counseling:** HIV testing is the first step to engagement in care, appropriate HIV management, and eventual prevention of transmission. However, more than half of HIV-infected individuals in Kenya do not know their HIV status. Our group has worked to innovate new solutions for efficient case detection through assisted partner services and has considered the implications of universal HIV testing. Our assisted partner services study (trial results manuscript under review) showed efficient case detection rates and high acceptability among newly diagnosed HIV-infected adults, and was affordable in the context of the Kenyan Ministry of Health budget. The study aims were built with the Kenyan government in mind as

an audience, with an eye towards translating findings into practice. Assisted Partner Services is another example of how implementation science can be utilized to inform government policy.

a. **Cherutich P**, Bunnell R, Mermin J. HIV testing: current practice and future directions. Curr HIV/AIDS Rep. 2013 Jun;10(2):134-41. doi: 10.1007/s11904-013-0158-8. PubMed PMID: 23526423.
b. Bunnell R, **Cherutich P**. Universal HIV testing and counselling in Africa. Lancet. 2008 Jun 28;371(9631):2148-50. doi: 10.1016/S0140-6736(08)60929-0. PubMed PMID: 18586156.
c. Wamuti BM, Erdman LK, **Cherutich P**, Golden M, Dunbar M, Bukusi D, Richardson B, Ng'ang'a A, Barnabas R, Mutiti PM, Macharia P, Jerop M, Otieno FA, Poole D, Farquhar C. Assisted partner notification services to augment HIV testing and linkage to care in Kenya: study protocol for a cluster randomized trial. Implement Sci. 2015 Feb 13;10:23. doi: 10.1186/s13012-015-0212-6. PubMed PMID: 25884936; PubMed Central PMCID: PMC4342094.
d. **Cherutich P**, Kaiser R, Galbraith J, Williamson J, Shiraishi RW, Ngare C, Mermin J, Marum E, Bunnell R; KAIS Study Group. Lack of knowledge of HIV status a major barrier to HIV prevention, care and treatment efforts in Kenya: results from a nationally representative study. PLoS One. 2012;7(5):e36797. doi: 10.1371/journal.pone.0036797. Epub 2012 May 4. PubMed PMID: 22574226; PubMed Central PMCID: PMC3344943.

3. **Combination prevention**: Combination HIV prevention is an essential component of curbing HIV incidence globally. We have studied the effect of community-level access to ART as an HIV prevention strategy, noting decreased incidence among female sex workers when access to treatment for HIV-infected individuals is scaled up. We have also investigated whether combination prevention strategies should be distributed uniformly or focused on certain geographic and demographic areas to match local epidemiology; our modeling studies revealed that focused roll out has larger gains in infections averted than uniform distribution approaches, in a setting of fixed resources. Finally, we have focused on the critical role of prevention with positives (PwP) in reducing HIV to low levels globally.
    a. Anderson SJ, **Cherutich P**, Kilonzo N, Cremin I, Fecht D, Kimanga D, Harper M, Masha RL, Ngongo PB, Maina W, Dybul M, Hallett TB. Maximising the effect of combination HIV prevention through prioritisation of the people and places in greatest need: a modelling study. Lancet. 2014 Jul 19;384(9939):249-56. doi: 10.1016/S0140-6736(14)61053-9. PubMed PMID: 25042235.
    b. Mcclelland RS, Richardson BA, **Cherutich P**, Mandaliya K, John-Stewart G, Miregwa B, Odem-Davis K, Jaoko W, Kimanga D, Overbaugh J. Impact of community antiretroviral therapy coverage on HIV incidence in Kenyan female sex workers: a 15-year prospective cohort study. AIDS. 2015 Jul 31. [Epub ahead of print] PubMed PMID: 26237099.
    c. Kidder DP, Bachanas P, Medley A, Pals S, Nuwagaba-Biribonwoha H, Ackers M, Howard A, Deluca N, Mbatia R, Sheriff M, Arthur G, Katuta F, **Cherutich P**, Somi G; PwP Evaluation Study team. HIV prevention in care and treatment settings: baseline risk behaviors among HIV patients in Kenya, Namibia, and Tanzania. PLoS One. 2013;8(2):e57215. doi: 10.1371/journal.pone.0057215. Epub 2013 Feb 25. PubMed PMID: 23459196; PubMed Central PMCID: PMC3581447.
    d. Jones A, Cremin I, Abdullah F, Idoko J, **Cherutich P**, Kilonzo N, Rees H, Hallett T, O'Reilly K, Koechlin F, Schwartlander B, de Zalduondo B, Kim S, Jay J, Huh J, Piot P, Dybul M. Transformation of HIV from pandemic to low-endemic levels: a public health approach to combination prevention. Lancet. 2014 Jul 19;384(9939):272-9. doi: 10.1016/S0140-6736(13)62230-8. Epub 2014 Apr 14. PubMed PMID: 24740087.

4. **Understanding and mitigating risk of HIV infection among vulnerable populations**: Marginalized and vulnerable populations require tailored prevention and treatment services. We have investigated prevalence of high-risk populations – MSM, commercial sex workers, injection drug users – in Kenya as well as prevalence, incidence, and risk factors for HIV. We have also focused on adolescent girls, who represent a group with high HIV incidence globally and the only demographic population among whom HIV-related mortality is increasing. Understanding these vulnerable and marginalized populations will be essential to inform effective and appropriate combination prevention and treatment programs.
    a. Githuka G, Hladik W, Mwalili S, **Cherutich P**, Muthui M, Gitonga J, Maina WK, Kim AA; KAIS Study Group. Populations at increased risk for HIV infection in Kenya: results from a national population-based household survey, 2012. J Acquir Immune Defic Syndr. 2014 May 1;66 Suppl 1:S46-56. doi: 10.1097/QAI.0000000000000137. PubMed PMID: 24732821.

b. **Cherutich P**, Brentlinger P, Nduati R, Kiarie JN, Farquhar C. Condom use among sexually active Kenyan female adolescents at risk for HIV-1 infection. AIDS Behav. 2008 Nov;12(6):923-9. doi: 10.1007/s10461-008-9445-6. Epub 2008 Aug 8. PubMed PMID: 18688705.
c. Kurth AE, Cleland CM, Des Jarlais DC, Musyoki H, Lizcano JA, Chhun N, **Cherutich P**. "HIV prevalence, estimated incidence, and risk behaviors among people who inject drugs in Kenya". J Acquir Immune Defic Syndr. 2015 Jul 28. [Epub ahead of print] PubMed PMID: 26226249.
d. Rositch AF, **Cherutich P**, Brentlinger P, Kiarie JN, Nduati R, Farquhar C. HIV infection and sexual partnerships and behaviour among adolescent girls in Nairobi, Kenya. Int J STD AIDS. 2012 Jul;23(7):468-74. doi: 10.1258/ijsa.2012.011361. PubMed PMID: 22843999; PubMed Central PMCID: PMC3571685.

D. Research Support

Ongoing Research Support

2011/07/15-2016/04/30
R01 DA032080-05, National Institute on Drug Abuse (NIDA)
KURTH, ANN Elizabeth (PI)
Test and Linkage to Care (TLC_IDU) Kenya
Role: PI

R01 A1099974 (PI: Carey Farquhar, Co-PI: Peter Cherutich) 06/20/12 – 05/31/2015
NIH/PEPFAR

Assisted Partner Notification to Augment HIV Treatment and Prevention in Kenya.
In the proposed study, we will notify and offer HIV testing to partners of newly diagnosed HIV-positive individuals, measure the number of people tested and linked to HIV care through this program, and determine its cost-effectiveness.
Role:Co-PI
1 R01 (PI: Ann Kurth, Co-PI: Irene Inwani)

Gender-Specific Combination HIV Prevention for Youth in High Burden Settings (**MP3 Youth**)
The goal of this NIH funded pilot study is to assess the feasibility and acceptability of a combination HIV prevention package specific to male and female youth in Kenya
Role: Co-investigator

PHS Fellowship Supplemental Form

OMB Number: 0925-0002

A. Application Type:

From SF424 (R&R) Cover Page. The response provided on that page, regarding the type of application being submitted, is repeated here for your reference, as you attach the sections that are appropriate for this Career Development Award.

● New ❍ Resubmission ❍ Renewal ❍ Continuation ❍ Revision

B. Research Training Plan

1. Introduction to Application (for RESUBMISSION applications only)	
2. Specific Aims*	1248-FINAL_Specific_Aims.pdf
3. Research Strategy*	1249-FINAL_Research_Strategy.pdf
4. Progress Report Publication List (for RENEWAL applications only)	

Human Subjects

Please note. The following item is taken from the Research & Related Other Project Information form. The response provided on that page, regarding the involvement of human subjects, is repeated here for your reference as you provide related responses for this Fellowship application. If you wish to change the answer to the item shown below, please do so on the Research & Related Other Project Information form; you will not be able to edit the response here.

Are Human Subjects Involved? ● Yes ❍ No

5. Human Subjects Involvement Indefinite?	❍ Yes ● No
6. Clinical Trial?	❍ Yes ● No
7. Agency-Defined Phase III Clinical Trial?	
8. Protection of Human Subjects	1250-FINAL_Human_Subjects.pdf
9. Inclusion of Women and Minorities	1251-FINAL_Inclusion_Women_Minorities.pdf
10. Inclusion of Children	1252-FINAL_Inclusion_Children.pdf

Other Research Training Plan Sections

Please note. The following item is taken from the Research & Related Other Project Information form. The response provided on that page, regarding the use of vertebrate animals, is repeated here for your reference as you provide related responses for this Fellowship application. If you wish to change the answer to the item shown below, please do so on the Research & Related Other Project Information form; you will not be able to edit the response here.

Are Vertebrate Animals Used? ❍ Yes ● No

11. Vertebrate Animals Use Indefinite?	
12. Vertebrate Animals	
13. Select Agent Research	
14. Resource Sharing Plan	1253-FINAL_Resource_Sharing_Plan.pdf
17. Respective Contributions*	1254-FINAL_Respective_Contributions.pdf
16. Selection of Sponsor and Institution*	1255-FINAL_Selection_Sponsor_Institution.pdf
17. Responsible Conduct of Research*	1256-FINAL_Responsible_Conduct_Research.pdf

PHS Fellowship Supplemental Form

OMB Number: 0925-0002

C. Additional Information

Human Embryonic Stem Cells

1. Does the proposed project involve human embryonic stem cells?* ❍ Yes ● No

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s), using the registry information provided within the agency instructions. Or, if a specific stem cell line cannot be referenced at this time, please check the box indicating that one from the registry will be used:

☐ Specific stem cell line cannot be referenced at this time. One from the registry will be used.

Cell Line(s):

Fellowship Applicant

2. Alternate Phone Number: 206-221-7635

3. Degree Sought During Proposed Award:

Degree:	If "other", please indicate degree type:	Expected Completion Date (month/year):
PHD: Doctor of Philosophy		2015-12

4. Field of Training for Current Proposal*: 3960 Health Services Research

5. Current Or Prior Kirschstein-NRSA Support?* ● Yes ❍ No

If yes, please identify current and prior Kirschstein-NRSA support below:

Level*	Type*	Start Date (if known)	End Date (if known)	Grant Number (if known)
Predoctoral	Individual	12/16/2012	12/15/2015	F31MH099988

6. Applications for Concurrent Support?* ❍ Yes ● No

If yes, please describe in an attached file:

7. Goals for Fellowship Training and Career* 1257-FINAL_Goals_Fellowship_Training_Career.pdf

8. Activities Planned Under This Award* 1258-FINAL_Activites_Planned_Under_Award.pdf

9. Doctoral Dissertation and Other Research Experience 1259-FINAL_Research_Experience.pdf

10. Citizenship*
- ☑ U.S. Citizen or noncitizen national
- ☐ Permanent Resident of U.S.
  (If a permanent resident of the U.S., a notarized statement must be provided by the time of award)
- ☐ Permanent Resident of U.S. Pending
- ☐ Non-U.S. Citizen with temporary U.S. visa

Institution

11. ☐ Change of Sponsoring Institution

Name of Former Institution:*

Funding Opportunity Number: PA-14-149. Received Date: 2015-09-02T11:24:31.000-04:00

PHS Fellowship Supplemental Form

OMB Number: 0925-0002

D. Sponsor(s) and Co-Sponsor(s)

Sponsor(s) and Co-Sponsor(s) Information*	1260-FINAL_Sponsor_Cosponsor_Information.pdf

E. Budget

All Fellowship Applicants:

1. Tuition and Fees*:

❍ None Requested ● Funds Requested

Year 1	$10,284.00
Year 2	$10,798.00
Year 3	$11,338.00
Year 4	
Year 5	
Year 6 (when applicable)	
Total Funds Requested:	$32,420.00

Senior Fellowship Applicants Only:

2. Present Institutional Base Salary:

Amount	Academic Period	Number of Months
$22,920.00	12-month	12.00

3. Stipends/Salary During First Year of Proposed Fellowship:

a. Federal Stipend Requested:

Amount	Number of Months
$42,840.00	12.00

b. Supplementation from other sources:

Amount	Number of Months

Type (sabbatical leave, salary, etc.)

Source

F. Appendix

Funding Opportunity Number: PA-14-149. Received Date: 2015-09-02T11:24:31.000-04:00

RATIONALE

UNAIDS has set ambitious 90-90-90 targets for HIV: 90% of HIV-infected people know their status, 90% linked to care, and 90% virally suppressed. Children experience severe deficits in HIV testing and treatment; in Kenya, nearly 60% of HIV-infected children are undiagnosed and just 31% are on treatment. In the absence of antiretroviral treatment (ART), children with HIV experience high mortality—50% die before their second birthday. However, the benefits of ART are limited when treatment is deferred until children are symptomatic with HIV. ***It is critical to scale up strategies for pediatric HIV testing prior to symptomatic illness.***

Children born before the scale up of PMTCT programs, and children who continue to slip through the cracks in the PMTCT cascade remain untested and at risk for severe illness and death. There is an absence of scaled systems to routinely test these children prior to symptomatic illness. Targeted HIV testing for children of HIV-infected adults in care is an efficient, evidence-based strategy for case detection, identifying a high prevalence of pediatric HIV. Yet, programmatic scale-up of this targeted strategy remains low. ***There is an absence of tested interventions to improve the scale and performance of pediatric HIV testing strategies.***

The pediatric HIV testing and care cascade is similar to the PMTCT cascade; systems interventions that have been effective in reducing PMTCT drop off may be applicable. ***Translating and testing the application of these previously developed interventions to new cascades is an efficient approach to innovation.*** Industrial and systems engineering have developed robust methods for systems optimization; cascade flow analysis, process mapping, and continuous quality improvement provide flexible tools for locally-informed changes for systems optimization.

The *Systems Analysis and Improvement Approach (SAIA)* trial (R01, PI: Sherr) tested a 5-step approach to reduce PMTCT cascade drop off, which was effective in increasing ARV uptake in pregnancy in Kenya. The *Counseling and Testing for Children at Home (CATCH)* study (R21, PI: John-Stewart) tested targeted pediatric HIV testing for the children of HIV-infected adults in care and found it to be efficient for case detection, but with low uptake. Applying the SAIA approach for systems optimization to the CATCH model provides an opportunity to increase the scale and reach of targeted pediatric testing. ***If found to be effective, the SAIA approach represents a flexible, and locally-adaptable intervention to address systems-level barriers to optimize pediatric HIV testing and care, reducing pediatric morbidity and mortality and promoting long-term growth and development.***

SPECIFIC AIMS

Aim 1: To determine facility-level factors associated with high and low pediatric testing rates at facilities throughout Kenya, we will compare commodity procurement, facility volume and location, human resources, information systems, and management between facilities with high rates and those with low rates of pediatric HIV testing.

Aim 2: To test whether the SAIA 5-step systems analysis and improvement approach increases a) the rate of pediatric HIV testing and b) linkage to care. We will adapt the SAIA cascade analysis tool, process mapping, and iterative quality improvement tools and approach to be specific to pediatric HIV testing in a model where children of HIV-infected adults in care are targeted for testing. We will extend the SAIA intervention to pediatric HIV testing in 6 intervention clinics in Kenya and compare to the 6 control clinics.

Secondary aim: To determine whether the impact of the SAIA intervention is sustained after the mentored study period.

SIGNIFICANCE

A1. Pediatric HIV testing and treatment remain far from 90-90-90 targets. Recently, UNAIDS has called for 90-90-90 targets – to identify 90% of infected individuals, treat 90%, and achieve viral suppression for 90% [1]. The first step for children to attain these goals is diagnosis. Globally, 3.2 million children have HIV—the majority of whom live in sub-Saharan Africa—and just 24% have access to treatment [2]. The 2012 Kenya AIDS Indicator Survey (KAIS) revealed that 59% of HIV-infected children in Kenya are undiagnosed [3]. In order to reach the ambitious 90-90-90 targets, focus needs to be placed on strategically scaling up strategies known to increase uptake of testing and treatment.

A2. Prompt testing and treatment of HIV-infected children dramatically reduce mortality and improve child growth and development. In the absence of ART, approximately half of children with untreated HIV infection will die before 2 years of age [4]. Early diagnosis and ART prior to symptomatic disease dramatically improve survival and slow disease progression by three quarters, and improve additional long-term developmental outcomes such as growth and cognition [5, 6]. However, the benefits of ART are limited when children are identified and initiated when already symptomatic [7, 8].

A3. Program gaps leave many children undiagnosed. PMTCT programs have scaled up over the last decade, reducing the rate of new infant infections. However, many HIV-exposed infants remained unidentified and at high risk for infection due to drop off in the PMTCT cascade and high incidence of undiagnosed and untreated maternal HIV during pregnancy/postpartum [9]. While repeat maternal testing during pregnancy and postpartum is recommended in national guidelines, it is poorly implemented; women with acute HIV infection are 3-4 times as likely to transmit to their infants, compared to chronically infected women [9]. Modeling studies suggest that acute maternal HIV infection accounts for a high and growing proportion of new infant infections [10]. Gaps in early infant diagnosis (EID) programs, including identifying HIV exposure, specimen collection and processing, and return of test results contribute to missed diagnoses [8, 11, 12] (Figure 1). Finally, a large group of older children who acquired HIV prior to the expansion of PMTCT coverage is undiagnosed.

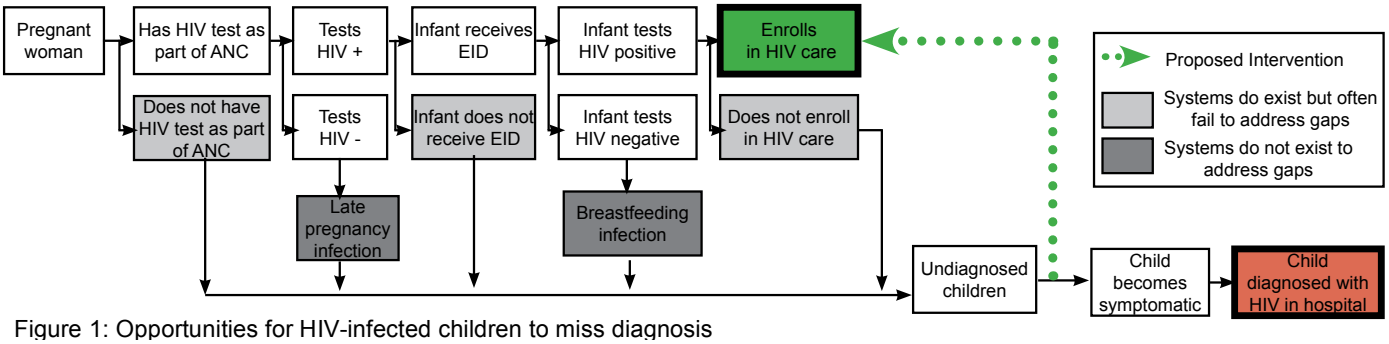


Figure 1: Opportunities for HIV-infected children to miss diagnosis

A4. There are few systems to routinely test older children for HIV prior to symptomatic illness. There are currently few programs systematically testing older children for HIV. PMTCT programs are not designed to identify older children. While universal provider-initiated testing and counseling (PITC) theoretically provides testing to older children, implementation is not universal, and preferentially tests the sickest children, compromising the benefits of ART. Additionally, strategies that universally test all children—rather than those with confirmed or suspected exposure—are comparatively inefficient as the prevalence of HIV among the general pediatric population in Kenya is just under 1%; ***strategies are needed to increase the efficiency of testing to optimize the limited resources available for pediatric case detection.***

A5. Testing the children of HIV-infected adults in care is efficient but not widely implemented. Targeted HIV testing for the children of HIV-infected parents in care may be a more efficient strategy for case detection than universal testing; prevalence is high among these children and over half of children with HIV-infected parents in Kenya have never been tested for HIV [3]. A third of children of parents at an ART clinic in Malawi were HIV-infected (Figure 2). A study in Western Kenya offered HIV testing to the children of HIV-infected adults in care and identified 18%

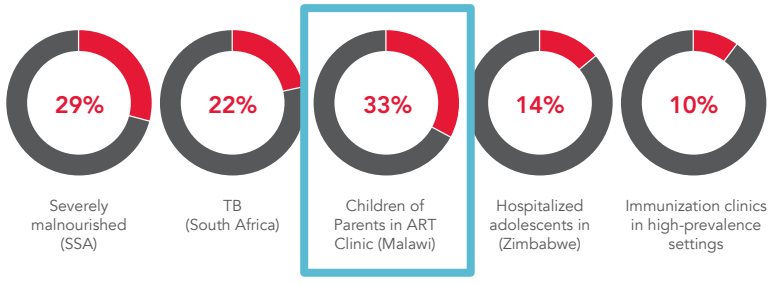


Figure 2: Efficiency of various case detection locations *(UNAIDS)*

prevalence among tested children [13]; a separate study offered home-based, door-to-door testing to children whose mother was known to be infected, of unknown HIV status, or deceased and found a 5% prevalence among tested children [14].

A6. Pediatric testing cascade is comparable to PMTCT cascade and may benefit from systems optimization intervention. While the underlying prevalence of HIV among children of adults in HIV care is high, there are multiple steps in the testing and care cascade, leaving multiple opportunities for drop off (Figure 3). Previous research has focused on downstream individual-level barriers to returning for testing [15-17], but this approach fails to address upstream systems barriers to testing children, which may have larger drop offs. Health care workers and administrators are often unaware of suboptimal performance of pediatric testing services due to absence of routine data collection documenting underlying burden and unmet need (*Wagner, manuscript in preparation*). Visualizing pediatric HIV testing and care as a cascade provides opportunity to optimize system performance at each step. Focusing on the treatment cascade in adults has highlighted the benefits of home-based testing, point-of-care CD4 counts, community mobilization, task-shifting, and decentralized care [18-20]. Simple system optimization interventions—such as implementing logs to routinely assess whether parents have any children of unknown status—have resulted in 4-fold increases in pediatric testing rates (*Wagner, manuscript in preparation*). ***Testing whether proven approaches for PMTCT system optimization are effective in reducing pediatric testing and care cascade drop off is an efficient approach to innovation.***

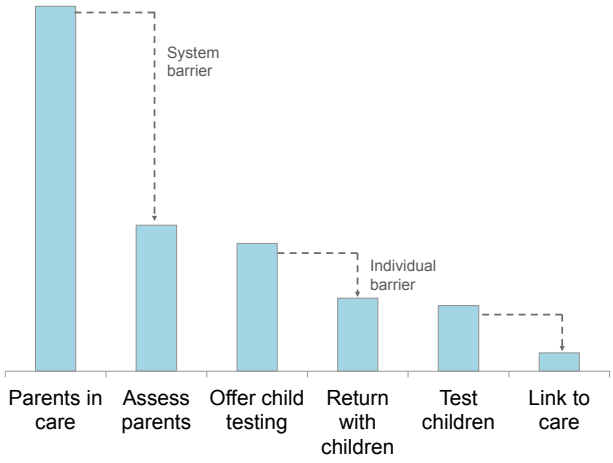


Figure 3: Potential drop off points in pediatric HIV care

A7. Industrial and systems engineering methods provide effective, low cost, simple, iterative intervention that adapts to changing local context. The *Systems Analysis and Improvement Approach to Optimize PMTCT (SAIA) study* utilized a 5-step operations research approach based on industrial and systems engineering tools to improve completion of PMTCT [21]. The SAIA approach is flexible to address the specific systems issues at each facility, iteratively tests ideas for improvement generated by frontline health care workers, and is comparatively low cost, requiring only occasional visits by CQI facilitator staff. In Kenya, SAIA resulted in a significant and substantial increase in the proportion of HIV-infected pregnant women initiating antiretroviral medications (*Sherr and Rustagi, manuscript in preparation*). Given SAIA's success in optimizing PMTCT in Kenya, ***this approach merits extension and testing in another type of HIV services.***

A8. Pediatric HIV testing in Kenya currently has time-bound resources, political will, and evidence-based guidance for case detection, but no proven interventions for achieving scale & optimizing delivery of services. PEPFAR and the Global Fund have committed time-bound funds to pediatric case detection through the Accelerating Children's HIV/AIDS Treatment Initiative (ACT) [22]. The National AIDS and STI Control Programme (NASCOP) within the Ministry of Health in Kenya is currently conducting a rapid results initiative (RRI) focused on pediatric and adolescent HIV case detection. There are several evidence-based practices for efficient pediatric case detection being considered for adoption by NASCOP [13, 23](*personal communication*). However, there are no tested interventions for bringing these interventions to scale and optimizing their performance. ***Effective, flexible, and locally adaptable strategies are urgently needed to address systems-level barriers to optimize pediatric HIV testing and care.***

APPROACH:

B1. Innovative partnerships:

a. The Kenyan Ministry of Health is enthusiastic about the need for and importance of this study. Our team has a long-standing collaborative relationship with the University of Nairobi, Kenyatta National Hospital and the Kenya National AIDS/STI Control Programme (NASCOP), a branch of the Ministry of Health, which directs Kenya's HIV policy and programs. In June 2015, we discussed this proposal with NASCOP leadership and gathered input regarding study design and approach to ensure that our proposal was consistent with the Ministry of Health's objectives regarding pediatric HIV. NASCOP was enthusiastic about the potential for the

project to inform national policy and has agreed to provide support and expertise for the proposed study, including access to nationally representative facility-level data for Aim 1.

b. Using program data represents new a data sharing relationship, is efficient, and allows for powerful analyses with minimal cost. NASCOP and University of Washington are beginning to directly share findings from pediatric HIV research (UW) and facility-level data (NASCOP) with one another. The first aim of this study provides an opportunity to strengthen this important collaborative bi-directional data sharing relationship. In the future, this relationship will allow UW researchers to address questions that are directly relevant to policymakers and will allow policymakers quick access to the relevant data to inform decision-making. Program data is routinely collected, suitable for health systems research, more representative than smaller project datasets, and low cost [24]. Utilizing program data to answer questions related to scaling and optimizing health interventions is a highly cost-effective method for achieving high coverage of important interventions.

c. Novel partnership between pediatric HIV experts and implementation science experts. **Dr. Kenneth Sherr** is the Director of Implementation Science for *Health Alliance International*, a faculty member at the UW in Global Health, Industrial and Systems Engineering, and Epidemiology, and co-Director of the UW Implementation Science PhD program. Dr. Sherr is PI of the 3-country SAIA trial, as well as numerous other implementation science projects related to PMTCT and has a strong implementation science record [25-28]. **Dr. Grace John-Stewart** is Director of the *UW Global Center for Integrated Health of Women, Adolescents and Children (Global WACh)*, core leadership in the *Kenya Research & Training Center (KRTC)*, and faculty in the UW Departments of Global Health, Pediatrics, Medicine, and Epidemiology. She is the PI of several pediatric HIV testing and treatment studies in Kenya and has a strong record of PMTCT and pediatric HIV research [8, 9, 29-33]. This proposed project is the second collaboration between the two research groups and will allow each group to expand its methodologic and content area expertise.

B2. Preliminary studies:

a. Pediatric HIV treatment studies (John-Stewart, Wagner). The Kenya Research and Training Center (KRTC) has >150 publications focused on HIV in women and children, including several pediatric HIV studies. KRTC has investigated early treatment of infants (OPH study) and treatment of older children (PAD study) presenting for care [4, 7, 33-42]. Ms. Wagner's MPH thesis noted that mortality was especially high among children identified in hospital, compared to PMTCT programs [8]. Recently, to address the high mortality noted in OPH, we compared urgent vs. early treatment among children diagnosed with HIV during hospitalization (PUSH study); however, even urgent ART initiated within 48 hours of diagnosis did not show a mortality benefit (*Njuguna, manuscript in preparation*). These studies motivated our team to conduct the CATCH study to promote early detection of HIV *before symptomatic illness*.

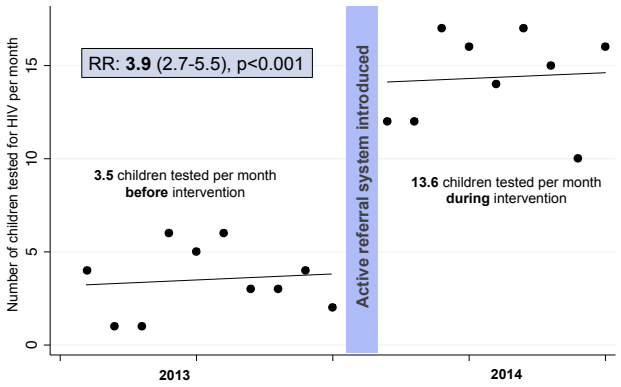


Figure 4: Routine offer of testing substantially increased uptake

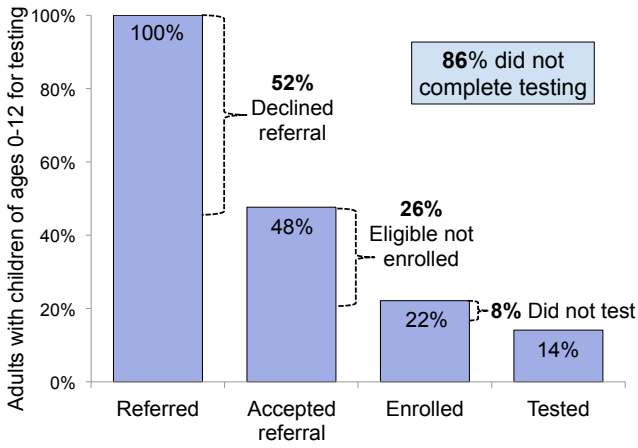


Figure 5: Uptake of testing was sub-optimal

b. Pediatric HIV testing studies (John-Stewart, Wagner, Sherr). The CATCH study routinely asked HIV-infected adults in care whether they had children of unknown status, and offered the choice of home- or clinic-based HIV testing. The study found that nearly *a third of parents in care had children of unknown HIV status* and that the simple, *routine offer of testing services quadrupled the number of children being tested* each month (RR: 3.9, p<0.001) (Figure 4) and that between *8 and 15% of tested children were HIV-infected* (*Wagner, manuscript in preparation*). However, uptake of testing was suboptimal and 86% of parents did not test their children during the study (Figure 5). Health systems interventions to decrease the drop off in the pediatric HIV testing and care cascade include documentation to the parent's HIV care file to note presence of HIV-exposed, untested children; development of tracking systems similar to those employed in

tracing HIV-exposed infants; and routine compiling and review of pediatric HIV testing indicators at the facility level. **The proposed study aims to optimize the CATCH testing model through the application of the SAIA approach.**

c. Systems Analysis and Improvement Approach to Optimize PMTCT (SAIA) trial (Sherr). The SAIA trial was a cluster-randomized trial conducted in 36 facilities across 3 countries in sub-Saharan Africa—Kenya, Mozambique, and Côte d'Ivoire [21]. SAIA involves a 5-step systems engineering approach: 1) PMTCT cascade analysis tool (development and testing described in [43], Figure 7), 2) process flow mapping, 3) identify & implement modification, 4) evaluate effect on cascade, and 5) iteratively repeat change process—(steps 3-5 are continuous quality improvement [CQI]) (Figure 6). SAIA resulted in a substantial increase in the proportion of HIV-infected pregnant women initiating antiretroviral medications and children completing early infant diagnosis (EID), differences which were statistically significant in Kenya (maternal ARVs) and Mozambique (EID) (*Sherr and Rustagi, manuscript in preparation, presented to NIH PEPFAR PMTCT Implementation Science Alliance meeting in May 2015*), but was not associated with changes in the proportion of women testing for HIV (already >90% at baseline). In closeout meetings with field staff, ideas for improvement of the SAIA intervention included: 1) repeating step 2 of process mapping several times throughout the course of the intervention, 2) engaging health care workers in the process of building a conceptual model and choosing change concepts that are directly related to the outcome indicator of interest, and 3) focusing on optimizing indicators where performance is low (e.g. excluding indicators like HIV testing during antenatal care where uptake is already >90%). **The proposed extension to pediatric HIV testing will modify the SAIA approach using lessons learned from the main trial.**

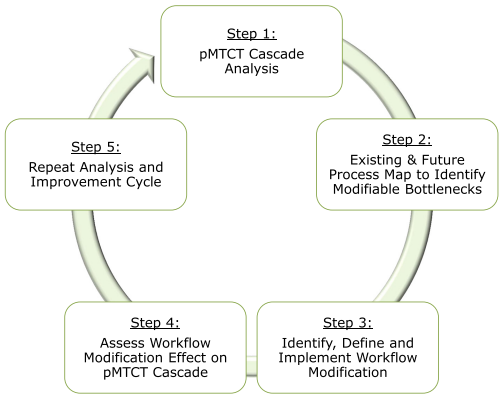


Figure 6: Five steps of SAIA intervention

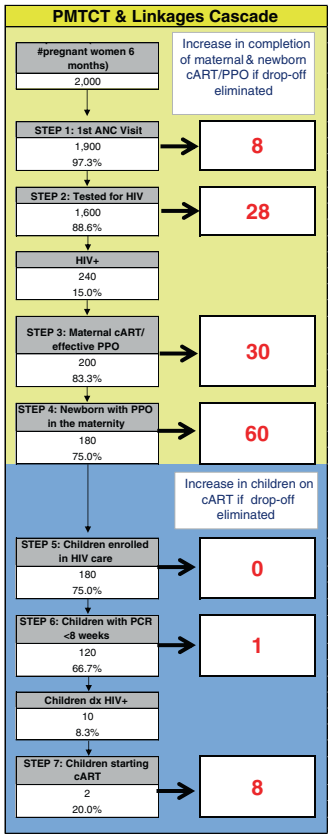


Figure 7: PMTCT cascade analysis tool

B.3 AIM 1: Identifying facility-level factors associated with high and low pediatric testing rates in facilities offering testing to children of adults identified in HIV care

Rationale: This aim will take advantage of natural heterogeneity in pediatric HIV testing rates, paired with the efficiency of using existing routine program indicators, to identify facility-level factors associated with high and low testing rates. Separation of modifiable from non-modifiable factors will inform Aim 2 of the study, in which health facilities use an iterative approach to improve testing rates. This analysis is restricted to comparing facilities' pediatric testing rates, rather than a composite indicator of testing and linkage to care because of the lack of standardized metrics between facilities in the definitions and documentation of linkage to care.

Table 1: Facility characteristics

Commodities	• Commodity distribution system for HIV testing kits • Test kit stock outs during the past 3 and 12 months
Facility characteristics	• Rural/urban/peri-urban • Facility level (hospital/health center/health post) • Facility type (NGO/Government) • Catchment area population • CCC clinic volume (adult and pediatric) • Availability of dedicated space for pediatric testing
Human resources	• # of health workers at CCC by training level and experience; stratified by whether involved in HIV testing • CCC staff turnover • Number of community health workers & responsibilities within HIV testing and linkage to care • Staff salaries and incentives
Information system	• Availability of information system (paper-based/linked EMR) • Presence of tools to track progress on pediatric HIV testing • Routine collection & review of data to track pediatric HIV testing
Management	• Involvement of leadership in service management • Frequency of management meetings

Sampling & categorization methods: Facility-level rates of pediatric HIV testing are defined as: **# of children tested per month / # of HIV-infected adults in care per month**. Data will be obtained from NASCOP, who have monthly, facility-level data available for facilities throughout Kenya conducting HIV testing through adult HIV care clinics. We will conduct a routine data quality audit (RDQA) by reviewing the source registry data for

10 clinics and comparing to the reported indicators for the same time period. If there is <10% error rate, we will use reported indicators exclusively (cutoff recommended in RDQA by Global Fund); if >10% error rate, we will abstract indicators from registries at a restricted sample of clinics. Methods for classification of high and low performers have been developed during the SAIA trial [44]. The average testing rate over 3 months will be used to limit the extent of monthly variability in classification and allow for stable estimates. Facilities will be ranked based on their 3-monthly average testing rates; high performers will be defined as the facilities in the highest 20th percentile and low performers as those in the lowest 20th percentile. Fifty high performance sites and 50 low performance sites will be selected randomly to conduct remote surveys to determine a) commodity procurement, b) facility characteristics, c) human resources, d) information systems, and e) management (Table 1). Facilities will not be matched in any way (volume, level, rural/urban location) to retain the ability to assess facility characteristics as cofactors. The completion of these remote surveys will be facilitated by NASCOP staff members; in cases where surveys are incomplete after repeat requests, SAIA study team members will visit facilities and fill the survey in person.

Analysis Plan & Power: The association between facility factors and high/low performance will be assessed using logistic regression (for continuous factors) and chi-squared tests (for categorical, proportion, and binary factors). We will have sufficient power to detect absolute differences in prevalence of cofactors between 22-28%, and differences in means between 0.6 and 11.3 (Table 2).

Table 2: Detectable difference in Aim 1

N = 50 high and 50 low performers

Binary		Continuous	
Prevalence of factor in low performers	Detectable difference	Standard deviation	Detectable mean difference
10%	23%	1	0.6
20%	26%	2	1.1
30%	28%	5	2.8
40%	28%	7	4.0
50%	27%	10	5.7
60%	25%	15	8.5
70%	22%	20	11.3

a = 0.05, power = 80%

B4. AIM 2: Impact of SAIA on pediatric HIV testing and linkage to care Hypothesis: We hypothesize that identifying modifiable barriers (in Aim 1) to steps in the pediatric HIV testing and care cascade and applying locally-defined innovations will increase the rate of pediatric HIV testing over and above the same time period in control facilities.

Study Design: Cluster randomized trial with 6 intervention and 6 control clinics in Kenya. We will use the same sites from the original SAIA trial, but re-randomize, stratifying on original randomization arm to ensure a balance between SAIA-experienced and SAIA-naïve sites. Utilizing the same sites capitalizes on the effort already expended by the original SAIA trial to build collaborative relationships with sites and select those ready for intervention [21]. Concurrent—rather than historic—control sites are essential to assess the impact of the SAIA intervention for a variety of reasons specific to pediatric HIV testing: 1) there is currently a rapid results initiative (RRI) ongoing in Kenya that provides time-varying resources for pediatric HIV testing, which would be expected to directly influence testing rates, 2) there is strong seasonality to testing rates with rainy seasons and holidays having low volume and school vacations having high volume of testing visits, 3) there is time-varying frequency of adult HIV care visits dependent on drug stocks, and 4) the expected rate of pediatric HIV testing would be expected to naturally decrease over time as the population of untested children is depleted. Unlike PMTCT and EID systems, older HIV-exposed children are not being replaced at the same rate at which they are depleted from the population due to testing; the existing population of undiagnosed children is expected to diminish as testing reaches children missed by PMTCT and EID.

Outcome ascertainment: ***Pediatric HIV testing rates***: We will abstract facility registry data to determine, monthly from each facility, a) numerator: the number of children (<18 years) tested for HIV, b) denominator: the number of adults (≥18 years) seen in HIV clinics during the previous month (to allow time for adults to bring their children for testing). These count data will enable estimation of the pediatric HIV testing rate during the pre-intervention, intervention, and post-intervention periods. Notably, this rate should not be seen as a proportion that should approach 100%. Previous data from a variety of Kenyan facilities suggest that a third of adults in HIV care have at least one child of unknown HIV status; this proportion is not routinely collected as a standardized indicator, but will be collected at baseline for each clinic to be used for adjustment purposes in analysis. Additionally, a parent may have more than one child requiring testing services; in the CATCH study the average number of children tested per adult was 1.5 but ranged from 1-8. While the rate of pediatric HIV testing metric in use may not be sensitive to *between*-facility variation in number of children per adult or proportion of adults with children of unknown status, these factors will not impact the *within*-facility *change* in rates over time, our outcome of interest.

Linkage to care rates: Due to existing heterogeneity in the documentation and definitions of linkage to care, the study will support facilities to keep a standardized linkage to care registry; we will abstract this registry data

to determine, monthly, from each facility, a) numerator: the number of children (<18 years) who opened new files at the HIV care clinic, and b) denominator: the number of children who tested positive for HIV during the previous month (to allow time for adults to bring their children for HIV care). While this metric does not account for the possibility that children will link to care in a clinic that is separate from the one where they were tested, this migration is not expected to differ, on average, between study randomization arms, or substantially affect the *within*-facility changes over time, our outcome of interest. This metric is robust as it is based on an unbiased, facility-representative sample. Estimates of linkage to care that could be estimated from an enrolled and longitudinally followed cohort would have the strong potential for selection bias, potentially excluding those children least likely to link and stay actively in care. ***Use of this type of simple, routinely collected indicator data to inform service delivery optimization will be of great benefit if this intervention were to be scaled and led exclusively by facility staff.***

Process indicators: In addition to our primary outcomes of pediatric HIV testing rates and linkage to care, we will collect process indicators related to completeness of a) assessment and documentation in adult medical records of HIV-exposed older children, b) linkage to care registry, and c) documentation of test children's HIV statuses in adult medical records. We will collect qualitative data on health care worker perceptions of the change process during CQI team meetings, and will document external contextual factors that might be expected to effect study outcomes (e.g. health care worker strikes, regional shortages in test kits, political violence/instability, etc.). These qualitative data will not be formally analyzed, but will be used to interpret the study findings in context.

Analysis: We will use generalized estimating equations (GEE) clustered on facility level to compare differences in testing rates and linkage to care between control and intervention communities during pre-intervention and intervention periods to address Aim 2. In order to decrease variability between our sites and increase precision of our outcome measures, we will control for pre-intervention pediatric HIV testing rates and linkage to care rates in our models. We hypothesize that the increases in testing rates between the pre-intervention and intervention periods will be greater among intervention than control facilities. To address our secondary aim regarding the sustainability of the intervention, we will test whether the magnitude of difference between intervention and control arms is sustained during the post-intervention period using a non-inferiority analysis. The general form of the GEE equation is in Figure 8.

$Y_{ij} = \mu + \beta_j + X_{ij}\theta_1 + Z_{ij}\theta_2$
(X = indicator for pre-intervention or intervention, Z = indicator for post-intervention)
H_0: $\theta_1 = 0$ *for evidence of improvement comparing pre-intervention to intervention*
H_0: $\theta_1 \neq \theta_2$ *for evidence of sustained effectiveness comparing intervention to post-intervention*

Figure 8: GEE formula to test differences in testing rates pre, intervention, and post

Power: With 6 intervention and 6 control sites, we will have sufficient power to detect an increase in testing rates of 1.5-fold. This assumes alpha of 0.05, 80% power, a harmonic mean of 140 adults attending HIV care clinic with children of unknown status (~420 total adults) per cluster, and a conservative estimate of the coefficient of variation of 0.64 (based on variability observed in the original SAIA trial), although this heterogeneity is expected to decrease with control for baseline testing rates, leading to increased power. To reach this number of adults per cluster, we anticipate needing to spend between 3-4 months in the intervention period, based on clinic attendance rates observed during the CATCH study. We will collect pre-intervention data for 4 months, intervention data for 4 months, and post-intervention data for another 4 months for a total of 12 months of data. Given the scope of funding and time frame, we will not have sufficient power to detect differences in linkage to care; we will describe, but not statistically compare these differences during the pre-intervention, intervention, and post-intervention time.

D. Approaches for addressing limitations: In the event that a sampled facility in Aim 1 is does not return their remote survey and the SAIA study team is not able to travel to the site in person due to security concerns, we will replace this site with a new clinic from the original NASCOP list. In the event that adult HIV care visit volume is lower than anticipated, we will increase the period of intervention and data collection.

E. Timeline

	2016				2017				2018			
AIM 1	Spring	Summer	Fall	Winter	Spring	Summer	Fall	Winter	Spring	Summer	Fall	Winter
Classification of high/low performers	■											
Remote surveys		■	■									
Data analysis & manuscript preparation			■	■								
AIM 2												
Study planning				■	■	■						
Pre-intervention							■					
Intervention								■	■			
Post-intervention										■		
Data analysis & manuscript preparation											■	■

1. PROTECTION OF HUMAN SUBJECTS

a. Human Subject Involvement and Characteristics

This proposed study will be reviewed by the Human Subjects Review Committee of the University of Washington and by the Kenyatta National Hospital (KNH) Ethical Review Committee in Kenya.

This research study will include 1) review of routinely reported facility-level data and health facility attributes in 100 health facilities in Kenya in Aim 1, and 2) abstraction of registry data from 12 facilities; 6 facilities will receive the proposed intervention.

The human subjects involved in this project are HIV-infected adults accessing services at the 12 facilities that will be either implementing the systems analysis and improvement intervention or acting as control clinics. Over the course of the study this group will number in the hundreds. Using routine health system records, we will be measuring pediatric HIV testing rates (# of children tested at each facility / # of adults in HIV care).

We will seek a waiver of informed consent from this group for the following reasons:

1. The study does not pose more than minimal risk to the subjects, since the data used in this study will be obtained from routine databases that are collected and maintained as a part of routine management activities. In addition, there will be no interaction between the subjects and the researchers for the purpose of this study, beyond the researchers' use of the aforementioned databases.

2. This waiver will not adversely affect the rights and welfare of the subjects, as the study procedures will not involve the collection of new data but rather use only existing data that has been collected as part of ongoing clinical care and management. Neither the study procedures nor the study results will bring harm to the participants.

3. This research could not be practically carried out without the waiver. It is not feasible to seek informed consent on a large number of patients for whom data has already been collected, and for whom obtaining consent would not be possible due to death, change of residence, or patient-initiated loss to follow-up.

At the end of the study, the results will be shared with Ministry of Health personnel and other organizations at the national, provincial, and local level. Presentations will be aimed at Ministry of Health officials, health care staff involved in HIV care, and at people living with HIV/AIDS, to obtain feedback and allow for a dissemination of the results at the community.

All of the participants are expected to be Black Africans, and 70% are expected to be women, reflecting the distribution of sex among adults enrolled in HIV care in Kenya.

b. Sources of material

Research material will consist of routine health systems indicators and surveys to collect facility-level characteristics. No identifying information will be accessed, collected, or stored.

c. Potential Risks

There are no specific risks beyond those entailed in accessing those same services before the intervention.

2. ADEQUACY OF PROTECTION AGAINST RISKS

a. Recruitment and Informed Consent

As previously mentioned, we will seek a waiver of informed consent to access data.

b. Protection Against Risk

Data collected from routine health services will not include any identifying information.

3. Potential Benefits of the Proposed Research to the Subjects and Others

Understanding factors associated with successful pediatric HIV testing programs is expected to assist in designing and implementing more effective and efficient service delivery strategies, leading to patients receiving higher quality services in the study facilities. Some patients will start treatment sooner than they normally would have if the intervention had not happened.

4. Importance of Knowledge to be Gained

If successful, the intervention will provide a model for how to more effectively understand and improve systems to test and treat children with HIV in high burden countries in Africa. Pediatric HIV has extremely high mortality when diagnosed late; solutions to scale testing and treatment efforts are urgently needed to bring care and treatment more effectively to poor populations. The risks to patients in this study are minimal, while the benefits gained for the individual patients and HIV-positive children are much larger.

5. Data and Safety Monitoring Plan

IRB monitoring. The IRB at the University of Washington (UW) and at the KNH ERC will review the study protocols and maintain ongoing oversight of the risks and benefits of the study and ensure compliance with institutional guidelines.

Monitoring of adverse events by PI and project staff. Research and clinical staff will be trained to identify potential adverse events and instructed to report them immediately to the site PIs and in-country research director.

Data handling procedures. Members of the research team have completed required training in human subjects, including training in data handling and confidentiality.

Security of electronic records. No personally identifiable data will be collected. All data will be stored on password protected computers, accessible only to the study staff.

Security of non-electronic records and files. No personally identifiable data will be collected. All data will be stored under lock and key in a study office accessible only to the study staff.

Inclusion of Women and Minorities

We will not enroll any participants directly in the proposed study (See Human Subjects Protection section). The clinics where we plan to work serve HIV-infected adults. Most participants are expected to be black African, which is typical of the population in Nairobi, Kenya and represent many ethnic and language groups. We expect roughly 70% females and 30% males in these clinics, reflective of the sex distribution of adults in HIV care in Kenya.

OMB Number: 0925-0002

Planned Enrollment Report

Study Title: Systems analysis and improvement approach to improve pediatric HIV testing and linkage to care

Domestic/Foreign: Foreign

Comments: Study will include abstraction of registry data from facilities. The human subjects involved in this project are HIV-infected adults accessing services at the 12 facilities that will be either implementing the systems analysis and improvement intervention or acting as control clinics. The parent trial in which this project is nested has received exemption status from the UW IRB, which we expect will be extended as this study only involves facility-level data collection.

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/Alaska Native	0	0	0	0	**0**
Asian	0	0	0	0	**0**
Native Hawaiian or Other Pacific Islander	0	0	0	0	**0**
Black or African American	0	0	0	0	**0**
White	0	0	0	0	**0**
More than One Race	0	0	0	0	**0**
Total	**0**	**0**	**0**	**0**	**0**

Study 1 of 1

Funding Opportunity Number: PA-14-149. Received Date: 2015-09-02T11:24:31.000-04:00

INCLUSION OF CHILDREN

We will not enroll any participants directly in the proposed study (See Human Subjects Protection section). The clinics where we plan to work serve HIV-infected adults with children of unknown HIV status. Children tested for HIV as part of routine clinical practice will be counted during registry data abstraction, but research staff will not have any direct contact with children in this study.

Resource Sharing Plan

As Drs. Sherr and John-Stewart, Health Alliance International and the Kenya Research Training Center are committed to the ideals of collaborative research and resource sharing, they are willing to share any tools and de-identified data developed as part of the proposed study with the broader scientific community upon request.

RESPECTIVE CONTRIBUTIONS

All five members on my mentorship team—Drs. Kenneth Sherr, Grace John-Stewart, James Hughes, Peter Cherutich, and Shan Liu—have been instrumental in the development of this scientific proposal and the review of training plan materials.

The initial research topic was developed between Drs. Kenneth Sherr, Grace John-Stewart, and myself this year through combining elements from two of their studies. Dr. John-Stewart served as my dissertation chair for the CATCH study—offering targeted HIV testing to children of HIV-infected adults in care. Dr. Sherr's *Systems Analysis and Improvement Approach to Optimize PMTCT (SAIA trial)* was the inspiration for optimizing the CATCH model. During mentorship sessions, the three of us developed the specific aims of this proposal and agreed on the additional methods training and mentorship that I would need to complete these aims.

Dr. Sherr provided strong mentorship in the SAIA methodology, which will be applied to pediatric HIV testing in my second aim, and helped guide the design and development of both aims. He provided substantial one-on-one mentorship and connected me with other SAIA team members to develop this research plan. Dr. Sherr also identified strengths and weaknesses in my training and helped to identify several methodologic areas for further training. Finally, he identified several courses to develop these methods and identified Drs. Cherutich, Hughes, and Liu as potential members of my postdoctoral mentorship team. Dr. Sherr will serve as my primary mentor (sponsor) for my postdoctoral training.

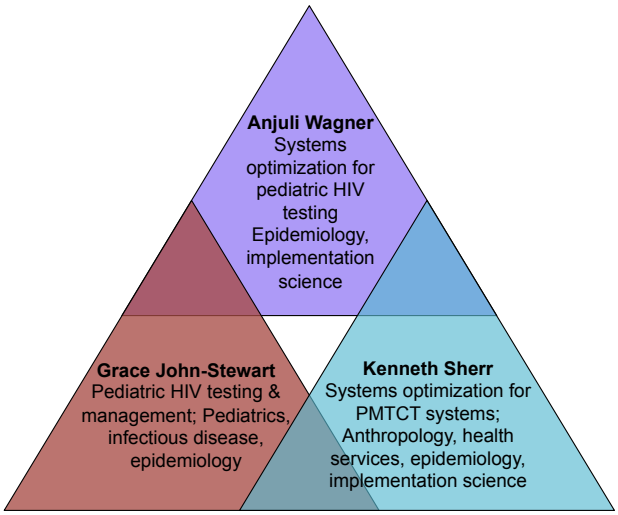
Dr. John-Stewart was instrumental in the adaptation of Dr. Sherr's SAIA approach to be applicable to the pediatric HIV testing and care cascade. She provided access to several forms of mentorship—individual, small group, and large group—through her research group during the development of this scientific proposal. She also provided individual mentorship on career development, identifying gaps in my training, and assisted in the identification of coursework and professional experiences to develop my leadership and management skills. Given her strong history of mentoring postdoctoral fellows, Dr. John-Stewart will play a strong role in guiding my career development. Throughout my postdoctoral training, Dr. John-Stewart will serve as my secondary mentor (co-sponsor) and will assist with analyses and manuscript preparation, as well as career development.

Dr. Peter Cherutich helped design and select data sources for my first aim, assisting in understanding the structure of national Ministry of Health offices, routine data collection, and limitations within the data and the system. He provided invaluable assistance linking me with the relevant senior policymakers within the National AIDS and STI Control Programme (NASCOP) and will facilitate my attachment to the pediatric program in Nairobi. Finally, he provided feedback on the process of utilizing implementation science methods to inform roll-out of a national program, based on his experience with NASCOP coordinating the national scale up of voluntary medical male circumcision (VMMC) services. During the course of my postdoctoral work, Dr. Cherutich will help with study design, collaborating with policymakers at NASCOP, and dissemination of results to a wide audience.

Dr. James Hughes assisted in the development of my statistical analysis plan, providing strong guidance in the design and analysis of my second aim, the cluster randomized trial. Dr. Hughes was particularly helpful in conducting sample size calculations in this atypical design and selecting an analysis method that made use of the power of registry-derived count data. Dr. Hughes has reviewed my analysis plan and identified coursework to provide the training I will need to conduct these hierarchical models and analysis. Dr. Hughes will assist with analysis of aims 1 & 2, as well as manuscript preparation.

Dr. Shan Liu was helpful in developing the operational research methods in aims 1 and 2, and helping to orient me to classical industrial and systems engineering methods. Dr. Liu identified several courses in the Department of Industrial Engineering to develop expertise in systems optimization. Dr. Liu will provide assistance in implementing the intervention in aim 2, as well as analysis and manuscript preparation.

SELECTION OF SPONSOR AND INSTITUTION



Selection of Sponsor & Co-Sponsor: The selection of Dr. Kenneth Sherr as my sponsor, Dr. Grace John-Stewart as my co-sponsor, and the collaborative partnerships represented in their groups—Health Alliance International (HAI), Global Center for Integrated Health of Women, Adolescents, and Children (Global WACh), and Kenya Research Training Center (KRTC)—will afford me strong mentorship opportunities and a collaborative research network with extensive resources in both the U.S. and Kenya. **Dr. Kenneth Sherr** has training in anthropology, infectious disease epidemiology, and health services, and currently conducts HIV-focused implementation science projects in Africa. His ongoing projects, expertise in implementation science, and strong collaborative research group make him an ideal sponsor for my postdoctoral studies. **Dr. John-Stewart** is a world-renowned expert in the field of pediatric HIV and vertical transmission of HIV; she has mentored over 100 students from masters to post-doctoral level and is the recipient of numerous mentorship awards and recognitions. Her training as a pediatrician, infectious disease specialist, and epidemiologist paired with over 20 years of experience as a researcher in Kenya, makes her an ideal co-sponsor.

Mentorship Team: In addition to my sponsor and co-sponsor, I have a carefully selected mentorship team to provide methods and subject-specific support during the proposed postdoctoral fellowship. **Drs. Peter Cherutich, James Hughes, and Shan Liu** have contributed substantially to the design of my proposed research, as well as to the development of my training plan. The combination of strong sponsors, mentorship team, and well-positioned institutional partnerships create a support system that will ensure that my proposed postdoctoral work is completed effectively.

***Selection of Institution*:** University of Washington School of Public Health (UW SPH) is rated as the #6 School of Public Health in the country; within the UW SPH, the Department of Epidemiology has 70 faculty members and the Department of Global Health has 250 faculty members in diverse fields. The UW is home to several collaborative research groups and is well known as a leader in HIV/AIDS and infectious disease global health research. I will benefit from two research homes corresponding to the research groups of my sponsor and co-sponsor:

> My primary research home, **Health Alliance International (HAI)** within the Department of Global Health, is a >25 year collaboration between researchers at the UW and ministries of health in developing countries. Dr. Sherr is the Director of Implementation Science at HAI; the group includes several principal investigators, post-doctoral fellows, and graduate students in the U.S. and several sub-Saharan African countries, including Kenya. The group has collective expertise in the use of implementation science to address issues related to optimizing the scale, speed, fidelity, and coverage of proven health interventions in resource-limited settings.
>
> My secondary research home, **Kenya Research Training Center (KRTC)**, is a >25 year long collaboration between the UW and the University of Nairobi; KRTC is directed by Drs. Carey Farquhar and Scott McClelland, and has numerous principal investigators, post-doctoral students, and graduate students in both the U.S. and Kenya from a broad range of disciplines in the health sciences. KRTC has expertise in maternal and child health research, clinical epidemiology, and biostatistics, with a special focus on HIV in Kenya. KRTC is closely tied to **Global WACh**, where Dr. John-Stewart serves as Director; Global WACh is a collaboration between the Departments of Obstetrics & Gynecology, Pediatrics, and Global Health and focuses on the interconnected lifecycle of women, adolescents, and children.

These unique partnerships make my postdoctoral project feasible in the proposed setting because of access to research space and personnel, and strong administrative infrastructure.

I have carefully chosen an appropriate sponsor and co-sponsor, mentorship team, and institutional partnerships for my postdoctoral work. This will enable me to develop as into an independent investigator involved in HIV-focused implementation science in resource-limited settings in Africa.

RESPONSIBLE CONDUCT OF RESEARCH

PAST YEARS AND FUTURE YEAR RCR SUMMARY

Coursework:

In the past 5 years, I have completed the following trainings related to the Responsible Conduct of Research:

Responsible Conduct of Research CITI Training and *HIPAA Training* (University of Washington 2011)
Responsible Conduct of International Research Course (University of Washington 2011) *
*Biomedical Research Integrity Program (2014)**

During the first year of the fellowship I plan to complete or refresh the following coursework and certificates:

Responsible Conduct of Research CITI Training
HIPAA Training
*Responsible Conduct of International Research Course **
*Biomedical Research Integrity Program **

Each of the in-person courses noted with an * above are detailed below in COURSEWORK DETAILS. Online courses (HIPAA Training and CITI Training) are not detailed here.

Informal Training: During the past 5 years, I have received additional mentorship and training on responsible conduct of research through discussions with Kenya Research Program (KRP) and Kizazi weekly meetings. During these meetings, which include all members of our collaborative group from PIs to masters students, we frequently have informal discussions about the ethical role of researchers as members of society, particularly in an international setting. We discuss potential conflicts of interest and the peer review process, share knowledge about successful data management, sharing and ownership, and discuss the prevention and handling of research misconduct. I plan to continue to participate both in KRP and Kizazi weekly meetings in the coming years.

In addition to these group settings, I have discussed issues of responsible conduct of research with sponsor, Dr. Kenneth Sherr, co-sponsor, Dr. John-Stewart, and the members of my mentorship team throughout the course of my fellowship. I plan to continue these weekly meetings throughout the course of my fellowship.

COURSEWORK DETAILS

Course Title: **Responsible Conduct of International Research (RCIR)**
Format: All-day intensive 2-week long course held in-person at the University of Washington Health Sciences Campus. Combination of formal lectures by faculty members and small group discussions. The class was composed of students and fellows from the U.S. and several African and Latin American countries. While many ethical training courses focus primarily on the U.S., this class was able to explore some of the more challenging ethical issues associated with conducting research in international and resource-limited settings.
Subject Matter: human subjects review policies, navigating relationships between mentors and mentees, identifying and disclosing conflicts of interest, collaboration in a research setting, and how to responsibly manage data and publications. Significant time was spent discussing how to prevent and handle misconduct.
Faculty Participation: Formal lectures were given by faculty members; following formal lectures, small groups discussed the topic of the day with the guest faculty speaker.
Duration of Instruction: 2 weeks, 9:30 am – 4 pm
Frequency of Instruction: once per year

Course Title: **Biomedical Research Integrity Program (BRIP)** *(http://depts.washington.edu/uwbri/)*
Format: BRIP was designed to address the need for interactive responsible conduct of research training among trainees and fellows. The course is designed to have formal lectures and small group discussions over the course of a year.
Subject Matter: conflict of interest, data acquisition and ownership, peer review, responsible authorship, and research misconduct.
Faculty Participation: Formal lectures will be given by faculty members; small group discussions will follow, engaging students and faculty
Duration of Instruction: 1 hour per lecture.
Frequency of Instruction: Lectures offered 2x/month. I will plan to attend 1-2 lectures per month depending on lecture topic and course schedule.

Goals for Fellowship Training and Career

Overview: My graduate plan has been crafted to prepare me for a career as an independent investigator conducting implementation science research related to HIV in resource-limited settings. My career goals have been inspired by travel in resource-limited settings, diverse research opportunities, and interest in operational health systems issues. In the short term, I propose to gain new methodologic expertise in implementation science through this F32 postdoctoral fellowship under the mentorship of Drs. Sherr and John-Stewart. In the next step of my career, I plan to carve my own unique research agenda through a K award and eventually apply for faculty positions focusing both on research and teaching.

Personal goals/values: Building on my formal training in epidemiology, I have become interested in successfully optimizing and scaling up interventions that are known to be effective in a research context. I would like to dedicate my career to closing the 'know-do' gap—the gap between what we *know* works from rigorous studies and what we routinely *do* in practice—using implementation science.

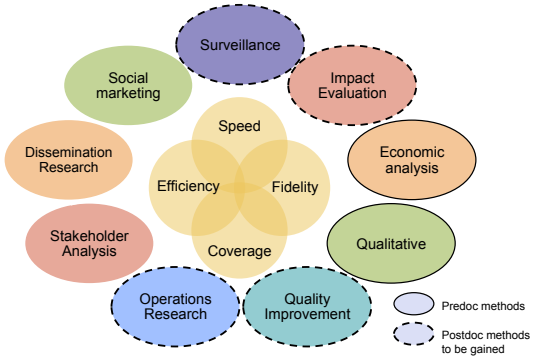


Figure 1: Implementation science methods

Pre-doctoral training experience: My dissertation work focused on pediatric HIV testing and linkage to care in the *Counseling and Testing for Children at Home (CATCH)* study. This implementation science study provided me with training in epidemiologic methods, cost-effectiveness, and qualitative methods (Figure 1). These three methods focus on individual-level issues associated with pediatric HIV testing, and provide me with a strong foundation. Additionally, this doctoral work included 3-4 months a year for 5 years in Kenya with study team members, Kenyan collaborators, and stakeholders. I learned to manage study administration—budget management; staff hiring, training, and capacity-building; data tool design, collection, database design and management, analysis; enrollment projections and tracking; ethical review and clearance. These skills will be essential in my future career plans as an independent investigator. Additionally, I had the opportunity to engage in results dissemination to a wide range of audiences—front line health care workers, advocacy groups, national-level policymakers, and international scientific audiences. In the next three years, I look forward to building upon my doctoral studies by working with national level groups in Kenya to optimize the CATCH model and scale its use in practice.

Postdoctoral training goals: During my postdoctoral training, I propose several shifts: 1) a shift in mentorship, 2) a shift from individual-level to facility-level data and analysis, 3) formal training in new methods—including operations research, quality improvement, use of surveillance data, and design and analysis of cluster randomized trials for impact evaluation (Figure 1), and 4) to collaborate directly with policy makers (NASCOP). These four large changes in methods and mentorship are complemented by retaining a focus on pediatric HIV testing, the subject area that I have focused on for my MPH and doctoral training. This familiar topic area makes the proposed training and ambitious research plan feasible.

I am also invested in continuing to build pediatric and adolescent HIV projects in the next several years of my career. In the past year, our collaborative team has designed and planned several pediatric and adolescent testing studies that use methods not usually employed in traditional biomedical research: *Developing Adolescent Strategies for HIV Testing (DASH)* challenged us to learn classical implementation science methods such as continuous quality improvement (CQI). *Financial incentives to increase pediatric HIV testing (FIT)* challenged us to expand to health economics and incentives. *Simulated Patient Encounters to Promote Early Detection and Engagement in HIV Care for Adolescents (SPEED)* challenged us to use simulated patients to build empathy skills in health care workers. I look forward to working on these innovative projects to learn about potential new interventions that may be scaled up in the future.

Finally, I look forward to continuing to work in close collaboration with young researchers in resource-limited settings to build research capacity to develop scientific proposals, obtain grant funding, and disseminate results. I have enjoyed the peer-to-peer mentorship afforded by my PhD project. In summary, I feel passionately about addressing gaps in pediatric HIV testing and linkage to care and look forward to building a career in implementation science. The shifts in mentorship and methods proposed in this postdoctoral fellowship will leave me well prepared to achieve my long-term career goal as an independent researcher conducting multi-disciplinary implementation science projects related to HIV in resource-limited settings in Africa.

ACTIVITES PLANNED UNDER THIS AWARD

Timeline of Planned Activities

	2016				2017				2018			
Location	Spring	Summer	Fall	Winter	Spring	Summer	Fall	Winter	Spring	Summer	Fall	Winter
Unviersity of Washington												
Nairobi, Kenya												
Coursework	30				30	30						
Mentorship	10	10	10	10	10	10	10	10	10	10	10	10
AIM 1												
Classification of high/low performers	60											
Remote surveys		90										
Data analysis & manuscript preparation			90	40								
AIM 2												
Study planning				50	60	60						
Pre-intervention							90					
Intervention								90	90			
Post-intervention										90		
Data analysis & manuscript preparation											90	90

The proposed project is expected to span three years, from Spring of 2016 to Spring of 2019. I plan to spend substantial time in Nairobi with the SAIA collaborative study team. My time allocated to different activities is noted in the grey cells above.

Year 1: During the first year of the project, I will complete courses and work on Aim 1, classifying high and low performing facilities using already collected data from the National AIDS and STI Control Programme (NASCOP), conducting the remote surveys to collect data on facility characteristics, and conduct Aim 1 analysis and manuscript preparation and submission. I will also begin working on study planning for Aim 2, the cluster randomized trial.

Year 2: During the second year of the project, I will spend 6 months doing coursework and planning the cluster RCT, training staff remotely and developing data capture and monitoring systems. I will spend the second half of the year in Kenya collecting pre-intervention and intervention data.

Year 3: During the third year, analysis will become my primary capacity, and I will aim to complete and publish the main study results during this time.

I will take the following courses to develop skills in operations research, quality improvement, impact evaluation, use of surveillance data, and leadership/management:

Table 3: Planned Coursework

Aim 1: Use of Surveillance Data, Operations Research
G H 539 Methods, Tools, and Data in Global Health
IND E 512 Introduction to Optimization Models
IND E 599 Healthcare Modeling & Decisionmaking
Aim 2: Impact Evaluation, Quality Improvement
G H 531 Research Methods in Developing Countries
G H 590 Impact Evaluation
STAT 536 Analysis of Categorical and Count Data
STAT 560 Hierarchical Modeling for the Social Sciences
Leadership & Management Training
G H 521 Leadership Development in Global Health
G H 522 Global Program Management and Leadership
G H 523 Policy Development and Advocacy for Global Health

DOCTORAL DISSERTATION AND RESEARCH EXPERIENCE

I have been involved in various aspects of research—including grant writing, protocol development, ethical review, planning, implementation, and analysis—for 11 studies during my undergraduate and graduate training. My MPH and PhD research focused on pediatric HIV testing and management in the Optimizing Pediatric HAART (OPH) study during my MPH and Counseling and Testing for Children at Home (CATCH) study during my PhD, both lead by Drs. Grace John-Stewart, Jennifer Slyker (referee for current application), and Dalton Wamalwa (referee for current application). My MPH thesis found that while the efficiency of case detection of infant HIV infection was high in hospital settings, mortality was substantially higher among hospital-diagnosed infants than their PMTCT-diagnosed counterparts (*Wagner, BMC Pediatrics, 2015*). These findings inspired the development of the CATCH study, which aimed to identify HIV-infected children prior to symptomatic illness. In this study we examined the acceptability, feasibility, and cost-effectiveness of targeted pediatric HIV testing through home- versus clinic-based testing using traditional epidemiologic, qualitative, and cost-effectiveness methods. This study noted that routine offering of HIV testing to HIV-infected adults with untested children quadrupled the number of children tested and identified 8% HIV prevalence among previously untested children. However, uptake of testing was low at 14% overall (*Wagner, manuscript in preparation*). The results from this study motivated the proposed postdoctoral work aimed at optimizing systems to deliver pediatric HIV testing and linkage to care services.

The CATCH study inspired a series of other pediatric and adolescent HIV testing studies listed below. I was involved in designing and applying for funding for the DASH, FIT, and SPEED studies (details below) and will be involved in beginning all 3 studies during the coming 6 months before transitioning to postdoctoral training. I have contributed to proposals involving saliva-based HIV testing during pregnancy, PrEP during pregnancy, and viral resistance testing to inform pediatric antiretroviral therapy management, which will either be submitted shortly or are being reviewed. Overall, I have contributed to 13 submitted grants and 6 fellowship applications during my graduate training.

<u>DOCTORAL DISSERTATION</u>

2011-present **HIV-1 Counseling and Testing for Children at Home (CATCH)**, *Research Assistant*, University of Washington, Seattle, WA and Nairobi, Kenya

- Developed traditional epidemiologic, qualitative, and cost-effectiveness specific aims, study methods & study protocol
- Designed data collection forms and developed and maintained study database in RedCap and Open Data Kit (ODK)
- Performed data maintenance and cleaning in STATA
- Created and maintained human subjects materials
- Developed statistical analysis plan & conducted analysis for primary study aims

<u>COMPLEMENTARY PEDIATRIC & ADOLESCENT PROJECTS DURING GRADUATE TRAINING</u>

2015-present **Simulated Patient Encounters Promote Early Detection and Engagement in HIV Care for Adolescents (SPEED)**, *Research Assistant*, University of Washington, Seattle, WA and University of Nairobi, Nairobi, Kenya

- Adapted in-depth interviews with adolescents to create standardized patient scripts
- Assisted in design of 18 site, stepped-wedge trial to test simulated patient encounter intervention

2015-present **Financial Incentives to Motivate Prompt Pediatric HIV Testing (FIT)**, *Research Assistant*, University of Washington, Seattle, WA and Kenyatta National Hospital, Nairobi, Kenya

- Designed pilot study and larger RCT of 3 levels of financial incentives

2015-present **Developing Adolescent Strategies for HIV Testing (DASH)**, *Research Assistant*, University of Washington, Seattle, WA and Kenyatta National Hospital, Nairobi, Kenya

- Developed implementation science specific aims (including continuous quality improvement, qualitative, and cost-effectiveness), study methods & study protocol
- Designed data collection forms, electronic data capture & storage system, standard operating procedures, human subjects materials
- Conducted flow mapping and time in motion exercises at Kenyatta National Hospital Voluntary Counseling & Testing (VCT) clinics

2010-2013 **Optimizing Pediatric HAART**, *Research Assistant*, University of Washington, Seattle, WA

- Conducted data cleaning and participated in ongoing data quality control for Kenyan pediatric HIV dataset
- Tracked adverse events in Kenyan pediatric HIV treatment clinical trial for DSMB reports and manuscript preparation
- Designed and conducted analysis on cofactors for hospital diagnosis of HIV versus diagnosis in prevention of mother to child transmission (PMTCT) programs among previously undiagnosed HIV infected children

ADDITIONAL RESEARCH PROJECTS DURING GRADUATE TRAINING

2010-2012 **HIV-1 Acquisition During and After Pregnancy Study**, *Research Assistant*, University of Washington, Seattle, WA and Nyanza Province, Kenya

- Designed data collection forms and developed and maintained study database in MS Access
- Performed data maintenance and cleaning and mentored Kenyan data manager
- Developed and compiled standard operating procedures
- Led weekly conference calls with Kenyan-based data team

2011 **Evaluation of Waiting Time at Two Maternal and Child Health Clinics in Rural Kenya**, Practicum Field Experience, Nyanza Province, Kenya

- Designed a quantitative evaluation of waiting time for all outpatient services offered at two maternal and child health clinics
- Coordinated program on-site, working with nurses, clinical officers, and hospital staff to collect evaluation data
- Concluded program with reports and presentations of results to the Medical Superintendents of both hospitals in Kenya and supervision team in Seattle

UNDERGRADUATE RESEARCH EXPERIENCE

2010 **The Water Institute,** *Research Assistant,* University of North Carolina, NC and sites in India

- Conducted in-country data collection through interviews and laboratory site visits in India to characterize microbial drinking water quality monitoring programs as part of the Aquatest project
- Assisted with developing qualitative and quantitative data collection methods for characterizing microbial drinking water quality monitoring during pilot field work in Ghana as part of the Aquatest project
- Created state-specific reports for The Water Institute and aided in the development of materials for publication and international presentation

2008-2009 **Urogenital Schistosomiasis Prevention Study,** *Research Assistant,* Tufts University, and field sites in Ghana

- Collected and tested biological samples for the purpose of screening Ghanaian schoolchildren for urogenital schistosomiasis; collaborated with Ghana Health Services to offer treatment to infected children
- Designed and implemented survey for the collection of qualitative data from community members
- Collected, entered, and performed preliminary interpretation on qualitative and quantitative data
- Led sample collection/testing team and supervised construction team responsible for implementing play area designed as an experimental form of primary prevention

2008 **Children in Balance Study,** *Research Assistant*, Tufts University, Boston, MA

- Coded and scored school wellness policies for Community Readiness Model assessment
- Created literature reviews and reports on physical activity and elementary school recess
- Developed and revised Kindergarten through 3rd grade program curriculum

2007 **Welcome Project,** *Research Assistant,* Somerville, MA

- Conducted and transcribed interviews with older immigrant groups in Somerville

Section II—Sponsor and Co-Sponsor Information

To the Review Committee:

As the sponsor (Dr. Kenneth Sherr) and co-sponsor (Dr. Grace John-Stewart) for the proposed project, we are pleased to write this letter describing our strongest support of Ms. Anjuli Wagner and her application for an Individual Fellowship Ruth L. Kirschstein National Research Service Award (NRSA). Ms. Wagner has excelled in her doctoral training in Epidemiology and aims to expand her methodologic expertise by acquiring new skills in Implementation Science during her postdoctoral training. We are confident that strong methods training, paired with extensive field experience, and commitment to conducting research that responds to the needs of policymakers will equip her to become a leader in global health and a strong independent investigator.

A. Research Support Available

Table 1: Drs. Kenneth Sherr (sponsor) and Grace John-Stewart's (co-sponsor) Current Research Support Relevant to Proposed Project

Funding source	ID number	Title of research or training program	PI name	Dates	Award amount (Annual Direct Costs)
NIH	***R01 HD0757***	***Systems Analysis and Improvement to Optimize pMTCT in Kenya, Mozambique, and Côte d'Ivoire: A Cluster Randomized Trial***	***Kenneth Sherr***	***09/28/2012-06/30/2016***	***$496,606 (main trial)***
	R01 HD0757 (1st supplement)				***$449,613 (1st supplement)***
	R01 HD0757 (2nd supplement) Minority Training				***$35,899 (2nd supplement)***
NIH	K02 TW009207	Health Systems Strengthening to Improve Health Outcomes: Applying Implementation Science in Central Mozambique	Kenneth Sherr	09/16/2011-07/30/2016	$89,399
USAID	AID-656-A-15-003	Strengthening Data Systems to Improve Delivery of Health Services in Mozambique	Kenneth Sherr	10/27/2014-10/30/2017	$512,511
Doris Duke Charitable Foundation	2009059	Strengthening Integrated Primary Health Care and Workforce Training in Sofala Province, Mozambique	Kenneth Sherr	08/01/2009-07/31/2016	$1,984,881
NIH	R21 HD079637	HIV-1 Counseling and Testing for Children at Home (CATCH study)	Grace John-Stewart	04/1/2014-03/31/2016	$131,533
NIH	R01 HD023412	Urgent Versus Post-Stabilization ART in HIV-1 Infected Children with Severe Co-infection (PUSH study)	Grace John-Stewart	04/15/11-03/31/16	$436,342
NIH	R24 TW008907	MEPI: Linked-Strengthening Maternal, Newborn and Child Health Research Training in Kenya	(PI, James Kiarie) Sub-Award to Grace John-Stewart	9/30/2010 - 9/30/15	$450,000
University of Washington		UW Center for Global Integrated Health of Women, Adolescents and Children (Global-WACh)	Grace John-Stewart (Center Director)	07/11-06/16	$300,000 As Needed
NIH	K24 HD054314	Pediatric HIV-1 in Africa: Pathogenesis and Management	Grace John-Stewart	09/29/2006-11/30/2016	$112,529

Only those awards that specifically offer infrastructure, staff, or training relevant to Anjuli's project are detailed above. In bold is the R01 on which Anjuli's postdoctoral work will be based (HD0757); this grant supports the existing SAIA trial, applied to PMTCT processes, and will support Ms. Wagner's proposed extension of SAIA to pediatric HIV testing, which will be run by the same experienced study team.

B1. Sponsor's Previous Trainees & Number of Trainees to be Supervised During the Fellowship

Dr. Kenneth Sherr: I have mentored 28 masters, pre- and postdoctoral individuals, including 2 postdoctoral trainees; 10 are currently active. A sample of my previous mentees and their current positions and titles are provided below (Table 2a).

Table 2a: Five representative past mentees of Dr. Kenneth Sherr

Trainee Name	Pre/Post-Doctoral Level	Training Period	Prior Academic Degree(s)	Year(s)	Institution(s)	Current Position and Organization of Past Trainees
Cherutich, P	Pre	2012-2015	MBChB, MPH	1999, 2006	U of Nairobi, U of Washington	Deputy Director of Medical Services, Ministry of Health, Kenya
Fernandes, Q	Pre	2012-2013	MBChB	2003	University of Eduardo Mondlane	Deputy National Director for Public Health, Ministry of Health, Mozambique

Heffron, R	Post	2011-2013	MPH, PhD	2004, 2012	Tulane University, U of Washington	Assistant Professor, Global Health, Epidemiology, University of Washington
Abe, T	Pre	2012-present	MPH, MS	2014, 2011	U of Washington	PhD Candidate, Industrial Engineering, University of Washington
Siems, B	Pre	2011-2013	--	--	University of Virginia	Deputy Director, Strategy Planning & Management, Family Planning Team, Bill & Melinda Gates Foundation

I will continue to mentor 8 students during Anjuli's fellowship—all are predoctoral students, and I serve as primary mentor for 6 of them. As such, I have sufficient time available to mentor Anjuli during her postdoctoral work. I have bi-weekly group mentorship meetings, and meet with my primary mentees weekly. (See Mentorship Team section.)

B2. Co-Sponsor's Previous Trainees & Number of Trainees to be Supervised During the Fellowship

Dr. Grace John-Stewart: I have mentored 101 masters, pre- and postdoctoral individuals during my 20 years with Kenya Research & Training Center; 19 are currently active. A sample of my previous mentees and their current positions and titles are provided below (Table 2b).

Table 2b: Five representative past mentees of Dr. Grace John-Stewart

Trainee Name	Pre/Post-Doctoral Level	Training Period	Prior Academic Degree(s)	Year(s)	Institution(s)	Current Position and Organization of Past Trainees
Kiarie, J.	Post	1998–2008	MBChB	1996	U Nairobi	Coordinator, Human Reproductive Team, World Health Organization Associate Professor, University of Nairobi
Farquhar, C.	Post	1999–2008	MD	1994	Harvard Med School	Professor, Medicine & Epidemiology, UW; Director, IARTP, UW, Director Afya Bora Fellowship, Director, UW Kenya Research and Training Center
Lohman-Payne, B.	Post	2000–2006	PhD	2000	U California, Davis	Research Associate Professor, University of Rhode Island
Sherr, K.	Pre	2008–2009	MPH	2000	U of Washington	Associate Professor, Global Health, UW
Walson, J.	Post	2004-2009	MD	2004	Tufts SOM	Associate Professor, Medicine, Global Health, Pediatrics, UW; Director UW START Program

I will continue to mentor 19 students during Anjuli's fellowship—16 are pre-doctoral students and 3 are post-doctoral; I serve as the primary mentor for 6. In addition to my research grants, I was fortunate to receive a K24 grant, a Mentoring Award, which allows me to dedicate a significant portion of my FTE to mentoring students. I have weekly dedicated group and individual mentorship sessions with each of my mentees, which is supplemented by large group mentorship through Kenya Research Training Center weekly meetings and s

C. Training Plan, Environment, Research Facilities

Ms. Wagner's long-term goals are to become an independent investigator, using implementation science to address pressing questions related to scaling evidence-based strategies to optimize child health. Implementation science relies on employing methods from a core set of disciplines to address questions related to speed, efficiency, fidelity, and coverage of intervention delivery (Figure 1).

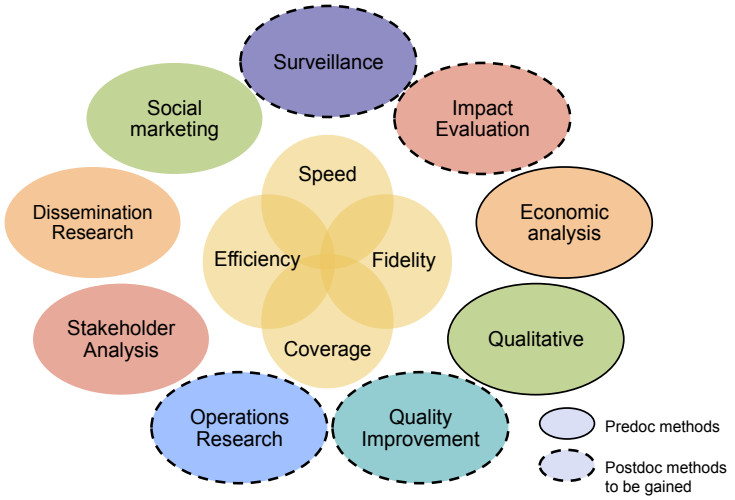


Figure 1: Core methods of implementation science

Ms. Wagner has already had strong training in epidemiology, qualitative data analysis, and economic analysis, supported by an F31 award between 2012 and 2015. Ms. Wagner's proposed research plan will provide her with new training in 1) use of surveillance data, 2) impact evaluation, 3) quality improvement, and 4) operations research. The proposed project will provide an opportunity for Ms. Wagner to shift from individual-level analysis—reflective of her doctoral training in Epidemiology—to facility-level analysis—reflective of her future research directions in health systems implementation science research. This complement of training and research will prepare Ms. Wagner to develop and execute health systems-focused implementation science studies, as a postdoctoral scientist, and ultimately as an independent investigator. Ms. Wagner will also be trained in global health leadership and management through formal coursework, mentorship, and experience-based learning within her sponsor and co-sponsor's research groups to enable her to grow as a leader in HIV research.

C.1 Coursework: During her post-doctoral fellowship, Anjuli will receive training in operations research, quality improvement, use of surveillance data, and impact evaluation (Table 3). She will also take coursework related to leadership, management, and advocacy for policy development.

Table 3: Planned Coursework

Aim 1: Use of Surveillance Data, Operations Research
G H 539 Methods, Tools, and Data in Global Health
IND E 512 Introduction to Optimization Models
IND E 599 Healthcare Modeling & Decisionmaking
Aim 2: Impact Evaluation, Quality Improvement
G H 531 Research Methods in Developing Countries
G H 590 Impact Evaluation
STAT 536 Analysis of Categorical and Count Data
STAT 560 Hierarchical Modeling for the Social Sciences
Leadership & Management Training
G H 521 Leadership Development in Global Health
G H 522 Global Program Management and Leadership
G H 523 Policy Development and Advocacy for Global Health

C.2 Mentorship Team: In addition to formal coursework, Anjuli will receive mentorship from a carefully crafted mentorship team of faculty at the University of Washington and policymakers in Kenya. *Dr. Peter Cherutich* will provide Anjuli with mentorship on the design and planning of implementation science projects, assistance liaising with national and local HIV policymakers and implementers, and support in the dissemination of the study results to relevant stakeholders; Dr. Cherutich is the Deputy Director of Medical Services for the Kenyan Ministry of Health, was the first graduate of the University of Washington's Implementation Science PhD program, and has over 15 years experience working in public health in Kenyan government. *Dr. James Hughes* will provide Anjuli with biostatistical mentorship, particularly focusing on the design and analysis of cluster randomized trials, analysis of time series data, and data validation techniques for routine program data. Dr. Hughes is an expert in the statistical considerations common in implementation science research. *Dr. Shan Liu* will provide Anjuli with mentorship in operations research and systems flow optimization. Dr. Liu has expertise in optimization modeling in health care settings.

Anjuli will meet with each of her mentorship team members each month and will continue to meet with her sponsor and co-sponsor once a week to discuss progress on her research and her training plan. Additionally, Anjuli will participate in several mentorship groups within our research groups:

C.2.1 Kenya Research Training Center (KRTC): The KRTC includes diverse faculty and trainees (see Research Environment), ranging from the group's PIs to pre-doctoral students. A weekly meeting allows students to build relationships with more senior students and faculty as well as be exposed to the most cutting edge research in the field of HIV/STIs in resource-limited settings. Anjuli will have the opportunity to present her work to KRTC several times throughout her postdoctoral training, gaining valuable feedback on study design, complex analyses, and manuscript development.

C.2.2 Kizazi: This smaller, more informal meeting involves students, postdocs, faculty, and program staff conducting research in women, children, and adolescents. In weekly meetings, members present updates and receive mentorship in project development, research progress, research ethics, dissertation development, and manuscript preparation. Anjuli attended Kizazi meetings to receive feedback and support during the development of her Masters thesis, doctoral work, and the proposed project. Anjuli will frequently have the opportunity to present to Kizazi, gaining timely feedback on study design, research ethics, and statistics.

C.2.3 Dr. John-Stewart's Weekly Mentorship Group: Dr. John-Stewart meets weekly with her pre- and postdoctoral students in a group setting to offer frequent feedback on their dissertation and postdoctoral work and career development. This weekly meeting will allow Anjuli to be exposed to a wide range of research topics and methods and will allow her fellow students to offer critiques and feedback on her postdoctoral work.

C.2.4 Center for AIDS Research Implementation Science Scientific Working Group: This group meets every 2 weeks and involves researchers in Dr. Sherr's research group working in implementation science, ranging from principal investigators to masters students. This collaborative environment allows for group members to design new studies in many areas, including HIV, tuberculosis, malaria, maternal and child health, and health systems strengthening.

C.2.5 Working in Implementation SciencE (WISE): This smaller meeting involves students, postdocs, faculty, and program staff conducting implementation science research in a variety of different settings. Every two weeks, members present works in progress, and receive mentorship and feedback regarding design and

analysis. Anjuli has attended WISE meetings for a year during her doctoral work and during the preparation of this proposal. She will have the opportunity to present frequently to WISE during the design, implementation, and analysis of the proposed project.

C.2.6 SAIA Project Team Meetings: The SAIA study has weekly team meetings that involve both Seattle and country study staff. Anjuli will participate in these calls throughout the duration of her time in Nairobi and Seattle. These meetings ensure direct communication between the Seattle and Nairobi teams, quickly identifying and addressing any issues that may arise in the clinic or with the data team. These calls will be of great value to Anjuli's training; having in-country feedback during the design phase of her analyses and continuing this frequent communication is one of the main reasons that we are sure her work will be a success.

C.3 Research Environment: During the course of her postdoctoral work, Anjuli will have two research homes, in the research groups of her sponsor and co-sponsor. Her primary research home will be with Dr. Sherr's research group in Health Alliance International (HAI). HAI's mission is to support government partners in strengthening public sector primary health care; it represents a >25 year multi-disciplinary collaboration between University of Washington and several sub-Saharan African countries, including ministries of health and local NGOs. Her secondary research home will be with Kenya Research Training Center (KRTC), a collaborative, multi-disciplinary >25 year research collaboration between the University of Washington and the University of Nairobi. KRTC comprises numerous principal investigators, post-doctoral students, and graduate students in both the U.S. and Kenya from a broad range of disciplines in the health sciences. These two unique partnerships make Anjuli's postdoctoral project feasible in the proposed setting because of access to clinical, administrative, and laboratory space and personnel across the two outstanding research homes.

D. Relation to Future Career Goals: Anjuli is determined to become an independent investigator who conducts implementation science projects in resource-limited settings. Receiving this fellowship would allow her to develop specific expertise in operations research, quality improvement, use of surveillance data, and impact evaluation (specifically design, conduct, and analysis of cluster randomized trials). These facility-level methods complement her existing skills in individual-focused research, and are increasingly needed to advance translational research, particularly in resource-limited settings. This fellowship will additionally provide Anjuli with the opportunity to temporarily attach to the Kenya National AIDS and STI Control Programme (NASCOP), which will be immensely beneficial. In order to conduct relevant and rigorous implementation science research, Anjuli will need both strong methodologic training as well as an intimate understanding of how health systems function. While Anjuli has substantial experience conducting research in Kenya, she has not spent time implementing programs; her attachment to NASCOP will be invaluable in this regard. Additionally, her attachment will allow Anjuli to build strong relationships with policymakers, enabling her to design relevant future implementation science projects that directly respond to locally identified issues. This postdoctoral training plan will leave Anjuli well poised to become an independent investigator.

E. Applicant's Qualifications and Potential for a Research Career

SPONSOR – Dr. Kenneth Sherr

I am delighted to serve as sponsor for Anjuli's NRSA application. I believe that this is a very important project and that Anjuli is an exceptional candidate. This fellowship will allow Anjuli to expand her methodologic toolkit to conduct rigorous studies, while simultaneously learning the realities of how health systems function, and build relationships with national policymakers to identify relevant public health questions and solutions. I enthusiastically support Anjuli's time, work, and collaboration in Nairobi, Kenya and look forward to mentoring her as she develops into an independent investigator in implementation science.

I have worked with Anjuli for 3 years as a member of her doctoral committee, providing mentorship in weaving together different implementation science methods. After she identified her interest in implementation science, Ms. Wagner sought my mentorship based on my interdisciplinary academic training—I was also trained in epidemiology and shifted to implementation science—and extensive field experience in Africa. Anjuli's pre-doctoral work focused on targeted pediatric HIV testing strategies in Kenya, aimed at identifying older, HIV-infected children prior to symptomatic illness. To address this issue holistically, she incorporated qualitative, cost-effectiveness, and traditional epidemiologic methods. I have helped Anjuli to combine these methods for her dissertation; results of this work have been disseminated to a wide range of stakeholders and will soon be published.

Anjuli's proposed post-doctoral work represents a clear shift in mentorship and methods, but retains the same subject area, as her pre-doctoral work—a notable strength of her application. For her PhD, Anjuli formed new collaborations and sought mentorship from implementation science experts to build aims that spanned qualitative work, cost-effectiveness, and classic epidemiology. In her post-doctoral work, Anjuli proposes to maintain focus on pediatric HIV testing, but shift methodologically. The familiarity with the content area of her project will help Anjuli to grow into a leader in pediatric HIV. Her transitions in primary mentorship from Dr. John-Stewart to myself, and new facility-based research approaches—with new training in operations research, quality improvement, use of surveillance data, and impact evaluation through cluster randomized trials—are very much in line with the spirit of the F32 mechanism, which emphasizes growth and new directions in the fellow's training. Anjuli has brought together a diverse mentorship committee—Dr. Grace John-Stewart (pediatric HIV prevention, diagnosis, and management), Dr. Peter Cherutich (implementation science and Ministry of Health program implementation), Dr. James Hughes (design and analysis of cluster randomized trials and analysis of time series data), and Dr. Shan Liu (operations research and industrial engineering)—to gain specific expertise in new implementation science methods. Anjuli is well positioned to distinguish herself in the future from both my research and Dr. John-Stewart's research, carving a niche as an independent investigator in the use of implementation science to address pediatric HIV questions.

Early in the course of her dissertation, Anjuli prioritized engagement of policymakers, implementers, and activists in Kenya, which will continue to be important as she grows in her career as an implementation scientist. The public health reach of this work is evident as she was invited to present her findings to CDC-Kenya and the National AIDS and STI Control Programme (NASCOP) as they launch a new initiative to improve pediatric HIV diagnosis and treatment in Kenya. The timing of Anjuli's doctoral and post-doctoral research is excellent as the Kenyan Ministry of Health and CDC seek improved strategies for pediatric HIV detection. A toolkit that Anjuli and team members built based on her doctoral work is being considered by NASCOP for inclusion in their Best Practices package, and has recently been adopted at the Kenyatta National Hospital (KNH) for pediatric HIV testing. She has also disseminated study results to international audiences through an oral presentation at the International AIDS Society (IAS) meeting in July, several poster presentations including one at the Conference on Retroviruses and Opportunistic Infections (CROI), and to advocacy audiences including the National Empowerment Network of PLWHIV in Kenya (NEPHAK) and the International Committee of Women with HIV/AIDS (ICW). This depth and breadth of stakeholder engagement is remarkable for a young researcher.

I am particularly excited about Anjuli's proposed attachment with NASCOP to accomplish her first aim. It is rare for a researcher to have the opportunity to work side-by-side with policymakers and implementers, but ultimately is of immense benefit to inform relevant research questions. NASCOP's enthusiasm for Anjuli's attachment and use of routinely collected data for research represents a new collaboration that will serve Anjuli well in the future as she designs new research studies and disseminates results. The relationships she builds will be critical to her development as an independent investigator.

Anjuli has had experience with a range of diverse public health research projects in resource-limited settings; this field experience has directly informed the realistic goals and timeframe she has developed for this project and has shown that she is capable of adapting to often challenging field settings. I am confident that Anjuli's previous international research experience and her wide and dedicated network of academic support at the University of Washington and the University of Nairobi will equip her well to undertake this critical research.

In conclusion, I wholeheartedly support Anjuli's proposed research and training. I am committed to mentoring Anjuli as she acquires a new set of implementation science methods and develops into an independent investigator.

CO-SPONSOR – Dr. Grace John Stewart

I have been Anjuli's academic advisor, mentor, supervisor and MPH thesis and PhD dissertation chair for the past five years and have had the opportunity to get to know her in both a professional and personal capacity. During this time, Anjuli has shown her dedication, independent learning, strong methods training, communication skills, and adaptability, all of which make her an ideal candidate for the F32 postdoctoral fellowship. Anjuli's post-doctoral plans, mentorship team, and training plan have all been carefully crafted to position her to become an independent investigator who conducts implementation science research in Africa.

When I met Anjuli in 2010, she was beginning her graduate career and was interviewing for research assistant positions. Impressed by her persistence and idealism, I offered her a short-term position, which has since turned into a 5-year mentored relationship based on her industriousness, enthusiasm and capabilities. Anjuli has been a pleasure to work with, has accepted guidance well, and has grown as a researcher and a team member throughout this time. She has shown great initiative and willingness to take on key leadership roles throughout her time with our group.

During her MPH, Anjuli went to Kenya and lived in a remote town in Western Kenya (Bondo) and worked in the District Maternal Child Health clinic on a project to determine waiting times for mothers using time-in-motion methods, classical operations research. She became proficient in data management and analyses and worked with the research teams contributing to several research studies. Following her MPH, Anjuli joined the UW PhD program and began to contribute strong leadership to a series of studies on pediatric HIV.

Anjuli has substantial experience writing grants and leading projects in the field in Kenya. She obtained funding for her PhD work with an F31 grant and then contributed substantively to several subsequent grants that aim to diagnose children and adolescents with HIV prior to the time they are symptomatic. She has contributed to writing 13 grants during her graduate training, 6 of which were funded. This includes a UW Royalty Research Fund pilot grant and an NIH R21 to conduct her doctoral study (Counseling and Testing Children at Home [CATCH]), an NIH CFAR supplement grant which employs continuous quality improvement (Developing Adolescent Strategies for HIV testing [DASH]), a CFAR pilot grant and CIPHER full trial grant to support a 4-arm randomized control trial of financial incentives (Financial Incentives to Increase Pediatric HIV Testing [FIT]), and an NIH R01 to use standardized patient actors (Standardized Patient Encounters for Early Detection and Engagement in Care Among Adolescents [SPEED]). She already has 4 publications in high impact journals to date, 1 under review, 5 close to submission, and has laid the foundation for several more in the coming 2 years as these studies complete their field procedures. Anjuli is a highly productive grant writer and is building a publication record to match; these skills will benefit her as a postdoctoral fellow and eventually as an independent investigator.

Anjuli is a strong communicator—she is able to coordinate multi-site teams remotely, enjoys teaching and capacity building, and prioritizes dissemination of results to stakeholders. Anjuli excels in classes—her transcript speaks for itself. She won the UW SPH Outstanding Teaching Assistant Award, a testament to her excellent organization and leadership skills. She was also awarded the prestigious Magnuson Scholar Award in April 2015, which recognizes one student from the UW School of Public Health for their excellent academic performance and outstsanding potential as a researcher. This award came with a substantial cash prize, which Anjuli will use to supplement Dr. Sherr's R01 to conduct her extension of the SAIA approach. Anjuli is refreshingly 'ego-free' and consistently deflects credit for her work to all the other team members, coaching Kenyan trainees, engaging stakeholders in Kenya and the research team, now dispersed between several sites. She has worked tirelessly with the CATCH and DASH study teams between 6 sites in Kenya and has been involved with all aspects of the studies: budgets, hiring staff, training the team, building and managing the database, conducting analyses, developing Human Subjects applications and communicating with the IRBs, and working with partners in the Ministry of Health in Kenya. Anjuli has spent 3-4 months of each year in Kenya during her doctoral work and will continue to spend substantial time abroad during her postdoctoral work.

In summary, Anjuli's remarkable competence, selfless dedication and industriousness, highly organized meticulous approach, compassion, diplomacy, and analytic skills make her an ideal candidate for an F32 fellowship. She has contributed initial concepts from her F31 into the foundation of several subsequently funded grants, she has inspired the research team, and formed linkages with policy-makers and community members who will be able to use these studies to improve outcomes for children with HIV. I cannot think of a more worthy candidate than Anjuli for this NRSA F32 training fellowship. I look forward to supporting her development as a postdoctoral fellow and later as an independent investigator.